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NOVADEL PHARMA INC  
Form SB-2  
February 13, 2004

As filed with the Securities and Exchange Commission on February 13, 2004  
Registration No. 333-\_\_\_\_\_

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

FORM SB-2

REGISTRATION STATEMENT  
UNDER  
THE SECURITIES ACT OF 1933

NovaDel Pharma Inc.  
(Exact name of Registrant as Specified in Its Charter)

|   |  |   |
|---|--|---|
| Delaware  | 2834   | 22-2407152                              |
| (State or other jurisdiction<br>of corporation or organization) | (Primary Standard Industrial<br>Classification Code) | (I.R.S. Employer<br>Identification No.) |

25 Minneakoning Road  
Flemington, NJ 08822  
(908) 782-3431

-----  
(Address, including zip code, and telephone number, including area  
code, of registrant's principal executive offices)

Gary A. Shangold, M.D.  
President and Chief Executive Officer  
NovaDel Pharma Inc.  
25 Minneakoning Road  
Flemington, NJ 08822  
(908) 782-3431

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(Name, address, including zip code, and telephone number  
including area code, of agents for service)

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Copies to:  
Ira L. Kotel, Esq.  
Dickstein Shapiro Morin & Oshinsky LLP  
1177 Avenue of the Americas, 47th Floor  
New York, New York 10036-2714  
(212) 835-1400

Approximate date of commencement of proposed sale to public: From  
time to time or at one time after this Registration Statement becomes effective  
in light of market conditions and other factors.

If the only securities being registered on this Form are being  
offered pursuant to dividend or interest reinvestment plans, please check the  
following box.

If any of the securities being registered on this Form are to be

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offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933 (the "Securities Act"), other than securities offered only in connection with dividend or interest reinvestment plans, check the following box. |X|

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. |\_|

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. |\_|

If delivery of the prospectus is expected to be made pursuant to Rule 434, please check the following box. |\_|

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CALCULATION OF FEE

| Title of Securities to be Registered | Amount to be Registered(1) | Proposed Maximum Offering Price Per Share(1) (2) | Proposed Maximum Aggregate Offering Price(2) |
|--------------------------------------|----------------------------|--|--|
| common stock, \$0.001 par value      | 20,484,217                 | 1.61   | 32,979,589.3                                 |

(1) The Company has outstanding 14 unit purchase options. Upon full exercise of such unit purchase options, the Company shall issue 1,330,296 shares of its common stock and warrants to purchase 399,082 shares of its common stock. This figure set forth above includes the shares issuable upon the exercise of the unit purchase options and the exercise of the warrants to be contained therein, as well as the exercise of other outstanding warrants of the Company to purchase an aggregate of 5,779,335 shares of its common stock. Also registered hereby are such additional and indeterminable number of shares as may be issuable due to adjustments for changes resulting from stock dividends, stock splits and similar changes.

(2) Pursuant to paragraphs (c) and (h) of Rule 457 of the Securities Act, the proposed per share maximum offering price of such shares of common stock is estimated solely for the purpose of determining the registration fee. The actual per share offering price of the common stock being registered will be determined from time to time by the registrant in connection with the issuance by the registrant of the shares registered hereunder. The aggregate amount of the registrant's common stock registered hereunder that may be sold in an "at the market" offering for the account of the registrant may not exceed 10% of the aggregate market value of our common stock held by non-affiliates that which is permissible under Rule 415(a) (4) promulgated under the Securities Act.

THE REGISTRANT HEREBY AMENDS THIS REGISTRATION STATEMENT ON SUCH DATE OR DATES AS MAY BE NECESSARY TO DELAY ITS EFFECTIVE DATE UNTIL THE REGISTRANT SHALL FILE A FURTHER AMENDMENT WHICH SPECIFICALLY STATES THAT THIS REGISTRATION STATEMENT SHALL THEREAFTER BECOME EFFECTIVE IN ACCORDANCE WITH SECTION 8(a) OF THE SECURITIES ACT OF 1933 OR UNTIL THE REGISTRATION STATEMENT SHALL BECOME EFFECTIVE ON SUCH DATE AS THE COMMISSION, ACTING PURSUANT TO SAID SECTION 8(a),

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MAY DETERMINE.

The information in this prospectus is not complete and may be changed or amended. The selling stockholders may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

Subject to Completion  
Preliminary Prospectus dated February 13, 2004

20,484,217 Shares of common stock

of

NovaDel Pharma Inc.

This prospectus relates to the public offering, which is not being underwritten, of up to 20,484,217 shares of our common stock, par value \$0.001 per share, for sale by certain of our stockholders identified in this prospectus for their own account. Such stockholders are referred to throughout this prospectus as "selling security holders." These shares include 5,779,335 shares that are issuable upon exercise of certain warrants and other derivative securities.

In this prospectus and any amendment or supplement hereto, unless otherwise indicated, the terms "NovaDel", the "Company", "we", "us", and "our" refer and relate to NovaDel Pharma Inc. The selling security holders who wish to sell their shares of our common stock may offer and sell such shares on a continuous or delayed basis in the future. These sales may be conducted in the open market or in privately negotiated transactions and at market prices, fixed prices or negotiated prices. We will not receive any of the proceeds from the sale of the shares of common stock owned by the selling security holders but we will receive funds from the exercise of their warrants, if at all. Any such proceeds will be used for working capital and general corporate purposes. One should read this prospectus and any amendment or supplement hereto together with additional information described under the heading "Available Information".

Our common stock is traded on the OTC Bulletin Board(R) under the symbol "NVDL.OB". On February 6, 2004, the closing sales price for the common stock on the OTCBB was \$1.75 per share.

Our principal executive offices are located at 25 Minneakoning Road, Flemington, NJ 08822. Our telephone number is (908) 782-3431.

OUR COMMON STOCK BEING OFFERED BY THIS PROSPECTUS INVOLVES A HIGH DEGREE OF RISK. YOU SHOULD READ THE "RISK FACTORS" SECTION BEGINNING ON PAGE 2 BEFORE YOU DECIDE TO PURCHASE ANY SHARES OF OUR COMMON STOCK.

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Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of the prospectus. Any representation to the contrary is a criminal offense.

The date of this Prospectus is February 13, 2004

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Any prospective investor should not rely on any information not contained in this document. We have not authorized anyone to provide any other information to the contrary. This document may only be used where it is legal to sell these securities. The information in this document may only be accurate as of and on the date of this document.

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### About this Prospectus

This summary highlights certain information contained elsewhere in this prospectus. One should read the following summary together with the more detailed information regarding NovaDel and our financial statements and the related notes appearing elsewhere in this prospectus.

### Company Summary

We are engaged in the development of novel application drug delivery systems for presently marketed prescription and over-the-counter ("OTC") drugs. Our patented and patent-pending delivery systems are lingual sprays enabling drug absorption through the oral mucosa and more rapid absorption into the bloodstream than presently available oral delivery systems. Our proprietary, novel delivery system is designed to provide patients with the therapeutic effects of a given drug within minutes of such drug's administration to the patient thereby enhancing and greatly accelerating the onset of the intended therapeutic benefits of the drug. Our development efforts for our novel drug delivery system are concentrated on making it available for drugs that are already available and proven in the marketplace. In addition to increasing the bioavailability of a drug by avoiding metabolism by the liver before entry into the bloodstream, we believe that our proprietary drug delivery system offers the following significant advantages: (i) more rapid delivery of drugs to the bloodstream allowing for quicker onset of therapeutic effects compared to conventional oral dosage forms; (ii) improved drug safety profile by reducing the required dosage,

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including possible reduction of side-effects; (iii) improved dosage reliability; (iv) allowing medication to be taken without water; and (v) improved patient convenience and compliance.

In light of the material expense and delays associated with independently developing and obtaining approval of pharmaceutical products, we intend to develop drug products through collaborative arrangements with major pharmaceutical companies, such pharmaceutical companies providing the funding for the development of specified drug products. To date, other than license agreements with Manhattan Pharmaceuticals, Inc., in connection with propofol, and the Veterinary Company, Inc., in connection with veterinary applications for carprofen, levothyroxine sodium and methimazole, we have not entered into any material development arrangements with any pharmaceutical companies. The lack of any such arrangements and our limited revenues and low level of working capital has restricted our ability 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 undertake and maintain our business plan.

At our inception in 1982, we engaged in the business of consulting to the pharmaceutical industry, focusing on product development activities of various European pharmaceutical companies. Since 1992, we have used our consulting revenues and the funds generated from financings to fund our own product development activities. Our focus on developing our own products evolved naturally out of our consulting experience on behalf of other pharmaceutical companies. Substantially all of our revenues previously were derived from our consulting activities. Effective October 1, 2002, we changed our corporate name from Flemington Pharmaceutical Corporation to NovaDel Pharma Inc.

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### Risk Factors

One should carefully consider the following risk factors and all other information contained in this prospectus 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, results of operations, performance, achievements and industry and could result in a complete loss of one's investment. The risks and uncertainties described below are not the only ones we may face.

WE ARE A DEVELOPMENT STAGE COMPANY AND HAVE A LIMITED OPERATING HISTORY AND HAVE NOT GENERATED ANY REVENUES FROM THE SALE OF PRODUCTS TO DATE. OUR AUDITORS HAVE QUALIFIED THEIR AUDIT OPINION WITH REGARD TO OUR ABILITY TO CONTINUE AS A GOING CONCERN.

We are a developmental stage biopharmaceutical company. Therefore, you must evaluate us in light of the uncertainties and complexities present in such companies. We have not generated any revenue from the commercial sale of our proposed products and do not expect to receive such revenue in the near future. We have no material licensing or royalty revenue or products ready for use or licensing in the marketplace. This limited history may not be adequate to enable one to fully assess our ability to develop our technologies and proposed products, obtain FDA approval and achieve market acceptance of our proposed products and respond to competition. We cannot be certain as to when to anticipate commercializing and marketing any of our proposed products in development, if at all, and do not expect to generate sufficient revenues from proposed product sales to cover our expenses or achieve profitability in the near future.

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We had an accumulated deficit as of October 31, 2003, of approximately \$17,355,000. We incurred operating losses in each of our the last eight fiscal years, including a net loss of approximately \$5,815,000 for the fiscal year ended July 31, 2003. Because we increased our product development activities, we anticipate that we will incur substantial operating expenses in connection with continued research and development, clinical trials, testing and approval of our proposed products, and expect these expenses will result in continuing and, perhaps, significant operating losses until such time, if ever, that we are able to achieve adequate product sales levels. Our ability to generate revenue and achieve profitability depends upon our ability, alone or with others, to complete the development of our proposed products, obtain the required regulatory approvals and manufacture, market and sell our proposed products.

We are a developmental stage biopharmaceutical company. Therefore, you must evaluate us in light of the uncertainties and complexities present in such companies. We have not generated any revenue from the commercial sale of our proposed products and do not expect to receive such revenue in the near future. We have no material licensing or royalty revenue or products ready for use or licensing in the marketplace. This limited history may not be adequate to enable one to fully assess our ability to develop our technologies and proposed products, obtain FDA approval and achieve market acceptance of our proposed products and respond to competition. We cannot be certain as to when to anticipate commercializing and marketing any of our proposed products in development, if at all, and do not expect to generate sufficient revenues from proposed product sales to cover our expenses or achieve profitability in the near future.

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Because our rate of expenses is high, and due to our very limited resources, our auditors have included an explanatory paragraph in their audit opinion with regard to our ability to continue as a going concern.

WE WILL REQUIRE SIGNIFICANT CAPITAL REQUIREMENTS FOR PRODUCT DEVELOPMENT AND COMMERCIALIZATION.

The research, development, testing and approval of our proposed products involve significant expenditures and accordingly we require significant capital to fund such expenditures. We anticipate, based on our current proposed plans and assumptions relating to our operations (including the timetable of, and costs associated with, new product development), that the proceeds of the private placements we completed during the year 2003 will be sufficient to satisfy our contemplated cash requirements through the second quarter of our fiscal year 2005. 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 additional financing may not be available to us on acceptable terms, if at all. Unless we raise additional financing, we may not have sufficient funds and we may not be able to complete development and commercialization of our proposed products or continue operating. See "Management's Discussion and Analysis of Financial Condition and Results of Operations."

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

The additional financings we require may be obtained through one or more

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transactions which effectively dilute the ownership interests of our stockholders. Further, we may not be able to secure such additional financing on terms acceptable to us, if at all. We have the authority to issue additional shares of common stock, as well as additional classes or series of ownership interests or debt obligations which may be convertible into any one or more classes or series of ownership interests. We are authorized to issue 50,000,000 shares of common stock and 1,000,000 shares of preferred stock. Such securities may be issued without the approval or other consent of our stockholders. In addition, certain of our stockholders who purchased shares of common stock in a private placement completed by us in April and May 2003 are entitled to a reset of the pricing of their original investment in us. According to such reset, if, prior to the first anniversary of the closing of each such stockholder's purchase of common stock, we sell shares of common stock in any subsequent financing at a purchase price that is lower than \$1.50 per share of common stock, we shall be obligated to issue to such stockholder, for no additional consideration, a number of additional shares of common stock equal to the difference between (a) the amount of shares of common stock purchasable for the total purchase price paid by such stockholder in connection with its original investment at the per share purchase price of the subsequent offering and (b) the number of shares of common stock actually purchased by such stockholder in connection with its original investment. Further, until the second anniversary of the closing of such a stockholder's purchase of common stock, such stockholders are entitled to purchase additional shares of common stock in connection with subsequent offerings by us so as to maintain their prior ownership percentages. As our recently consummated private placement triggered this reset obligation, the Company duly issued such stockholders a total of 1,371,549 shares of common stock. See "Risk Factors--Additional authorized shares of common stock and preferred stock available for issuance may adversely affect the market."

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

Our strategy is to concentrate our product development activities primarily on pharmaceutical products for which there already are significant prescription sales, where the use of our proprietary, novel drug delivery technology will greatly enhance speed of onset of therapeutic effect, reduce side effects through a reduction of the amount of active drug substance required to produce a given therapeutic effect and improve patient convenience or compliance. We have completed pilot pharmacokinetic studies for two antihistamine lingual sprays (loratadine and clemastine), an estradiol lingual spray, a progesterone lingual spray and a nitroglycerin lingual spray. In addition, a phase 2 clinical trial was completed for the nitroglycerin lingual spray. Additional development work on loratadine, clemastine, estradiol and progesterone has been put on hold due to changes in the marketplace which have significantly reduced the market potential for these compounds. We plan to file an NDA for the nitroglycerin lingual spray in 2004. We plan to initiate pilot pharmacokinetic studies on our Tier I priority products during the first half of calendar year 2004. These products are lingual spray formulations of sumatriptan, alprazolam, propofol, ondansetron and zolpidem. The goal of these pilot pharmacokinetic studies is to determine whether or not a specific lingual spray can achieve blood levels of an active ingredient via administration through the oral mucosa. If blood levels are not achieved, it could result in the need to reformulate the lingual spray and/or to terminate work on a specific compound which would have a material adverse effect on our operations.

Companies in the pharmaceutical and biotechnology industries have suffered

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

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

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

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THERE ARE CERTAIN INTERLOCKING RELATIONSHIPS AND POTENTIAL CONFLICTS OF INTEREST.

Lindsay A. Rosenwald, M.D., a significant stockholder of NovaDel, is the Chairman of the Paramount, the placement agent for the private placements we completed during calendar year 2003, and the Managing Member of BioMedical Investment Group, LLC, also a major stockholder of NovaDel. In the regular course of its business and the business of its affiliates, and outside of its arrangement with us, Paramount and/or its affiliates identify, evaluate and pursue investment opportunities in biomedical and pharmaceutical products, technologies and companies. In addition, Dr. Rosenwald may be deemed to beneficially own approximately 34.73% of our outstanding common stock (assuming exercise of certain warrants beneficially owned by Dr. Rosenwald) and 20.13% of our voting stock (assuming no exercise of such warrants). As such, Dr. Rosenwald and Paramount may be deemed to be our affiliates. Generally, Delaware corporate law requires that any transactions between us and any of our affiliates be on terms that, when taken as a whole, are substantially as favorable to us as those then reasonably obtainable in an arms-length transaction from a person who is not an affiliate. Nevertheless, neither such affiliates nor Paramount are obligated pursuant to any agreement or understanding with us to make any additional products or technologies available to us, nor can there be any assurance, and we do not expect and our stockholders should not expect, that any biomedical or pharmaceutical product or technology identified by such affiliates or Paramount in the future will be made available to us. In addition, certain of our current officers and directors or any officers or directors hereafter appointed by us may from time to time serve as officers or directors of other biopharmaceutical or biotechnology companies. Such other companies may have interests in conflict with our interests.

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

Revenue received from our product development efforts consists of payments by pharmaceutical companies for research and bioavailability studies, pilot clinical trials and similar milestone-related payments. Our future growth and profitability will be dependent upon our ability successfully to raise additional funds to complete the development of, obtain regulatory approvals for and license out or market our proposed products. Accordingly, our prospects must be considered in light of the risks, expenses and difficulties frequently

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encountered in connection with the establishment of a new business in a highly competitive industry, characterized by frequent new product introductions. We anticipate that we will incur substantial operating expenses in connection with the development, testing and approval of our proposed products and expect these expenses to result in continuing and significant operating losses until such time, if ever, that we are able to achieve adequate levels of sales or license revenues. We may not be able to raise additional financing, increase revenues significantly, or achieve profitable operations. See "Risk Factors - We will require significant capital requirements for product development and commercialization."

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### WE DO NOT HAVE COMMERCIALY AVAILABLE PRODUCTS

Our principal efforts are the development of, and obtaining regulatory approvals for, our proposed products. We anticipate that marketing activities for our proprietary products, whether by us or one or more of our licensees, if any, will not begin until 2005 at the earliest. Accordingly, it is not anticipated that we will generate any revenues from royalties or sales of proprietary products until regulatory approvals are obtained and marketing activities begin. Any one or more of our proposed proprietary products may not prove to be commercially viable, or if viable, may not reach the marketplace on a basis consistent with our desired timetables. The failure or the delay of any one or more of our proposed products to achieve commercial viability would have a material adverse effect on us. See "Description of Business - Proposed Products" and "Description of Business - Government Regulation."

### WE HAVE NOT COMPLETED PRODUCT DEVELOPMENT

We have not completed the development of our proposed products and we will be required to devote considerable effort and expenditures to complete such development. In addition to obtaining adequate financing, satisfactory completion of development, testing, government approval and sufficient production levels of such products must be obtained before the proposed products will become available for commercial sale. We do not anticipate generating material revenue from product sales until perhaps 2005 or thereafter. Other potential products remain in the conceptual or very early development stage and remain subject to all the risks inherent in the development of pharmaceutical products, including unanticipated development problems and possible lack of funds to undertake or continue development. These factors could result in abandonment or substantial change in the development of a specific formulated product. We may not be able to successfully develop any one or more of our proposed products or develop such proposed products on a timely basis. Further, such proposed products may not be commercially accepted if developed. The inability to successfully complete development, or a determination by us, for financial or other reasons, not to undertake to complete development of any proposed product, particularly in instances in which we have made significant capital expenditures, could have a material adverse effect on us.

### WE DO NOT HAVE DIRECT CONSUMER MARKETING EXPERIENCE

We have no experience in marketing or distribution at the consumer level of our proposed products. Moreover, we do not have the financial or other resources to undertake extensive marketing and advertising activities. Accordingly, we intend generally to rely on marketing arrangements, including possible joint ventures or license or distribution arrangements with third parties. 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. If we fail to

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enter into these agreements or if we or the third parties do not perform under such agreements, it could impair our ability to commercialize our products. If we do not develop a marketing force of our own, then we will depend on arrangements with corporate partners or other entities for the marketing and sale of our remaining products. Our strategy to rely on third party marketing arrangements could adversely affect our profit margins. See "Description of Business - Marketing and Distribution."

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### 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 comparable foreign authorities, or both, before commercial manufacture of any such products and periodic cGMP compliance inspections thereafter by the FDA. We, or any of our third party manufacturers, may not be able to comply with cGMP or satisfy pre- or post-approval inspections by the FDA or comparable Foreign authorities in connection with the manufacture of our proposed products. Failure or delay by us or any such manufacturer to comply with cGMP or satisfy pre- or post-approval inspections would have a material adverse effect on us. See "Description of Business - Manufacturing."

### WE ARE DEPENDENT ON OUR SUPPLIERS

We believe that the active ingredients used in the manufacture of our proposed pharmaceutical products are presently available from numerous suppliers located in the United States, Europe, India and Japan.

We believe that certain raw materials, including inactive ingredients, are available from a limited number of suppliers and that certain packaging materials intended for use in connection with our spray products currently are available only from sole source suppliers. Although we do not believe we will encounter difficulties in obtaining the inactive ingredients or packaging materials necessary for the manufacture of our proposed products, we may not be able to enter into satisfactory agreements or arrangements for the purchase of commercial quantities of such materials. We have a written supply agreement with Dynamit Nobel for certain raw materials for our nitroglycerin lingual spray 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, or the failure of Dynamit Nobel to comply with its supply obligations to us, could have a material adverse effect on our ability to arrange for the manufacture of formulated products. In addition, development and regulatory approval of our products are dependent upon our ability to procure active ingredients and certain packaging materials from FDA-approved sources. Since the FDA approval process requires manufacturers to specify their proposed suppliers of active ingredients and certain packaging materials in their applications, FDA approval of a supplemental application to use a new supplier would be required if active ingredients or such packaging materials were no longer available from the originally specified supplier, which may result in manufacturing delays. If we do not maintain important manufacturing relationships, we may fail to find a replacement manufacturer or to develop our own manufacturing capabilities. If we cannot do so, it could delay or impair our ability to obtain regulatory approval for our products and substantially increase our costs or deplete any profit margins. If we do find replacement manufacturers, we may not be able to enter into agreements with them on terms and conditions favorable to us and, there could be a substantial delay before a new facility could be qualified and

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registered with the FDA and foreign regulatory authorities. See "Description of Business - Raw Materials and Suppliers."

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### WE FACE INTENSE COMPETITION

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

Accordingly, our competitors may succeed in obtaining patent protection, receiving FDA or comparable foreign approval or commercializing products before us. If we commence commercial product sales, we will compete against companies with greater marketing and manufacturing capabilities who may successfully develop and commercialize products that are more effective or less expensive than ours. These are areas in which, as yet, we have limited or no experience. In addition, developments by our competitors may render our product candidates obsolete or noncompetitive.

We are aware of several companies that are selling or developing lingual spray products. First Horizon Pharmaceutical Corporation, headquartered in Alpharetta, Georgia, currently markets Nitrolingual(R) Pumpspray, a nitroglycerin lingual spray which is in an "air" propelled dispensing system (our nitroglycerin lingual spray is in a "propellant" based dispensing system). Generex Biotechnology Corporation, based in Toronto, Canada, is developing an insulin formulation that is delivered directly into the mouth via their RapidMist(TM) device. They also state that they have begun research on four specific target molecules for their RapidMist delivery system: morphine, fentanyl, heparin and flu vaccine. Sirius Pharmaceuticals Ltd., based in the United Kingdom, also claims to be developing drugs to be delivered sublingually via an aerosol spray. Sirius is working in the areas of pain and emesis. There are several other companies that we are aware of that market lingual spray products containing vitamins and homeopathic ingredients.

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

THE ABSENCE OF PRODUCT LIABILITY INSURANCE COVERAGE MAY AFFECT OUR BUSINESS

We may be exposed to potential product liability claims by consumers. We presently do not maintain product liability insurance coverage. Although we will seek to obtain product liability insurance before the commercialization of any of our proposed 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. Any product liability claim, even one that was not in excess of our insurance coverage or one that is meritless and/or unsuccessful, could adversely affect our cash available for other purposes, such as research and development. In addition, the existence of a product liability claim could affect the market price of our common stock. In addition, certain food and drug retailers require minimum product liability insurance coverage as a condition precedent to purchasing or accepting products for retail distribution. Product liability insurance coverage includes various deductibles, limitations and exclusions from coverage, and in any event might not fully cover any potential claims. Failure to satisfy such insurance requirements could impede the ability of us or our distributors to achieve broad retail distribution of our proposed products, which could have a material adverse effect on us. See "Description of Business - Product Liability."

EXTENSIVE GOVERNMENT REGULATION MAY AFFECT OUR BUSINESS

The development, manufacture and commercialization of pharmaceutical products is generally subject to extensive regulation by various federal and state governmental entities. The FDA, which is the principal United States regulatory authority over pharmaceutical products, has the power to seize adulterated or misbranded products and unapproved new drugs, to request their recall from the market, to enjoin further manufacture or sale, to publicize certain facts concerning a product and to initiate criminal proceedings. As a result of federal statutes and FDA regulations pursuant to which new pharmaceuticals are required to undergo extensive and rigorous testing, obtaining pre-market regulatory approval requires extensive time and expenditures. Under the United States Federal Food, Drug, and Cosmetic (FDC) Act, as amended (21 U.S.C. 301 et. seq.), a new drug may not be commercialized or otherwise distributed in the United States without the prior approval of the FDA. The FDA approval processes relating to new drugs differ, depending on the nature of the particular drug for which approval is sought. With respect to any drug product with active ingredients not previously approved by the FDA, a prospective drug manufacturer is required to submit a new drug application an NDA, which includes complete reports of pre-clinical, clinical and laboratory studies to prove such product's safety and efficacy. The NDA process generally requires, before the submission of the NDA, submission of an investigative new drug application, an IND, pursuant to which permission is sought to begin preliminary clinical testing of the new drug. An NDA, based on published safety and efficacy studies conducted by others, may also be required to be submitted for a drug product with a previously approved active ingredient if the method of delivery, strength or

dosage form is changed. Alternatively, a drug having the same active ingredients as a drug previously approved by the FDA may be eligible to be submitted under an ANDA, which is significantly less stringent than the NDA approval process. While the ANDA process requires a manufacturer to establish bioequivalence to

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the previously approved drug, it permits the manufacturer to rely on the safety and efficacy studies contained in the NDA for the previously approved drug. We believe that the products we develop in spray dosage form will require submission of an NDA. We estimate that the development of new formulations of pharmaceutical products, including formulation, testing and obtaining FDA approval, generally takes four to seven years for the NDA process. Our determinations may prove to be inaccurate or pre-marketing approval relating to our proposed products may not be obtained on a timely basis, if at all. The failure by us to obtain necessary regulatory approvals, whether on a timely basis, or at all, would have a material adverse effect on our business.

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

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

The approval process is lengthy, expensive and uncertain. It is also possible that the FDA or comparable foreign regulatory authorities could interrupt, delay or halt any one or more of our clinical trials. If we, or any regulatory authorities, believe that trial participants face unacceptable health risks, any one or more of our trials could be suspended or terminated. We also may not reach agreement with the FDA and/or comparable foreign agencies on the design of any one or more of the clinical studies necessary for approval. Conditions imposed by the FDA and comparable agencies in foreign countries on our clinical trials could significantly increase the time required for completion of such clinical trials and the costs of conducting the clinical trials. Data obtained from clinical trials are susceptible to varying interpretations which may delay, limit or prevent regulatory approval.

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

The FDA and comparable foreign agencies could withdraw any approvals we obtain. Further, if there is a later discovery of unknown problems or if we fail to comply with other applicable regulatory requirements at any stage in the regulatory process, the FDA may restrict or delay our marketing of a product or force us to make product recalls. In addition, the FDA could impose other sanctions such as fines, injunctions, civil penalties or criminal prosecutions. To market our products outside the United States, we also need to comply with foreign regulatory requirements governing human clinical trials and marketing approval for pharmaceutical products. The FDA and foreign regulators have not

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yet approved any of our products under development for marketing in the United States or elsewhere. If the FDA and other regulators do not approve our products, we will not be able to market our products.

WE EXPECT TO FACE UNCERTAINTY OVER REIMBURSEMENT AND HEALTHCARE REFORM.

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

OUR STRATEGY, IN MANY CASES, IS TO ENTER INTO COLLABORATION AGREEMENTS WITH THIRD PARTIES AND WE MAY REQUIRE ADDITIONAL COLLABORATION AGREEMENTS. IF WE FAIL TO ENTER INTO THESE AGREEMENTS OR IF WE OR THE THIRD PARTIES DO NOT PERFORM UNDER SUCH AGREEMENTS, IT COULD IMPAIR OUR ABILITY TO COMMERCIALIZE OUR PROPOSED PRODUCTS.

Our strategy for the completion of the required development and clinical testing of our proposed products and for the manufacturing, marketing and commercialization of such products, in many cases, depends upon entering into collaboration arrangements with pharmaceutical companies to market, commercialize and distribute the products. Our success depends upon obtaining collaboration partners. In addition, we may depend on our partners' expertise and dedication of sufficient resources to develop and commercialize our proposed products. We may, in the future, grant to collaboration partners rights to license and commercialize pharmaceutical products developed under collaboration agreements. Under these arrangements, our collaboration partners may control key decisions relating to the development of the products. The rights of our collaboration partners would limit our flexibility in considering alternatives for the commercialization of the products. If we fail to successfully develop these relationships or if our collaboration partners fail to successfully develop or commercialize any of our products, it may delay or prevent us from developing or commercializing our proposed products in a competitive and timely manner and would have a material adverse effect on our business.

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

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

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

The patent position of firms relying upon biotechnology is highly uncertain and involves complex legal and factual questions for which important legal principles are unresolved. To date, the United States Patent and Trademark

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Office has not adopted a consistent policy regarding the breadth of claims that the United States Patent and Trademark Office allows in biotechnology patents or the degree of protection that these types of patents afford. As a result, there are risks that we may not develop or obtain rights to products or processes that are or may seem to be patentable.

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

We, and the parties licensing technologies to us, have filed various United States and foreign patent applications with respect to the products and technologies under our development, and the United States Patent and Trademark Office and foreign patent offices have issued patents with respect to our products and technologies. These patent applications include international applications filed under the Patent Cooperation Treaty. Our pending patent applications, those we may file in the future or those we may license from third parties may not result in the United States Patent and Trademark Office or foreign patent office issuing patents. Also, if patent rights covering our products are not sufficiently broad, they may not provide us with sufficient proprietary protection or competitive advantages against competitors with similar products and technologies. Furthermore, if the United States Patent and Trademark Office or foreign patent offices issue patents to us or our licensors, others may challenge the patents or circumvent the patents, or the patent office or the courts may invalidate the patents. Thus, any patents we own or license from or to third parties may not provide any protection against competitors.

Furthermore, the life of our patents is limited. Such patents, which include relevant foreign patents, expire on various dates. We have filed, and when possible and appropriate, will file, other patent applications with respect to our products and processes in the United States and in foreign countries. We may not be able to develop additional products or processes that will be patentable or additional patents may not be issued to us. See also "Risk Factors - If we cannot meet requirements under our license agreements, we could lose the rights to our products."

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

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

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

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

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

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

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

Although we believe that we take reasonable steps to protect our intellectual property, including the use of agreements relating to the non-disclosure of confidential information to third parties, as well as agreements that purport to require the disclosure and assignment to us of the rights to the ideas,

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

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

WE ARE DEPENDENT ON EXISTING MANAGEMENT

Our success is substantially dependent on the efforts and abilities of our President and Chief Executive Officer, Gary A. Shangold, M.D., our founder and Chief Scientific Officer, Harry A. Dugger, III, Ph.D. Decisions concerning our business and our management are and will continue to be made or significantly influenced by these individuals. The loss or interruption of their continued services would have a materially adverse effect on our business operations and prospects. Although our employment agreements with such members of management generally provide for severance payments that are contingent upon the applicable officer's refraining from competition with us, the loss of any of these persons' services would adversely affect our ability to develop and market our products

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and obtain necessary regulatory approvals, and the applicable noncompetition provisions can be difficult and costly to monitor and enforce. Further, we do not maintain key-man life insurance.

Our future success also will depend in part on the continued service of our key scientific and management personnel and our ability to identify, hire and retain additional personnel, including marketing and sales staff. We experience intense competition for qualified personnel, and the existence of non-competition agreements between prospective employees and their former employers may prevent us from hiring those individuals or subject us to suit from their former employers.

While we attempt to provide competitive compensation packages to attract and retain key personnel, some of our competitors are likely to have greater resources and more experience than we have, making it difficult for us to compete successfully for key personnel.

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### WE ARE CONTROLLED BY CURRENT STOCKHOLDERS, OFFICERS AND DIRECTORS

Our directors, executive officers and principal stockholders and certain of our affiliates have the ability to influence the election of our directors and most other stockholder actions. Management and our affiliates currently beneficially own (including shares they have the right to acquire) approximately 42.93% of our common stock. Specifically, Dr. Rosenwald has the ability to exert significant influence over the election of the Board and other matters submitted to our stockholders for approval. Such positions may discourage or prevent any proposed takeover of NovaDel, including transactions in which our stockholders might otherwise receive a premium for their shares over the then current market prices. Our directors, executive officers and principal stockholders may influence corporate actions, including influencing elections of directors and significant corporate events.

### THE 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 OTCBB is an unorganized, inter-dealer, over-the-counter market which provides significantly less liquidity than Nasdaq and the national securities exchange, and quotes for securities quoted on the OTCBB are not listed in the financial sections of newspapers as are those for Nasdaq and the national securities exchange. In addition, the overall market for securities 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.

### LIMITATIONS IN CONNECTION WITH THE AVAILABILITY OF QUOTES AND ORDER INFORMATION ON THE OTCBB

Trades and quotations on the OTCBB involve a manual process and the market information for such securities cannot be guaranteed. In addition, quote information, or even firm quotes, may not be available. The manual execution process may delay order processing and intervening price fluctuations may result

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in the failure of a limit order to execute or the execution of a market order at a significantly different price. Execution of trades, execution reporting and the delivery of legal trade confirmation may be delayed significantly. Consequently, one may not be able to sell shares of our common stock at the optimum trading prices.

### DELAYS IN ORDER COMMUNICATION IN THE OTCBB

Electronic processing of orders is not available for securities traded on the OTCBB and high order volume and communication risks may prevent or delay the execution of one's OTCBB trading orders. This lack of automated order processing may affect the timeliness of order execution reporting and the availability of firm quotes for shares of our common stock. Heavy market volume may lead to a delay in the processing of OTCBB security orders for shares of our common stock, due to the manual nature of the market. Consequently, one may not be able to sell shares of our common stock at the optimum trading prices.

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

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

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

- o control of the market for the security by one or more broker-dealers that are often related to the promoter or issuer;
- o manipulation of prices through prearranged matching of purchases and

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sales and false and misleading press releases;

- o "boiler room" practices involving high pressure sales tactics and unrealistic price projections by inexperienced sales persons;
- o excessive and undisclosed bid-ask differentials and markups by selling broker-dealers; and

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- o 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.

### RISK OF MARKET FRAUD

OTCBB securities are frequent targets of fraud or market manipulation. Not only because of their generally low price, but also because the OTCBB reporting requirements for these securities are less stringent than for listed or NASDAQ traded securities, and no exchange requirements are imposed. Dealers may dominate the market and set prices that are not based on competitive forces. Individuals or groups may create fraudulent markets and control the sudden, sharp increase of price and trading volume and the equally sudden collapse of the market price for shares of our common stock.

### LIMITED LIQUIDITY ON THE OTCBB

When fewer shares of a security are being traded on the OTCBB, volatility of prices may increase and price movement may outpace the ability to deliver accurate quote information. Due to lower trading volumes in shares of our common stock, there may be a lower likelihood of one's orders for shares of our common stock being executed, and current prices may differ significantly from the price one was quoted by the OTCBB at the time of one's order entry.

### LIMITATION IN CONNECTION WITH THE EDITING AND CANCELING OF ORDERS ON THE OTCBB

Orders for OTCBB securities may be canceled or edited like orders for other securities. All requests to change or cancel an order must be submitted to, received and processed by the OTCBB. Due to the manual order processing involved in handling OTCBB trades, order processing and reporting may be delayed, and one may not be able to cancel or edit one's order. Consequently, one may not be able to sell shares of our common stock at the optimum trading prices.

### INCREASED DEALER COMPENSATION

The dealer's spread (the difference between the bid and ask prices) may be large and may result in substantial losses to the seller of shares of our common stock on the OTCBB if the stock must be sold immediately. Further, purchasers of shares of our common stock may incur an immediate "paper" loss due to the price spread. Moreover, dealers trading on the OTCBB may not have a bid price for shares of our common stock on the OTCBB. Due to the foregoing, demand for shares of our common stock on the OTCBB may be decreased or eliminated.

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

We are authorized to issue 50,000,000 shares of our common stock. As of February 6, 2004, there were 32,877,642 shares of common stock issued and outstanding. However, the total number of shares of our common stock issued and outstanding does not include shares reserved in anticipation of the exercise of options or warrants. As of February 6, 2004, we had outstanding stock options and warrants to purchase approximately 20,814,196 shares of our common stock, the exercise price of which range between \$0.63 per share to \$3.18 per share, and we have reserved shares of our common stock for issuance in connection with the potential exercise thereof. Of the reserved shares, a total of 2,145,000 shares are currently reserved for issuance in connection with our 1992, 1997 and 1998 Stock Option Plans, of which options to purchase an aggregate of 500,000, 500,000 and 1,238,500 shares have been issued under the respective stock option plans. Another 3,800,000 shares are reserved for issuance and available for the options granted pursuant to the terms of the employment agreements of various of our current and former officers. A significant number of such options and warrants contain provisions for cashless exercise. To the extent such options or warrants are exercised, the holders of our common stock will experience further dilution. In addition, in the event that any future financing should be in the form of, be convertible into or exchangeable for, equity securities, and upon the exercise of options and warrants, investors may experience additional dilution. See "Risk Factors - Our additional financing requirements could result in dilution to existing stockholders."

The exercise of the outstanding derivative securities, will reduce the percentage of common stock held by our stockholders. Further, the terms on which we could obtain additional capital during the life of the derivative securities may be adversely affected, and it should be expected that the holders of the derivative securities would exercise them at a time when we would be able to obtain equity capital on terms more favorable than those provided for by such derivative securities. As a result, any issuance of additional shares of common stock may cause our current stockholders to suffer significant dilution which may adversely affect the market.

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

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WE DO NOT HAVE A SUFFICIENT NUMBER OF UNRESERVED AUTHORIZED COMMON STOCK TO ISSUE ALL OF THE SHARES OF COMMON STOCK REQUIRED TO BE ISSUED IN CONNECTION WITH OUTSTANDING WARRANTS AND OPTIONS.

We are required to hold a meeting of stockholders to, among other things, seek the authorization of its stockholders to amend our Certificate of Incorporation to, among other things, provide for the issuance of a number of additional shares of common stock to allow us to issue shares of common stock issuable upon the exercise of all our outstanding derivative securities. We intends to hold our annual stockholders meeting during the first half of calendar year 2004 and to request that the stockholders approve an amendment to the Certificate of

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Incorporation as set forth above. The stockholders may not approve such amendment. Further, we may not be able to hold our annual meeting of stockholders in a timely manner, if at all. In the event that the holders of our outstanding derivative securities exercise such securities at a time that we do not have a sufficient number of shares of common stock authorized for issuance, we will be forced not to honor the exercise of such securities. In such an event, any related liability incurred by us may have a material adverse effect on our business.

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

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

### LIMITATION ON DIRECTOR/OFFICER LIABILITY.

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

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

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

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

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

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to our assets upon liquidation, the right to receive dividend payments before dividends are distributed to the holders of common stock and the right to the redemption of the shares, together with a premium, prior to the redemption of our common stock.

### Forward-Looking Statements

The statements set forth under the captions "Company Summary" and elsewhere in this prospectus, including under "Risk Factors," and those incorporated by reference herein which are not historical constitute "Forward Looking Statements" within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act of 1934, including statements regarding the expectations, beliefs, intentions or strategies for the future. We intend that all forward-looking statements be subject to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are only predictions and reflect our views as of the date they are made with respect to future events and financial performance. Forward-looking statements are subject to many risks and uncertainties which could cause our actual results to differ materially from any future results expressed or implied by the forward-looking statements.

Examples of the risks and uncertainties include, but are not limited to: the inherent risks and uncertainties in developing products of the type we are developing; possible changes in our financial condition; the progress of our research and development; clinical trials require adequate supplies of drug substance and drug product, which may be difficult or uneconomical to procure or manufacture; timely obtaining sufficient patient enrollment in our clinical trials; the impact of development of competing therapies and/or technologies by other companies; our ability to obtain additional required financing to fund our research programs; our ability to enter into agreements with collaborators and the failure of collaborators to perform under their agreements with us; the progress of the FDA approvals in connection with the conduct of our clinical trials and the marketing of our products; the additional costs and delays which may result from requirements imposed by the FDA in connection with obtaining the required approvals.

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

### Use of Proceeds

We will not receive any of the proceeds from the sale of the shares owned by the selling security holders. However, we will receive funds from the exercise of outstanding warrants and unit purchase options, if such warrants and unit purchase options are exercised. Some of the outstanding warrants and unit purchase options contain provisions for cashless exercise. We intend to use all of such proceeds for working capital and general corporate purposes.

### Selling Security Holders

The following table sets forth the stockholders who are offering their shares of our common stock for sale under this prospectus, the amount of shares owned by such stockholder prior to this offering, the amount to be offered by such stockholder and the amount to be owned by such stockholders following completion of the offering. The prior-to-offering figures are as of February 6, 2004. All share numbers are based on information that these stockholders supplied to us. This table assumes that each stockholder will sell all of its shares available

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for sale during the effectiveness of the registration statement that includes this prospectus. Stockholders are not required to sell their shares. Beneficial ownership is determined in accordance with Commission rules and regulations and includes voting or investment power with respect to the securities.

The percentage interest of each selling security holder is based on the beneficial ownership of such selling security holder divided by the sum of the current outstanding shares of common stock plus the additional shares, if any, which would be issued to such selling security holder (but not any other selling stockholder) when exercising warrants, unit purchase options or other rights in the future.

| Name                                   | Number of<br>Shares of<br>Common<br>Stock, not<br>including<br>Warrants,<br>Benefi-<br>cially<br>Owned | Number of<br>Shares<br>Represented<br>by<br>Warrants<br>Benefi-<br>cially<br>Owned | Total<br>Number of<br>Shares of<br>Common<br>Stock<br>Benefi-<br>cially<br>Owned | Percentage<br>Benefi-<br>cially<br>Owned<br>Before<br>Offering |
|--|--|--|--|--|
| Atlas Fund, LLC.                       | 808,179  | 242,453  | 1,050,632  | 3.17%  |
| The Bahr Family Limited Partnership    | 40,409   | 12,122   | 52,531   | *  |
| Barry J. Lind revoc trust Dtd 12/19/89 | 161,636  | 48,490   | 210,126  | *  |
| Beechwood Ventures LLC                 | 310,022  | 30,306   | 340,328  | 1.03%  |
| Brino Investment Ltd.                  | 108,232  | 26,517   | 134,749  | *  |
| Bristol Investment Fund, Ltd.          | 285,714  | 85,714   | 371,428  | 1.13%  |
| CC LifeScience Ltd.                    | 285,714  | 85,714   | 371,428  | 1.13%  |
| Chicago Private Investments Inc.       | 50,511   | 15,153   | 65,664   | *  |
| Clearwater Fund I, LP                  | 404,090  | 121,227  | 525,317  | 1.59%  |
| Clearwater Offshore Fund, Ltd.         | 404,090  | 121,227  | 525,317  | 1.59%  |
| Coqui Capital Partners, LP             | 80,818   | 24,245   | 105,063  | *  |
| Domaco Venture Capital Fund            | 20,204   | 6,061  | 26,265   | *  |

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|   |           |         |           |       |
|---|-----------|---------|-----------|-------|
| Dov Perlysky Grantor Retained Annuity Trust DTD 1/5/01            | 101,022   | 30,306  | 131,328   | *     |
| E&M RP Trust  | 164,084   | 36,368  | 200,452   | *     |
| Ellis International Ltd.  | 40,409    | 12,122  | 52,531    | *     |
| The Esther Stahler Grantor Retained Annuity Trust DTD 1/5/01      | 121,227   | 36,368  | 157,595   | *     |
| Gitel Family Partnership, LP                                      | 121,227   | 36,368  | 157,595   | *     |
| Moise E. Hendeles Trustee for the Hendeles Grandchildren Trust #2 | 20,204    | 6,061   | 26,265    | *     |
| Moise Hendeles Trustee for the Hendeles Grandchildren Trust       | 20,204    | 6,061   | 26,265    | *     |
| Hyman Lezell Revocable Trust                                      | 20,204    | 6,061   | 26,265    | *     |
| Kanter Family Foundation  | 50,511    | 15,153  | 65,664    | *     |
| Keys Foundation   | 1,047,619 | 254,762 | 1,302,381 | 3.93% |
| Lind Family Investments LP DTD 8/15/01                            | 20,204    | 6,061   | 26,265    | *     |
| MEH Revocable Trust   | 40,409    | 12,122  | 52,531    | *     |
| Michael H. Schwartz Profit Sharing Plan                           | 40,409    | 12,122  | 52,531    | *     |
| Milstein Family Ltd Partnership                                   | 40,409    | 12,122  | 52,531    | *     |

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|   |           |         |           |       |
|---|-----------|---------|-----------|-------|
| PCG Tagi (Series L), LLC  | 848,588   | 254,576 | 1,103,164 | *     |
| Perceptive Life Sciences Master Fund, Ltd.                          | 1,648,696 | 494,609 | 2,143,305 | 6.42% |
| Quogue Capital LLC  | 422,274   | 126,682 | 548,956   | 1.66% |
| Rachel Family Partnership   | 101,022   | 30,306  | 131,328   | *     |
| Rawls Family L.P.   | 202,045   | 60,613  | 262,658   | *     |
| RL Capital Partners, L.P.   | 60,613    | 18,183  | 78,796    | *     |
| Smithfield Fiduciary LLC  | 344,902   | 85,613  | 430,515   | 1.31% |
| Stephan P. Vermut & Barbara T. Vermut<br>2000 Trust                 | 169,718   | 50,915  | 220,633   | *     |
| Steven M. Oliveira 1998 Charitable<br>Remainder Unitrust            | 242,454   | 72,736  | 315,190   | *     |
| Symmetry Capital Offshore Fund Ltd.                                 | 44,018    | 13,205  | 57,223    | *     |
| Symmetry Capital Partners, L.P.                                     | 114,140   | 34,242  | 148,382   | *     |
| Symmetry Capital Qualified Partners, L.P.                           | 153,306   | 45,991  | 199,297   | *     |
| Symmetry Parallax Partners, L.P.                                    | 92,625    | 27,787  | 120,412   | *     |
| Tisu Investment Ltd.  | 108,231   | 18,183  | 126,414   | *     |
| Vertical Ventures, LLC  | 202,045   | 60,613  | 262,658   | *     |
| Weiss Peck & Greer Investments, a<br>division of Robeco USA, L.L.C. | 476,190   | 142,857 | 619,047   | 1.87% |
| Alan Bresler and Hanna Bresler JTWROS                               | 60,613    | 18,183  | 78,796    | *     |
| Alan Jay Young  | 80,818    | 24,245  | 105,063   | *     |
| Albert Bruno  | 8,082     | 2,424   | 10,506    | *     |
| Albert Fried, Jr.   | 484,908   | 145,472 | 630,380   | 1.91% |
| Albert Milstein   | 40,409    | 12,122  | 52,531    | *     |
| Alexander Pomper  | 202,045   | 60,613  | 262,658   | *     |
| Anthony G. Polak "S"  | 20,204    | 6,061   | 26,265    | *     |
| Fiserv Securities Inc. A/C/F Anthony G.<br>Polak Std IRA            | 20,204    | 6,061   | 26,265    | *     |
| Clark Schubach  | 88,644    | 19,093  | 107,737   | *     |
| Dr. Daniel Kessel   | 30,204    | 6,061   | 36,265    | *     |
| Daniel Lenchner   | 12,123    | 3,636   | 15,759    | *     |
| David and Nancy Pudelsky JTWROS                                     | 20,204    | 6,061   | 26,265    | *     |
| David J. Bershad  | 42,429    | 12,728  | 55,157    | *     |
| David Jaroslawicz   | 155,818   | 24,245  | 180,063   | *     |
| David Moss  | 20,204    | 6,061   | 26,265    | *     |
| David Saks  | 80,818    | 24,245  | 105,063   | *     |

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|   |         |         |         |       |
|---|---------|---------|---------|-------|
| David W. Ruttenberg   | 52,381  | 12,143  | 64,524  | *     |
| Dean Glasser  | 12,123  | 3,636   | 15,759  | *     |
| Edmund A. Debler  | 80,818  | 24,245  | 105,063 | *     |
| Gary J. Strauss   | 74,857  | 16,505  | 91,362  | *     |
| Gregg Dovolis   | 20,204  | 6,061   | 26,265  | *     |
| Gregory & Donna Lenchner JTWROS                                     | 20,204  | 6,061   | 26,265  | *     |
| Hans F. Heye  | 404,090 | 121,227 | 525,317 | 1.59% |
| Susan and Harry Newton JTWROS                                       | 58,409  | 12,122  | 70,531  | *     |
| Harvey Lenchner   | 16,164  | 4,849   | 21,013  | *     |
| Harvey & Ronnie Lustig JTWROS                                       | 20,204  | 6,061   | 26,265  | *     |
| Hillel Weinberger   | 142,857 | 30,000  | 172,857 | *     |
| Howard Gittis   | 309,524 | 63,095  | 372,619 | 1.13% |
| Delaware Charter Guarantee & Tr. Co.<br>F/B/O Howard M. Tanning IRA | 121,227 | 36,368  | 157,595 | *     |
| Isaac R. Dweck  | 142,857 | 30,000  | 172,857 | *     |
| Ivan Kaufman  | 142,857 | 30,952  | 173,809 | *     |
| J. Jay Lobell   | 80,818  | 24,245  | 105,063 | *     |
| J. William Doyle  | 80,818  | 24,245  | 105,063 | *     |

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|  |         |         |         |       |
|--|---------|---------|---------|-------|
| Fiserv Securities A/C/F Jack Polak IRA     | 20,204  | 6,061   | 26,265  | *     |
| Jacob Gottlieb                             | 161,636 | 48,490  | 210,126 | *     |
| Jay Kestenbaum                             | 40,409  | 12,122  | 52,531  | *     |
| Jedd Wider                                 | 84,859  | 25,457  | 110,316 | *     |
| John O. Dunkin                             | 40,409  | 12,122  | 52,531  | *     |
| Joseph J. Vale                             | 80,818  | 24,245  | 105,063 | *     |
| Larry & Shirley Kessel JTWROS (1)          | 20,204  | 6,061   | 26,265  | *     |
| Mark Berg IRA                              | 510,714 | 167,500 | 678,214 | 1.90% |
| Mark Mazzer                                | 43,333  | 9,964   | 53,297  | *     |
| Naomi Waldman                              | 20,204  | 6,061   | 26,265  | *     |
| Nathan Eisen                               | 40,409  | 12,122  | 52,531  | *     |
| Neel B & Martha N. Ackerman JTWROS         | 202,045 | 60,613  | 262,658 | *     |
| Paul F. Berlin                             | 40,409  | 12,122  | 52,531  | *     |
| Phil Lifschitz                             | 40,409  | 12,122  | 52,531  | *     |
| Philip Schiller                            | 40,409  | 12,122  | 52,531  | *     |
| Praful Desai                               | 20,204  | 6,061   | 26,265  | *     |
| Richard Pashayan                           | 12,931  | 3,879   | 16,810  | *     |
| Robert J. Leaf                             | 20,204  | 6,061   | 26,265  | *     |
| Robert L. McEntire                         | 121,227 | 36,368  | 157,595 | *     |
| Robert S. Waldman                          | 20,204  | 6,061   | 26,265  | *     |
| Ronald M. Lazar IRA                        | 40,409  | 12,122  | 52,531  | *     |
| S. Edmond Farber                           | 20,204  | 6,061   | 26,265  | *     |
| Lucile A. Slocum and Stanley Slocum JTWROS | 40,409  | 12,122  | 52,531  | *     |
| Scott & Amy Koppelman JTWROS               | 40,409  | 12,122  | 52,531  | *     |
| S. Alan Lisenby                            | 121,227 | 36,368  | 157,595 | *     |
| Steven Lisi                                | 80,818  | 24,245  | 105,063 | *     |
| Wayne Saker                                | 40,409  | 12,122  | 52,531  | *     |
| William S. Tyrrell                         | 40,409  | 12,122  | 52,531  | *     |
| William S. Silver MD                       | 20,204  | 6,061   | 26,265  | *     |
| William Weinstein & Mary Sandell JTWROS    | 20,204  | 6,061   | 26,265  | *     |
| Glennen, Thomas J.                         | 190,476 | 33,334  | 223,810 | *     |

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|                                 |         |         |           |       |
|---------------------------------|---------|---------|-----------|-------|
| Lipton, Eva                     | 23,809  | 4,167   | 27,976    | *     |
| Sanzo, Carmine                  | 47,619  | 8,334   | 55,953    | *     |
| Colby, Trevor                   | 47,619  | 8,334   | 55,953    | *     |
| Falk, Robert                    | 142,857 | 25,000  | 167,857   | *     |
| Kash Family Trust               | 23,809  | 4,167   | 27,976    | *     |
| Levitin, Eli                    | 23,809  | 4,167   | 27,976    | *     |
| Schain, Howard                  | 14,285  | 2,500   | 16,785    | *     |
| Wolfson, Aaron                  | 38,095  | 6,667   | 44,762    | *     |
| South Ferry #2, LP              | 476,190 | 83,334  | 559,524   | 1.70% |
| Cornell Capital Partners, LP-   | 95,238  | 16,667  | 111,905   | *     |
| Ivette's Isaac Dabah 2002 Trust | 280,952 | 49,167  | 330,119   | 1.00% |
| Grunstein, Leonard              | 23,809  | 4,167   | 27,976    | *     |
| The Mataponi Trust              | 23,809  | 4,167   | 27,976    | *     |
| Riverside Contracting, LLC      | 47,619  | 8,334   | 55,953    | *     |
| Lydon, Harris R.L. Jr.          | 23,809  | 4,167   | 27,976    | *     |
| Kazam, Bonnie B.                | 95,238  | 16,667  | 111,905   | *     |
| Koffman, Burton I.              | 23,809  | 4,167   | 27,976    | *     |
| MHR Capital Partnership, LP     | 952,380 | 166,667 | 1,119,047 | 3.39% |
| Mullen, Michael A.              | 23,809  | 4,167   | 27,976    | *     |
| The Osterweis Revocable Trust   | 47,619  | 8,334   | 55,953    | *     |
| Wolcot Capital, Inc             | 42,857  | 7,500   | 50,357    | *     |
| Prager, Dr. Tis                 | 108,232 | 27,147  | 135,379   | *     |
| Bruno Widmer                    | 108,232 | 27,147  | 135,379   | *     |

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|                            |           |           |            |        |
|----------------------------|-----------|-----------|------------|--------|
| Lindsay A. Rosenwald, M.D. | 6,616,666 | 7,355,243 | 13,971,909 | 34.72% |
| William Corcoran           | 11,303    | 3,390     | 14,693     | *      |
| Timothy McInerney          | 220,794   | 89,772    | 310,566    | *      |
| Scott Katzmann             | 69,569    | 55,108    | 124,677    | *      |
| Peter Kash                 | 54,450    | 68,923    | 123,373    | *      |
| Joshua Kazam               | 54,450    | 65,829    | 120,279    | *      |
| Michael Weiser             | 62,007    | 18,602    | 80,609     | *      |
| John Knox                  | 11,303    | 3,391     | 14,694     | *      |
| Stephen Rocamboli          | 17,333    | 5,200     | 22,533     | *      |
| Basil Christakos           | 14,333    | 4,300     | 18,633     | *      |
| John Papadimitropoulos     | 6,432     | 1,929     | 8,361      | *      |
| Michael Rosenman           | 33,215    | 9,964     | 43,179     | *      |
| Benjamin Bernstein         | 5,000     | 1,500     | 6,500      | *      |
| Bernard Gross              | 2,000     | 600       | 2,600      | *      |
| Michael A. Mullen          | 76,127    | 19,862    | 95,989     | *      |
| Vito Balsamo               | 10,102    | 3,030     | 13,132     | *      |
| Charles M. Raspa           | 2,500     | 750       | 3,250      | *      |
| Steven Markowitz           | 26,159    | 7,847     | 34,006     | *      |
| Robert P. Petrozzo         | 25,255    | 7,576     | 32,831     | *      |
| Joseph Sorbara             | 26,159    | 7,847     | 34,006     | *      |
| Fabio Migliaccio           | 10,000    | 3,000     | 13,000     | *      |
| Robert D. Millstone        | 28,488    | 8,546     | 37,034     | *      |
| Steven A. Sherman          | 16,243    | 4,273     | 20,516     | *      |
| Sandgrain Securities, Inc. | 4,747     | 1,424     | 6,171      | *      |

\* Less than 1%.

(1) Lawrence J. Kessel serves on our Board of Directors.

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The information contained in this table reflects "beneficial" ownership of common stock within the meaning of Rule 13d-3 under the Exchange Act. As of February 6, 2004, the Company had 32,877,642 shares of common stock outstanding. Beneficial ownership information reflected in the table includes shares issuable upon the exercise of outstanding warrants issued by the Company at their initial exercise prices. Except as set forth above, none of the selling stockholders named in the preceding table has had any position, office or other material relationship with us or any of our affiliates within the past three years.

### Plan of Distribution

In this section of the prospectus, the term "selling security holder" means and includes: (1) the persons identified in the tables above as the selling security holders; and (2) any of their donees, pledgees, distributees, transferees or other successors in interest who may (a) receive any of the shares of our common stock offered hereby after the date of this prospectus and (b) offer or sell those shares hereunder.

The shares of our common stock offered by this prospectus may be sold from time to time directly by the selling security holders. Alternatively, the selling security holders may from time to time offer such shares through underwriters, brokers, dealers, agents or other intermediaries. The selling security holders as of the date of this prospectus have advised us that there were no underwriting or distribution arrangements entered into with respect to the common stock offered hereby. The distribution of the common stock by the selling security holders may be effected: in one or more transactions that may take place on the OTCBB (including one or more block transaction) through customary brokerage channels, either through brokers acting as agents for the selling security holders, or through market makers, dealers or underwriters acting as

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principals who may resell these shares on the OTCBB; in privately-negotiated sales; by a combination of such methods; or by other means. These transactions may be effected at market prices prevailing at the time of sale, at prices related to such prevailing market prices or at other negotiated prices. Usual and customary or specifically negotiated brokerage fees or commissions may be paid by the selling security holders in connection with sales of our common stock.

The selling security holders may enter into hedging transactions with broker-dealers in connection with distributions of the shares or otherwise. In such transactions, broker-dealers may engage in short sales of the shares of our common stock in the course of hedging the positions they assume with the selling security holders. The selling security holders also may sell shares short and redeliver the shares to close out such short positions. The selling security holders may enter into option or other transactions with broker-dealers which require the delivery to the broker-dealer of shares of our common stock. The broker-dealer may then resell or otherwise transfer such shares of common stock pursuant to this prospectus.

The selling security holders also may lend or pledge shares of our common stock to a broker-dealer. The broker-dealer may sell the shares of common stock so lent, or upon a default the broker-dealer may sell the pledged shares of common stock pursuant to this prospectus. Any securities covered by this prospectus which qualify for sale pursuant to Rule 144 may be sold under Rule 144 rather than pursuant to this prospectus. The selling security holders have advised us that they have not entered into any agreements, understandings or arrangements with any underwriters or broker-dealers regarding the sale of their securities. There is no underwriter or coordinating broker acting in connection with the proposed sale of shares of common stock the selling security holders.

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Although the shares of common stock covered by this prospectus are not currently being underwritten, the selling security holders or their underwriters, brokers, dealers or other agents or other intermediaries, if any, that may participate with the selling security holders in any offering or distribution of common stock may be deemed "underwriters" within the meaning of the Securities Act and any profits realized or commissions received by them may be deemed underwriting compensation thereunder.

Under applicable rules and regulations under the Exchange Act, any person engaged in a distribution of shares of the common stock offered hereby may not simultaneously engage in market making activities with respect to the common stock for a period of up to five days preceding such distribution. The selling security holders will be subject to the applicable provisions of the Exchange Act and the rules and regulations promulgated thereunder, including without limitation Regulation M, which provisions may limit the timing of purchases and sales by the selling security holders.

In order to comply with certain state securities or blue sky laws and regulations, if applicable, the common stock offered hereby will be sold in such jurisdictions only through registered or licensed brokers or dealers. In certain states, the common stock may not be sold unless they are registered or qualified for sale in such state, or unless an exemption from registration or qualification is available and is obtained.

We will bear all costs, expenses and fees in connection with the registration of the common stock offered hereby. However, the selling security holders will bear any brokerage or underwriting commissions and similar selling expenses, if any, attributable to the sale of the shares of common stock offered pursuant to this

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prospectus.

We have agreed to indemnify certain of the selling security holders against certain liabilities, including liabilities under the Securities Act, or to contribute to payments to which any of those security holders may be required to make in respect thereof.

### Legal Proceedings

There are no legal proceedings pending to which we are a party and we are unaware of any contemplated material legal actions against us.

### Directors, Executive Officers, Promoters and Control Persons

The names and ages of our directors and executive officers are set forth below. All directors are elected annually by the stockholders to serve until the next annual meeting of the stockholders and until their successors are duly elected and qualified. Officers are elected annually by the Board to serve at the Board's pleasure.

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| Name                           | Age | Position with the Company                             |
|--------------------------------|-----|---|
| Gary A. Shangold, M.D.         | 50  | President, Chief Executive Officer and Director       |
| Harry A. Dugger, III, Ph.D.    | 67  | Chief Scientific Officer                              |
| John H. Klein                  | 57  | Chairman  |
| Robert F. Schaul, Esq.         | 64  | Secretary and Director                                |
| Donald J. Deitman              | 61  | Chief Financial Officer                               |
| Mohammed Abd El-Shafy          | 50  | Vice President, Formulation Development               |
| William F. Hamilton, Ph.D.     | 64  | Director  |
| Lawrence J. Kessel, M.D., FACP | 50  | Director  |
| Mark H. Rachesky, M.D.         | 44  | Director  |
| Charles Nemeroff, M.D., Ph.D.  | 54  | Director  |
| Barry Cohen                    | 41  | Vice President - New Business and Product Development |

Gary A. Shangold, M.D., President, Chief Executive Officer and Director. Dr. Shangold joined NovaDel in December 2002 and was elected as a director in March 2003. Previously, he had been Vice President and Regulatory Head of Drug Development at Johnson & Johnson Pharmaceutical Research and Development, LLC. Before joining the Johnson & Johnson family of companies in 1992, he had been Medical Director of Obstetrics, Gynecology & Infertility at Serono Laboratories, Inc., and had been a member of the faculty of Obstetrics and Gynecology at the University of Chicago's Pritzker School of Medicine from 1983 to 1991. Dr. Shangold also was an Associate Clinical Professor at the Harvard University School of Medicine and a Clinical Associate at Massachusetts General Hospital. Dr. Shangold is a graduate of the University of Pennsylvania and received his M.D. from Columbia University's College of Physicians and Surgeons.

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

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

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

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Donald J. Deitman, Chief Financial Officer. Mr. Deitman joined NovaDel in 1998. From 1988 until joining NovaDel, Mr. Deitman was employed as a business consultant implementing multi-module MRP II software systems. From 1982 to 1988, Mr. Deitman was corporate controller for FCS Industries, Inc., of Flemington, New Jersey. From 1975 to 1982, he was manager of materials and systems for the Walworth Company operations located in Linden and Elizabeth, NJ and from 1966 to 1975, he was employed by Ortho Pharmaceuticals, Inc., and Ortho Diagnostics, Inc. Mr. Deitman received a BS in Accounting from Rutgers University in 1972.

Robert F. Schaul, Esq., Secretary and Director. Mr. Schaul has been a Director of NovaDel since November 1991 and was Vice President, Secretary and General Counsel of NovaDel from November 1991 to February 1995. He has advised NovaDel since its formation. Mr. Schaul is also a part-time Municipal Court Judge for a number of New Jersey municipalities. From 1995 to 1998, Mr. Schaul was Vice President and General Counsel of Landmark Financial Corp. From 1989 to 1991, Mr. Schaul was a partner with the law firm of Glynn, Byrnes and Schaul, and for 20 years prior thereto was an attorney and partner with the law firm Kerby, Cooper, English, Schaul & Garvin, specializing in business law and business related litigation. Mr. Schaul received a BA from New York University in 1961 and a JD from Harvard University in 1964.

William F. Hamilton, Ph.D., Director. Dr. Hamilton was elected to the Board in March 2003. Dr. Hamilton has served on the University of Pennsylvania faculty since 1967, and is the Landau Professor of Management and Technology, and Director of the Jerome Fisher Program in Management and Technology at The Wharton School and the School of Engineering and Applied Science. He serves as a director of Neose Technologies, Inc., a company developing a drug manufacturing process and proprietary drugs. Dr. Hamilton received his B.S. and M.S. in chemical engineering and his M.B.A. from the University of Pennsylvania, and his Ph.D. in applied economics from the London School of Economics. Dr. Hamilton is a member of the Board's Audit Committee and Compensation Committee.

Lawrence J. Kessel, M.D., FACP, Director. Dr. Kessel was elected to the Board in March 2003. He is President of Lawrence J. Kessel, MD & Associates, PC. Dr. Kessel is president of a five physician practice specializing in Internal Medicine and Geriatrics since 1984. He graduated Magna Cum Laude with a B.S. degree from the University of Pittsburgh as an honors major in Biology and subsequently graduated with an MD degree from Temple Medical School. He completed a formal residency in Internal Medicine at Abington Memorial Hospital and is Board Certified in Internal Medicine with added qualification as a diplomat in Geriatric Medicine. He is an active staff attending and Clinical

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Instructor at Chestnut Hill Hospital (University of Pennsylvania affiliate) and Roxborough Memorial Hospital in Philadelphia, Pennsylvania. Dr. Kessel is a Board Reviewer for the American Board of Internal Medicine, as well as a Fellow of the American College of Physicians. He also serves on the advisory board of Independence Blue Cross and is a Clinical Assistant Professor in the Department of Medicine at Temple University Medical School. Dr. Kessel presently serves as a director to Cypress Biosciences, Inc., of San Diego, California, Keryx Biopharmaceuticals, Inc., of New York, New York, and Dor BioPharma, Inc., of Lake Forest, Illinois. He previously served on the Board of Directors of Genta Incorporated.

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Mohammed Abd El-Shafy, Ph.D., Vice President-Formulation Development. Dr. El-Shafy has been an employee of NovaDel since May of 2002. From 1999 to 2002 he was employed as a Team Leader and Senior Scientist with Nasteck Pharmaceutical Company Inc., Hauppauge, New York. From 1998 to 1999, Dr. El-Shafy was a Post-Doctoral Fellow at the University of Wisconsin's School of Pharmacy. He received his doctorate in 1997 from the School of Pharmacy, University of Wales, Cardiff, Wales, UK. From 1983 to 1993, he was an Assistant Lecturer of Pharmaceutical Sciences on the Faculty of Pharmacy, Al-Azhar University, Cairo, Egypt.

Barry Cohen, Vice President of New Business and Product Development. Mr. Cohen joined Novadel in May 2003. Before joining Novadel, he was Vice President-Business Development at Keryx, and before that held several executive marketing and business development positions at Novartis Consumer Health. Mr. Cohen holds a BBA in Marketing from Hofstra University and an MBA in Marketing from Pace University.

Mark H. Rachesky, M.D., Director. Dr. Rachesky joined the Board in June 2003. Dr. Rachesky is the founder and President of MHR Fund Management LLC and affiliates, investment managers of various private investment funds that invest in inefficient market sectors, including special situation equities and distressed investments. Dr. Rachesky is currently on the Board of Directors of Neose. Dr. Rachesky is a graduate of Stanford University School of Medicine and Stanford University School of Business. Dr. Rachesky graduated from the University of Pennsylvania with a major in Molecular Aspects of Cancer.

Charles Nemeroff, M.D., Ph.D., Dr. Nemeroff joined the Board in September 2003. Dr. Nemeroff has been the Reunette W. Harris Professor and Chairman of the Department of Psychiatry and Behavioral Sciences at the Emory University School of Medicine in Atlanta, Georgia, since 1991. He has served on the Mental Health Advisory Council of the National Institute of Mental Health and the Biomedical Research Council for NASA. Dr. Nemeroff is a past President of the American College of Psychiatrists and a past President of the American College of Neuropsychopharmacology and is Editor-in-Chief of Neuropsychopharmacology. He has served as Editor-in-Chief of the Psychopharmacology Bulletin, Associate Editor of Biological Psychiatry and as the Co-Editor-in-Chief of both critical reviews in Neurobiology and Depression and Anxiety. Dr. Nemeroff serves on the Scientific Advisory Board of numerous pharmaceutical companies, including Acadia Pharmaceuticals, Astra Pharmaceuticals, Forest Laboratories, Janssen, Organon, Glaxo-SmithKline Beecham and Wyeth-Ayerst. Dr. Nemeroff has received numerous awards for his research, including the Bowis Award from the American College of Psychiatrists and the Menninger Prize from the American College of Physicians. In 2002 he was elected to the Institute of Medicine.

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### Audit Committee Expert

Our Board of Directors believes that Mr. Rachesky is an audit committee financial expert as defined in the regulations promulgated by the Commission.

### Director Compensation

Our directors are elected annually and serve until the next annual meeting of stockholders and until a successor shall have been duly elected and qualified. Effective July 2003, our directors, who are not employees or consultants, receive for each Board meeting attended fees equal to \$2,000 (telephone meetings are compensated at the rate of \$1,000 per meeting). Such directors are also reimbursed for expenses incurred in connection with their attendance at meetings of the Board. Directors may be removed with or without cause by a vote of the majority of the stockholders then entitled to vote for the election of directors. There were no other arrangements pursuant to which any director was compensated during the fiscal year ended July 31, 2003, for any services provided as a director. The Chairman of each of the Audit and Compensation Committees receives an annual fee equal to \$5,000 for serving as such; other members of the Committees receive an annual fee equal to \$3,000.

### Security Ownership of Certain Beneficial Owners and Management

The following table sets forth information, as of February 6, 2004, with respect to the beneficial ownership of the outstanding shares of our common stock as of such date plus, where relevant for particular beneficial owners, shares which such beneficial owner has the right to acquire within 60 days), by (i) any holder known to us owning more than five percent (5%) of the outstanding shares of our common stock; (ii) our officers and directors; and (iii) our officers and directors as a group:

| Title of<br>Class<br>----- | Name and Address of<br>Beneficial Owner(1)<br>----- | Amount and Nature of<br>Beneficial Ownership<br>----- |
|----------------------------|---|---|
| Common Stock               | Harry A. Dugger, III, Ph.D.                         | 2,104,003 (2)   |
| Common Stock               | Gary A. Shangold, M.D.                              | 333,333 (3)   |
| Common Stock               | John H. Klein                                       | 333,333 (4)   |
| Common Stock               | Donald J. Deitman                                   | 0   |
| Common Stock               | Robert F. Schaul, Esq.                              | 274,286 (5)   |
| Common Stock               | Mohammed Abd El-Shafy                               | 150,000 (6)   |
| Common Stock               | William F. Hamilton, Ph.D.                          | 33,333 (7)  |
| Common Stock               | Lawrence J. Kessel, M.D., FACP                      | 59,598 (8)  |
| Common Stock               | Barry Cohen   | 0 (9)   |
| Common Stock               | Mark H. Rachesky                                    | 1,119,047 (10)  |
| Common Stock               | Charles Nemeroff, M.D., Ph.D.                       | 0 (11)  |
| Common Stock               | Lindsay A. Rosenwald, M.D.                          | 13,971,909 (12)                                       |

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|              |  |   |
|--------------|--|---|
| Common Stock | Biomedical Investment Group, LLC                             | 5,333,332 (12) (13)                             |
| Common Stock | All Executive Officers and Directors as a group (11 persons) | 4,406,933 (2) (3) (4) (6) (7) (8) (9) (10) (11) |

\* Less than 1%.

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

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

(3) Represents 333,333 Non-Plan options, issued in December 2002, exercisable at \$1.93 per share. Does not include additional Non-Plan options to purchase 666,667 shares of common stock at an exercise price of \$1.93 per share. These additional options vest in two equal annual installments, beginning in December 2004. All of such options expire in December 2007.

(4) Represents 333,333 Non-Plan Options exercisable at \$2.40 per share. The options expire in March 2004.

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

(6) Includes Non-Plan Options exercisable at \$3.02 per share; does not include additional Non-Plan Options to purchase 50,000 shares of common stock at an exercise price of \$3.02 per share, which additional options vest in May 2004. All of such options expire in May 2012. Also includes 50,000 options issued under the 1998 Option Plan to purchase common stock at an exercise price of \$1.51 per share, expiring in March 2008.

(7) Represents 33,333 Non-Plan Options exercisable at \$1.51 per share which vest in March 2004. Does not include additional Non-Plan options to purchase 66,667 shares of common stock at an exercise price of \$1.51 per share, which shall vest in two annual installments beginning in March of 2004. All of such options expire in 2008.

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(8) Represents 20,204 shares of common stock, warrants to purchase 6,061 shares of common stock at an exercise price of \$1.40 per share which expire in January 2009 and 33,333 Non-Plan options exercisable at \$1.51 per share which vest in March 2004. Does not include additional Non-Plan options to purchase 66,667 shares of common stock at an exercise price of \$1.51 per share, which shall vest in two annual installments beginning in March of 2004. All of such options expire in 2008.

(9) Does not include 75,000 options issued under the 1998 Plan to purchase common stock at an exercise price of \$2.01 per share. The options expire in May 2008 and vest subject to certain conditions.

(10) Does not include options to purchase 100,000 shares of common stock at an exercise price of \$2.15 per share, which shall vest in three annual installments beginning June, 2004. Includes 666,667 shares of common stock and warrants to purchase 166,667 shares of common stock at an exercise price of \$2.00 per share which expire in April, 2008. Such shares and warrants are held by MHR Capital Partnership, LP, which is controlled by Dr. Rachesky.

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(11) Does not include options to purchase 100,000 shares of common stock at an exercise price of \$1.85 per share, which shall vest in three annual installments beginning September 2004.

(12) Includes 3,950,000 shares of common stock and warrants to purchase 3,950,000 shares of common stock at an exercise price of \$.75 per share which expire in December 2008. Also includes 2,666,666 shares of common stock and warrants to purchase 2,666,666 shares of common stock, which expire in March 2009, owned by Biomedical Investment Group, LLC, which is an affiliate of Lindsay A. Rosenwald. Also includes unit purchase options entitling Dr. Rosenwald to purchase 568,136 shares of common stock and warrants to purchase an additional 170,441 shares of common stock, each at a purchase price equal to \$1.40 per share. Such options and warrants expire on December 30, 2008.

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

### Description of Securities

#### General

The following description of our capital stock does not purport to be complete and is subject to and qualified in its entirety by our certificate of incorporation and bylaws, which are included as exhibits to the registration statement of which this prospectus forms a part, and by the applicable provisions of Delaware law.

We are authorized to issue up to 50,000,000 shares of common stock, \$.001 par value per share, of which 32,877,642 shares were issued and outstanding as of February 6, 2004. Our certificate of incorporation authorizes 1,000,000 shares of "blank check" preferred stock, none of which are outstanding.

#### Common Stock

Subject to the rights of holders of preferred stock, if any, holders of shares of our common stock are entitled to share equally on a per share basis in such dividends as may be declared by our Board out of funds legally available therefore, if at all. There are presently no plans to pay dividends with respect

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to the shares of our common stock. Upon our liquidation, dissolution or winding up, after payment of creditors and the holders of any of our senior securities, including preferred stock, if any, our assets will be divided pro rata on a per share basis among the holders of the shares of our common stock. Our common stock is not subject to any liability for further assessments. There are no conversion or redemption privileges nor any sinking fund provisions with respect to our common stock. The stockholders that purchased shares of our common stock in connection with the private placement consummated in April and May of 2003 are entitled to participate in further offerings, for a two-year period, so as to maintain their percentage ownership in NovaDel. Subject to the foregoing, the holders of our common stock do not have any pre-emptive or other subscription rights.

Holders of shares of our common stock are entitled to cast one vote for each share held at all stockholders' meetings for all purposes, including the election of directors. The common stock does not have cumulative voting rights.

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All of the issued and outstanding shares of our common stock are fully paid, validly issued and non-assessable.

### Preferred Stock

None of our 1,000,000 "blank check" authorized preferred shares are currently outstanding. Our Board has the authority, without further action by the holders of our outstanding common stock, to issue shares of preferred stock from time to time in one or more classes or series, to fix the number of shares constituting any class or series and the stated value thereof, if different from the par value, and to fix the terms of any such series or class, including dividend rights, dividend rates, conversion or exchange rights, voting rights, rights and terms of redemption (including sinking fund provisions), the redemption price and the liquidation preference of such class or series.

### Warrants

As of February 6, 2004, we had 14,215,288 warrants or other derivative securities (but not including stock options) to purchase shares of our common stock outstanding as follows: 200,000 warrants exercisable at \$1.00 per share; 100,007 warrants exercisable at \$2.00 per share; 840,102 warrants exercisable at \$2.00 per share; 160,016 warrants exercisable at \$1.65 per share; 50,000 warrants exercisable at \$1.50 per share; 3,999,957 warrants exercisable at \$1.40 per share; and the balance at \$.75 per share. All of such warrants, except the warrants issued to the investors in the April, May and December 2003 private placements, contain provisions for cashless exercise. The exercise price of the warrants and the number of shares issuable upon exercise of the warrants are subject to adjustment to protect against dilution in certain events such as stock splits, combinations, subdivisions and reclassifications.

### Class B Warrants

We have 840,102 outstanding Class B Warrants with an exercise price equal to \$2.00 per share. The Class B Warrants expire in April and May of 2008, and contain certain demand and piggyback registration rights. The Class B Warrants are exercisable in whole or in part and may be exercised on a cashless basis, subject to any applicable law, rule or regulation. The exercise price of the Class B Warrants and the number of shares issuable upon exercise of the Class B Warrants are subject to adjustment for certain dilution events.

### Class C Warrants

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We have 3,999,957 outstanding Class C Warrants with an exercise price equal to \$1.40 per share. Further, Paramount and/or its designees hold unit purchase options exercisable for, among other securities, an additional 399,994 Class C Warrants. The Class C Warrants expire on December 30, 2008, and contain certain demand and piggyback registration rights. The Class C Warrants will be exercisable in whole or in part and may be exercised on a cashless basis, subject to any applicable law, rule or regulation. The exercise price of the Class C Warrants and the number of shares issuable upon exercise of the Class C Warrants are subject to adjustment for certain dilution events.

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Transfer agent and registrar

The transfer agent and registrar for our common stock is American Stock Transfer & Trust Company, 59 Maiden Lane, New York, NY 10038.

### Disclosure of Commission Position on Indemnification for Securities Act Liabilities

Our bylaws provide that we will indemnify our officers and directors and for all costs and expenses incurred by them on account of their being or having served as our directors or officers.

Section 145 of the Delaware General Corporation Law, the DGCL, empowers a corporation to indemnify its directors and officers and to purchase insurance with respect to liability arising out of the performance of their duties as directors and officers. The DGCL provides further that the indemnification permitted thereunder shall not be deemed exclusive of any other rights to which the directors and officers may be entitled under the corporation's by-laws, any agreement, vote of stockholders or otherwise.

Article Ninth of our Certificate of Incorporation eliminates the personal liability of our directors to the fullest extent permitted by Section 102 of the DGCL. Article Tenth provides for indemnification of all persons whom we have the power to indemnify pursuant to Section 145 of the DGCL.

The effect of the foregoing is to require us, to the extent permitted by law, to indemnify our officers and directors for any claim arising against such persons in their official capacities if such persons acted in good faith and in a manner that they reasonably believed to be in or not opposed to our best interests, and, with respect to any criminal action or proceeding, had no reasonable cause to believe their conduct was unlawful. Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers or persons controlling NovaDel pursuant to the foregoing provisions, we have been informed that in the opinion of the Commission, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

### Description of Business

We are engaged in the development of novel application drug delivery systems for presently marketed prescription and over-the-counter ("OTC") drugs. Our (both patented and patent-pending) delivery systems are lingual sprays, enabling drug absorption through the oral mucosa and more rapid absorption into the bloodstream than presently available oral delivery systems. Our proprietary delivery system enhances and greatly accelerates the onset of the therapeutic benefits which the drugs are intended to produce, to provide therapeutic benefits within minutes of administration. Our development efforts for our novel

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drug delivery system are concentrated on drugs which are already available and proven in the marketplace. In addition to increasing bioavailability by avoiding metabolism by the liver before entry into the bloodstream, we believe that our proprietary delivery system offers the following significant advantages: (i) more rapid delivery of drugs to the bloodstream allowing for quicker onset of therapeutic effects compared to conventional oral dosage forms; (ii) improved drug safety profile by reducing the required dosage, including possible reduction of side-effects; (iii) improved dosage reliability; (iv) allowing medication to be taken without water; and (v) improved patient convenience and compliance.

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In light of the material expense and delays associated with independently developing and obtaining approval of pharmaceutical products, we intend to seek to develop such products through collaborative arrangements with major pharmaceutical companies, which will fund the development of the products. Due to our small revenue base, low level of working capital and the inability to conclude development agreements with major pharmaceutical companies, we have been unable 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 undertake our business plan. See "Management Discussion and Analysis."

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

### Business Strategy

Our strategy is to concentrate our product development activities primarily on those pharmaceutical products for which there already are significant prescription and OTC sales, where the use of our 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/or improve patient convenience or compliance.

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

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### Patented and Patent Pending Delivery Systems

We have certain patents and pending patent applications for our Lingual (Oral) Spray delivery system. Our Lingual (Oral) Spray delivery system is available in both aerosol and pump spray formulations. The system, in either form, releases

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the drug in the form of a fine mist into the mouth for immediate absorption into the bloodstream via the mucosal membranes. We believe that this delivery system offers certain advantages, including more rapid delivery of drugs to the bloodstream allowing for quicker onset of therapeutic effects compared to conventional oral dosage forms, improved drug safety profile by reducing the required dosage, including possible reduction of side-effects, improved dosage reliability, allowing medication to be taken without water and improved patient convenience and compliance. Drug absorption through the mucosal membranes of the mouth is rapid and minimizes the first-pass metabolism effect (i.e., total or partial inactivation of a drug as it passes through the gastrointestinal tract and liver).

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 our proprietary 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.

### Proposed Products

Our 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' bioavailability, or if it is intended to make additional or different claims regarding therapeutic effect for the newly developed product, submission is made to the FDA via an NDA for its review and approval under Section 505(b)(1) or Section 505(b)(2) of the FDC Act. An NDA submitted under section 505(b)(2) of the FDC Act is generally less complex than an ordinary NDA. We expect that the majority of our products in development will require the filing of these shorter versions of an NDA because the products are known chemical entities, but we or our licensees will be making new claims as to therapeutic effects, lessened side effects or both of such products.

We estimate that development of new formulations of pharmaceutical products, including formulation, testing and obtaining FDA approval, generally takes three to five years for the 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 such estimations 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. See "Description of Business - Government Regulation."

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

Cardiovascular (Nitroglycerin) Lingual Spray

Our Nitroglycerin product has been formulated and stability testing has been completed. A United States patent was issued in 1999. An IND was filed with the FDA in early 2002 and clinical trials began in July 2002 and were completed in

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December 2002. We anticipate filing an NDA in 2004.

### Antihistamine Lingual Sprays (Clemastine and Loratadine)

These projects have been put on hold as the commercial opportunity for this active has been greatly diminished by the entry of generic versions of clemastine into the marketplace and the switch of clemastine from prescription to over-the-counter status.

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### Estradiol and Progesterone Lingual Sprays

We have formulated a lingual spray version of estradiol and have opened two INDs. We have also formulated a lingual spray version of progesterone. We have performed pharmacokinetic studies in connection with both of these therapies. This project has been put on hold due to questions that recently have been raised about estrogen therapy.

### Migraine (Sumatriptan) Lingual Spray

A sumatriptan lingual spray has been formulated and is currently undergoing stability testing. A pilot pharmacokinetic study is planned for the First half of 2004.

### Anxiolytic (Alprazolam) Lingual Spray

An alprazolam lingual spray has been formulated and is currently undergoing stability testing. A pilot pharmacokinetic study is planned for the First half of 2004.

### Anti-emetic (Ondansetron) Lingual Spray

An ondansetron lingual spray has been formulated and is currently undergoing stability testing. A pilot pharmacokinetic study is planned for the First half of 2004.

### Hypnotic (Zolpidem) Lingual Spray

A zolpidem lingual spray has been formulated and is currently undergoing stability testing. A pilot pharmacokinetic study is planned for the First half of 2004.

### Anesthetic (Propofol) Lingual Spray

A propofol lingual spray has been formulated and is currently undergoing stability testing. A pilot pharmacokinetic study is planned for the First half of 2004. This product has been licensed to Manhattan Pharmaceuticals.

### Agreement with Manhattan Pharmaceuticals

In April 2003, we entered into a license and development agreement with Manhattan Pharmaceuticals, Inc., for the worldwide, exclusive rights to our lingual spray technology to deliver Propofol for pre-procedural sedation. The terms of the agreement call for certain milestones and other payments, the first of which was received during June 2003. Our affiliate, Dr. Rosenwald is also an affiliate of Manhattan Pharmaceuticals. Manhattan Pharmaceuticals is a development stage company and has no revenues to date. The agreement provides that Manhattan Pharmaceuticals must raise certain funds before we receive the remaining license fee. Manhattan Pharmaceuticals has raised these funds and the

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license fee has been paid to NovaDel. If Manhattan Pharmaceuticals is unable to raise additional funds, there is significant doubt it will be able to fulfill its remaining commitments to us. See also Notes 6 and 7 to the Financial Statements to the Audited Annual Financial Statements attached below.

### Marketing and Distribution

We intend, generally, to license products developed with our technology to other drug companies or to market our products to pharmaceutical wholesalers, drug distributors, drugstore chains, hospitals, United States governmental agencies, health maintenance organizations and other drug companies. We anticipate that promotion of our proposed products will be characterized by an emphasis on their distinguishing characteristics, such as dosage form and packaging, as well as possible therapeutic advantages of such products. We intend to position our proposed products as alternatives or as line extensions to brand-name products. We believe that to the extent that our formulated products are patent-protected, such formulations may offer brand-name manufacturers the opportunity to expand their product lines. Alternatively, products which are not patented may be offered to brand-name manufacturers as substitute products after patent protection on existing products expire.

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

We believe that such third-party arrangements will permit us to maximize the promotion and distribution of our products while minimizing our direct marketing and distribution costs. Except for our license with Manhattan Pharmaceuticals, we have not entered into any 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. See "Description of Business - Agreement with Manhattan Pharmaceuticals." See also see Notes 6 and 7 to the Financial Statements to the Audited Annual Financial Statements attached below. We may not be able to successfully market our proposed products.

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

### Manufacturing

We intend to internalize the manufacturing of our proposed products. Presently, we have established a pilot manufacturing facility at one of our present locations, which we believe is adequate for our needs with respect to our requirements for formulation development, stability testing and clinical supplies. We have also leased a new, larger facility which will have adequate space for our future foreseeable requirements for production, manufacturing and warehouse space. We began to occupy this new space during the third quarter of 2003. The manufacture of our 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 "Description of Business - Government Regulation" and "Description of Business - Raw Materials and Suppliers." We may

not be successful in constructing and maintaining such a manufacturing and warehousing facility in compliance with cGMP. If we are unable to do so, it will become necessary for us to make arrangements with a third party contract manufacturer to satisfy our requirements. We may not be able to enter into arrangements with third party manufacturers, or be able to do so on terms favorable to us. Failure by us to complete successfully the internalization of our manufacturing requirements or to conclude an alternative contract manufacturing arrangement could have an adverse effect our efforts to obtain regulatory approval for or to commercialize our products.

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#### Raw Materials and Suppliers

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

Generally, certain raw materials, including inactive ingredients, are available from a limited number of suppliers and certain packaging materials intended for use in connection with our lingual spray products may be only available from sole source suppliers. Although we believe that we will not encounter difficulties in obtaining the inactive ingredients or packaging materials necessary for the manufacture of our products, we may not be able to enter into satisfactory agreements or arrangements for the purchase of commercial quantities of such materials. 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 our ability to manufacture formulated products.

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

#### Government Regulation

The development, manufacture and commercialization of pharmaceutical products are generally subject to extensive regulation by various federal and state governmental entities. The FDA, which is the principal United States regulatory authority, has the power to seize adulterated or misbranded products and unapproved new drugs, to request their recall from the market, to enjoin further

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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.

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

The FDA approval process relating to a new drug differs, depending on the nature of the particular drug for which approval is sought. With respect to any drug product with active ingredients not previously approved by the FDA, a prospective drug manufacturer is required to submit a NDA, including complete reports of pre-clinical, clinical and laboratory studies to prove such product's safety, quality and efficacy. The NDA process generally requires, before the submission of the NDA, submission of an IND pursuant to which permission is sought to begin preliminary clinical testing of the new drug. An NDA based on published safety and efficacy studies conducted by others may also be required to be submitted for a drug product with a previously approved active ingredient, if the method of delivery, strength or dosage is changed. Alternatively, a drug having the same active ingredients as a drug previously approved by the FDA may be eligible to be submitted under an ANDA, which is significantly less stringent than the NDA approval process.

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

The NDA approval process generally requires between 10 to 24 months from NDA submission to pre-marketing approval, although in the case of an NDA submitted pursuant to Section 505(b)(2) of the Act this time frame may be significantly shorter. We believe that most products developed in lingual spray delivery systems (dosage forms) usually will require submission of an NDA under Section 505(b)(2).

We estimate that the development of new formulations of pharmaceutical products, including formulation, testing and obtaining FDA approval, generally takes four to seven years for the NDA process, although NDAs submitted under Section 505(b)(2) are generally less complex than an ordinary NDA and may be acted upon by the FDA in a shorter period of time. There can be no assurance that our determinations will prove to be accurate or that pre-marketing approval relating to our proposed products will be obtained on a timely basis, if at all. The FDA application procedure has become more rigorous and costly and the FDA currently performs pre-approval and periodic inspections of each finished dosage form and each active ingredient.

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

### Competition

The markets which we intend to enter are characterized by intense competition. We will be competing against established pharmaceutical companies which currently market products which are equivalent or functionally similar to those we intend to market. Prices of drug products are significantly affected by

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competitive factors and tend to decline as competition increases. In addition,

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numerous companies are developing or may, in the future, engage in the development of products competitive with our proposed products. We expect that technological developments will occur at a rapid rate and that competition is likely to intensify as enhanced delivery system technologies gain greater acceptance. Additionally, the markets for formulated products which we have targeted for development are intensely competitive, involving numerous competitors and products. We intend to enhance our competitive position by focusing our efforts on our novel dosage forms.

We are aware of several companies that are selling or developing lingual spray products. First Horizon Pharmaceutical Corporation, headquartered in Alpharetta, Georgia, currently markets Nitrolingual(R) Pumpspray, a nitroglycerin lingual spray which is in an "air" propelled dispensing system (our nitroglycerin lingual spray is in a "propellant" based dispensing system). GenereX Biotechnology Corporation, based in Toronto, Canada, is developing an insulin formulation that is delivered directly into the mouth via their RapidMist(TM) device. They also state that they have begun research on four specific target molecules for their RapidMist delivery system: morphine, fentanyl, heparin and flu vaccine. Sirius Pharmaceuticals Ltd., based in the United Kingdom, also claims to be developing drugs to be delivered sublingually via an aerosol spray. Sirius is working in the areas of pain and emesis. There are several other companies that we are aware of that market lingual spray products containing vitamins and homeopathic ingredients.

There are several other companies that we are aware of that market lingual spray products containing vitamins and homeopathic ingredients.

### Patents and Protection of Proprietary Information

We have applied for United States and foreign patent protection for the buccal spray delivery systems which are the primary focus of our development activities as well as for our delayed contact allergy topical formulations. Five United States patents have been issued and other applications are pending. Additional patent applications may not be granted, or, if granted, may not provide adequate protection to us. We also intend to rely on whatever protection the law affords to trade secrets, including unpatented know-how. Other companies, however, may independently develop equivalent or superior technologies or processes and may obtain patents or similar rights with respect thereto.

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

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We also rely on confidentiality and nondisclosure arrangements with our licensees and potential development candidates. Our competitors may acquire information which we consider to be proprietary. Moreover, our competitors may independently develop know-how comparable to or superior to our know-how.

Buccal Nonpolar Sprays. On April 12, 1996, we filed an application with the United States Patent and Trademark Office ("USPTO") with claims directed to a buccal spray composition containing certain amounts of propellant, a non-polar solvent, and certain classes of drugs, as well as specific drugs within those classes. The application also included claims directed to soft-bite gelatin capsules containing these drugs. On September 1, 1998, the USPTO allowed the claims directed to buccal spray propellant compositions, but rejected the claims directed to the capsules. In November 1998, we deleted the capsule claims from this application to pursue issuance of a patent with claims directed to the buccal non-polar spray compositions and methods of administering the class of drugs using the buccal spray compositions. On September 21, 1999, U.S. Patent No. 5,955,098 issued to us with claims directed to the above-described buccal non-polar spray propellant compositions and methods.

On February 21, 1997, we filed an application under the Patent Cooperation Treaty for the above-subject matter. The International Preliminary Examination Authority issued an International Preliminary Examination Report alleging that the subject matter of the invention lacked novelty and/or lacked an inventive step. This opinion, with which we disagree, is not dispositive. The opinion, however, may be persuasive to individual national patent offices in countries where we enter the national phase.

With respect to the above PCT application, in October and November 1998, we entered the national phase in Canada and Europe, respectively, with claims directed to the above subject matter. On April 16, 2003, European patent no. EP 0 904 055 was granted to us with claims directed to propellant containing buccal non-polar spray compositions containing similar drugs to those in the corresponding issued U.S. patent. We have filed a divisional application based on this European patent with claims directed to a buccal spray composition containing a propellant, a non-polar solvent and an active compound selected from alkaloids and analgesics. With respect to the Canadian application, we filed a request for examination with the Canadian Patent Office on February 7, 2002. An office action has not yet been received from the Canadian Patent Office.

Buccal Polar Sprays. On April 12, 1996, we filed an application with the USPTO with claims directed to propellant free buccal polar spray compositions containing certain amounts of a polar solvent and certain classes of drugs, as well as specific drugs within those classes. The application also contained claims to soft-bite gelatin capsules containing such drugs. A continuation-in-part ("CIP") application was filed directed to this subject matter before the original application was allowed to go abandoned. The USPTO initially rejected the claims in the CIP application. We deleted the claims from this application (including the soft-bite capsule claims) and replaced them with claims directed to methods of using the above-described propellant free buccal polar spray compositions to administer the drugs. On August 29, 2000, U.S. Patent No. 6,110,486 issued to us with claims directed to the above-described methods of administering the drugs.

On February 21, 1997, we filed a PCT application directed to the above-described subject matter. The International Preliminary Examination Authority issued an International Preliminary Examination Report alleging that the subject matter of the invention lacked novelty and/or lacked an inventive step. This opinion, with

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which we disagree, is not dispositive. The opinion, however, may be persuasive to individual national patent offices in countries where we enter the national phase.

With respect to the above PCT application, in October and November 1998, we entered the national phase in Canada and Europe, respectively. We filed a request for examination in Canada on February 7, 2002. An office action has not yet been received from the Canadian Patent Office. In Europe, claims directed to using specific drugs to prepare a medicament that can be used as a buccal polar pump spray composition containing the various classes of drugs are currently being prosecuted.

Buccal Nonpolar Spray for Nitroglycerin. On April 12, 1996, we filed an application with the USPTO with claims directed to a buccal spray containing certain amounts of nitroglycerin, a non-polar solvent, and a propellant. The claims were allowed and on February 9, 1999, the USPTO issued U.S. Patent No. 5,869,082 to us for said nitroglycerin buccal spray.

On February 21, 1997, we filed a PCT application directed to the above-described subject matter. The International Preliminary Examination Authority issued an International Preliminary Examination Report alleging that the subject matter of the invention lacks an inventive step. This opinion, with which we disagree, is not dispositive. The opinion, however, may be persuasive to individual national patent offices in countries where we enter the national phase.

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

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

Buccal Polar/Nonpolar Sprays or Capsules. On October 1, 1997, we filed a PCT application designating a large number of countries including the United States, directed to the buccal sprays and capsules. The application included claims directed to (A) a buccal spray composition containing either (1) a polar solvent with certain classes of drugs, as well as specific drugs in those classes with or without a propellant or (2) a non-polar solvent and a propellant with certain classes of drugs, as well as specific drugs in those classes; (B) buccal spray composition containing a non-polar solvent, a flavoring agent and certain classes of drugs; and (C) methods of administering these drugs using the buccal spray compositions. The application also contained claims to soft-bite gelatin capsules containing such drugs. This application differs from the first three applications, discussed above, in that the claimed compositions include different classes of drugs from those described in the first three applications. The International Preliminary Examination Authority issued an International Preliminary Examination Report alleging that the subject matter of the invention lacked novelty and/or lacked an inventive step. This opinion, with which we disagree, is not dispositive. The opinion, however, may be persuasive to individual national patent offices in countries where we enter the national phase.

On March 29, 2000, we entered the national phase in the United States by filing a CIP of the above-identified PCT application with the USPTO. The CIP application included claims directed to propellant free buccal spray compositions containing certain amounts of polar or non-polar solvents, and certain classes of drugs, as well as specific drugs in those classes; buccal

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spray compositions containing certain amounts of a propellant, a polar or non-polar solvent and certain classes of drugs, as well as specific drugs in those classes; and methods of administering said drugs using these types of buccal spray compositions. The application is currently being prosecuted with claims directed to the propellant free buccal spray compositions and methods of administering said drugs using these types of buccal spray compositions. Subsequently, we filed two divisional applications claiming priority to the CIP. The first divisional application is currently being prosecuted with claims directed to the buccal spray compositions containing certain amounts of a propellant, a polar or non-polar solvent, and certain classes of drugs, as well as specific drugs in those classes and methods of administering said drugs using these types of buccal spray compositions. The second divisional application has issued as U.S. patent No. 6,671,931. The claims of this patent are directed to a propellant free pump spray composition containing certain amounts of a polar solvent, certain amounts of a flavoring agent and certain amounts of cyclosporin or ondansetron hydrochloride. Another application has been filed directed to the additional classes of drugs and specific drugs that were not included in the claims of the '931 patent.

Based on the above-identified PCT application, we entered the national phase in Canada on March 29, 2000. We filed a request for examination in Canada on August 29, 2002. An office action has not been received from the Canadian Patent Office. Based on the above-identified PCT application, we also entered the national phase in Japan on April 3, 2000. We have not yet filed a request for examination. A request for examination must be filed before October 1, 2004, to pursue patent protection in Japan.

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

Furthermore, we filed a number of U.S. patent applications directed to buccal spray compositions containing certain classes of drugs as well as specific drugs for treating particular types of disorders. We are currently prosecuting these applications.

Antihistamine Syrup and Ointment. On November 10, 1997, we filed an application with the USPTO with claims directed to a spray composition for topical administration containing an antihistamine and a polar solvent or an antihistamine, a non-polar solvent and a propellant. In October 1998, the PTO rejected the claims. The claims were deleted and replaced with a claim directed to a method of controlling the occurrence of delayed contact dermatitis by applying a lotion composition containing certain amounts of certain antihistamines in certain amounts of a polar or non-polar solvent. On May 21,

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2002, U.S. Patent No. 6,391,282 was issued to us for the above-described method.

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

General Comment with Respect to entering the national phase for each of the foregoing PCT Applications. In addition to our patents and patent applications in the United States, we are interested in entering the national phase and obtaining patent protection in Europe and Canada. At the present time, it is not possible accurately to predict the expenses involved in pursuing the foregoing applications in Canada and Europe. For example, we anticipate that, in the case of the European applications, it may become necessary to file appeals with the Board of Appeals in Munich. Expenses may exceed \$100,000 (in the aggregate) before a final disposition is obtained. We expect that this process may take between two and four years.

### Product Liability

We may be exposed to potential product liability claims by consumers. We do not presently maintain product liability insurance coverage. Although we intend to obtain product liability insurance prior to the commercialization of any products, we may not be able to obtain such insurance or, if obtained, such insurance may not be sufficient to cover all possible liabilities. In the event of a successful suit against us, insufficiency of insurance coverage could have a material adverse effect on us. In addition, certain food and drug retailers require minimum product liability insurance coverage as a condition precedent to purchasing or accepting products for retail distribution. Failure to satisfy such insurance requirements could impede our ability and that of our distributors to achieve broad retail distribution of its proposed products which would have a material adverse effect upon our business and financial condition.

### Employees

We currently have 23 full-time employees, five of whom are executive officers of the Company, 12 of whom are laboratory or support personnel and six of whom are engaged in administrative functions. Our success will be dependent, in part, upon our ability to hire and retain additional qualified sales, manufacturing and distribution personnel, however, we may not be able to hire or retain such necessary personnel.

### Recent Private Offering

On December 30, 2003, we accepted binding subscriptions from accredited investors for units consisting of an aggregate of 13,333,333 shares of common stock and warrants to purchase 3,999,957 shares of common stock. The warrants are exercisable for five years, at an exercise price equal to \$1.40 per share. The units were sold through Paramount. The gross proceeds of the private

offering were approximately \$14 million. For its services as placement agent, we paid Paramount a 7% commission on the aggregate amount raised (approximately \$1,000,000 including an accountable expense allowance equal to \$25,000) and also issued to Paramount or its designees unit purchase options to purchase 14 units at an exercise price equal to \$110,000 per unit. In connection with the offering, we agreed to file a registration statement with the Commission to register the resale of the shares of common stock and the shares of common stock underlying the warrants (as well as the shares underlying the warrants issuable to Paramount or its designees upon the exercise of the unit purchase options).

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### Management's Discussion and Analysis of Financial Condition and Results of Operations

#### General

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

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 October 31, 2003, of approximately \$17,355,000. 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 dependent upon its ability to successfully develop its products and to enter into license agreements with drug companies who will market and distribute the final products.

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

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The Company's continued existence is dependent upon its ability to achieve profitable operations or obtain additional financing. The Company is currently seeking collaborative arrangements with pharmaceutical companies for joint development of delivery systems and the successful marketing of these delivery systems. In order to pursue this strategy, the Company will be required to obtain financing and/or consummate a strategic alliance with a well-funded business partner in the near future. In view of the Company's very limited resources, its anticipated expenses (resulting in significant operating losses) and the competitive environment in which the Company operates, there can be no assurance that the Company's operations will be sustained for the duration of its next fiscal year.

#### Results of Operations

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Fiscal Year 2003 Compared to Fiscal Year 2002

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

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

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

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

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

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

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

First Quarter Fiscal Year 2004 Compared to First Quarter Fiscal Year 2003

Total costs and expenses for the fiscal quarter ended October 31, 2003, increased approximately \$4,000 to \$1,733,000 from \$1,729,000 for the fiscal quarter ended October 31, 2002. Costs and expenses increases for the fiscal quarter ended October 31, 2003, as compared to the fiscal quarter ended October 31, 2002, includes approximately: \$426,000 in payroll expense primarily due to the hiring of additional employees; \$91,000 in employee recruiting expense; \$57,000 in rent expense due to the Company's leasing of new facilities; \$31,000 in outside services; \$25,000 in insurance costs due primarily to employee health insurance, \$23,000 in legal and professional fees and \$21,000 in travel expense. Decreases include approximately: \$497,000 in outside consultants fees due primarily to a reduction in the options issued to consultants; \$151,000 in laboratory testing and clinical studies expenses due to no clinical studies

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being conducted during the fiscal quarter ended October 31, 2003 and \$17,000 in trade shows and conferences.

Interest income decreased during the fiscal quarter ended October 31, 2003 by approximately \$9,000 or 60% to \$6,000 for the fiscal quarter ended October 31, 2003 from \$15,000 for the fiscal quarter ended October 31, 2002 due to a decreased average cash balance.

The resulting net loss for the fiscal quarter ended October 31, 2003 was \$1,727,000 compared to a net loss of \$1,714,000 for the fiscal quarter ended October 31, 2002.

### Liquidity and Capital Resources

From its inception, the Company's principal sources of capital have been provided by consulting revenues, private placements and a public offering of its warrants, as well as loans and capital contributions from the Company's principal stockholders. At October 31, 2003, we had working capital of approximately \$790,000 as compared to working capital at July 31, 2002, of approximately \$2,799,000 representing a net decrease in working capital of approximately \$2,009,000. During fiscal year 2003, we successfully closed a private offering of our securities. The offering provided for the sale of approximately 3,200,000 shares of common stock, par value \$.001 per share. We received proceeds, net of offering costs, of approximately \$4,336,000 in connection with that offering. During the second quarter of fiscal year 2004, we successfully closed a second offering of approximately 13,333,330 shares of common stock, par value \$0.001 per share. We received proceeds, net of offering costs, of approximately \$13 million.

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

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Net cash used in operating activities approximated \$1,462,000 for the fiscal quarter ended October 31, 2003 compared to net cash used in operating activities of approximately \$993,000 for the fiscal quarter ended October 31, 2002. Net cash used in operating activities for both periods was primarily attributable to the net loss of \$1,727,000 and \$1,714,000, respectively. For the fiscal quarter ended October 31, 2003, \$308,000 was used for investing activities compared to \$110,000 for the fiscal quarter ended October 31, 2002. Total cash for the fiscal quarter ended October 31, 2003 decreased approximately \$1,770,000 as compared to a \$1,103,000 decrease for the fiscal quarter ended October 31, 2002.

The Company believes that its current cash levels together with revenues from operations, will be sufficient to satisfy its cash requirements through the second quarter of our fiscal year 2005. However, beyond this point there is substantial doubt about our ability to continue operations without obtaining additional financing and/or consummating a strategic alliance with a well-funded business partner. Although the Company is actively seeking additional financing and strategic alliances, there are a number of risks and uncertainties related to our attempt to complete a financing or strategic partnering arrangement that are outside its control. We may not be able to successfully obtain additional financing on terms acceptable to us, or at all. These uncertainties raise substantial doubt as to the Company's ability to continue as a going concern. The Company's auditors have included an explanatory paragraph in their audit opinion with regard to the Company's ability to continue as a going concern.

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### Critical Accounting Policies

Use of Estimates - The accompanying financial statements have been prepared in conformity with United States generally accepted accounting principles. When more than one accounting principle, or method of its application, is generally accepted, management selects the principle or method that is appropriate in the Company's specific circumstances. Application of the accounting principles requires the Company's management to make estimates about the future resolution of existing uncertainties and that affect the reported amounts of assets, liabilities, revenues, expense which in the normal course of business are subsequently adjusted to actual results. Actual results could differ from such estimates. In preparing these financial statements, management has made its best estimates and judgments of the amounts and disclosures included in the financial statements giving due regard to materiality.

Revenue Recognition, Accounts Receivable and Allowance for Doubtful Accounts - Revenue is recognized as earned. Invoices, for client project costs, are created and presented at the end of each month, for that month. Accounts Receivable reflects such invoices at the end of the month in which the invoice was created. An Allowance for Doubtful Accounts is created for each invoice remaining unpaid after 90 days from the invoice date.

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

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Capital Expenditures - The Company anticipates that it will take 12 to 18 months to complete the remaining build-out of its recently occupied leased facilities for laboratory and manufacturing purposes. The Company estimates the costs of the build-out and necessary equipment to be up to \$3,500,000.

### Off-Balance Sheet Arrangements

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

### Inflation

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.

### Description of Property

Our executive offices are located at 25 Minneakoning Road, Flemington, New Jersey. In March 2003, we entered into a 10 year lease for approximately 31,800 sq. feet of office, laboratory, manufacturing and warehouse space at that location. Partial occupancy began in September 2003 and will continue in stages. In addition, the Company leases laboratory space at 32 Route 12 West, Flemington, New Jersey, which laboratory will eventually be transferred to the Company's new, main facility.

### Certain Relationships and Related Transactions

To the best of our knowledge, other than as set forth below, there were no

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material transactions, or series of similar transactions, or any currently proposed transactions, or series of similar transactions, to which we were or are to be a party, in which the amount involved exceeds \$60,000, and in which any director or executive officer, or any security holder who is known by us to own of record or beneficially more than 5% of any class of our common stock, or any member of the immediate family of any of the foregoing persons, has an interest.

In February 2002, we entered into a consulting agreement with John H. Klein, who was simultaneously elected as our chairman of the Board. In February 2003 the agreement was renewed for an additional one year term. Under the agreement, Mr. Klein was granted non-plan options to purchase 1,000,000 shares of our common stock at an exercise price equal to \$2.40 per share. The options have a term of 10 years and vest in three equal annual installments, beginning in February 2003. Mr. Klein was also entitled to certain bonuses, in the form of stock, stock options or other rights or property, as determined by the Board. In addition, Mr. Klein was entitled to receive certain success fees (based upon a percentage of net revenues) upon completion of certain types of corporate transactions (i.e., strategic partnerships, licensing arrangements and the like) which are introduced to us by Mr. Klein. The percentage of net revenue (which is between 4% and 10%) depends upon the share of profits to which we are entitled in such transactions. In December 2003, the Company elected not to renew Mr. Klein's consulting agreement, which then expired at the end of January 2004. The one third of Mr. Klein's options which are vested are due to expire on March 1, 2004.

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In April 2003, we entered into a license and development agreement with Manhattan Pharmaceuticals for the worldwide, exclusive rights to our lingual spray technology to deliver Propofol for pre-procedural sedation. The terms of the agreement call for certain milestones and other payments, the first of which was received during June 2003. Our affiliate, Dr. Rosenwald, is also an affiliate of Manhattan Pharmaceuticals. See "Description of Business - Agreement with Manhattan Pharmaceuticals."

In April and May 2003, we engaged Paramount to assist us in the placement of units on a "best efforts" basis in connection with a private placement. Dr. Rosenwald is Chairman and Chief Executive Officer of Paramount. In connection with this offering, we entered into a non-exclusive Placement Agent Agreement dated as of January 15, 2003, with Paramount, pursuant to which we paid to Paramount for its services, a cash payment equal to approximately \$360,000 and issued to Paramount or its designees 160,017 warrants with an exercise price equal to \$1.65 per share and warrants to purchase 40,004 shares of common stock at an exercise price equal to \$2.00 per share. We also agreed to pay to Paramount a non-accountable expense allowance equal to \$25,000 to reimburse Paramount for its out-of-pocket expenses. Lastly, we agreed to indemnify Paramount against certain liabilities, including liabilities under the Securities Act.

In November 2003, we engaged Paramount to assist us in the placement of units on a "best efforts" basis in connection with a private placement. In connection with this offering, we entered into a non-exclusive Placement Agent Agreement dated as of November 14, 2003, with Paramount, pursuant to which we paid to Paramount for its services, a cash payment equal to approximately \$1,000,000 and issued to Paramount or its designees 14 unit purchase options with a per unit exercise price equal to \$110,000. Upon full exercise of such unit purchase options, we shall issue to Paramount or its designees 1,330,296 shares of our common stock and warrants to purchase 399,082 shares of our common stock for a purchase price equal to \$1.40 per share. We also agreed to pay to Paramount a

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non-accountable expense allowance equal to \$25,000 to reimburse Paramount for its out-of-pocket expenses. Lastly, we agreed to indemnify Paramount against certain liabilities, including liabilities under the Securities Act.

We paid Mr. Schaul approximately \$125,000 and \$160,000, respectively, for legal services performed on our behalf and during fiscal years 2002 and 2003, respectively.

We have agreed pursuant to our charter documents to indemnify our directors to the maximum extent permissible under the General Corporation Law of the State of Delaware.

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### Market for Common Equity and Related Stockholders Matters

#### Market Information

Since the November 1997 closing of our public offering, our common stock has traded in the over-the-counter market on the OTCBB. Since October 1, 2002, the symbol has been "NVDL.OB". Prior thereto, our common stock traded under the symbol "FLEM". The following table sets forth the range of high and low closing bid quotations of our 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 Price<br>----- |
|--|--------------------|
|  | High<br>----       |
| FISCAL YEAR 2004   |                    |
| First Quarter (August 1, 2003 through October 31, 2003)    |                    |
| Second Quarter (November 1, 2003 through January 31, 2004) |                    |
| FISCAL YEAR 2003   |                    |
| First Quarter (August 1, 2002 through October 31, 2002)    | \$1.90             |
| Second Quarter (November 1, 2002 through January 31, 2003) | \$2.80             |
| Third Quarter (February 1, 2003 through April 30, 2003)    | \$2.43             |
| Fourth Quarter (May 1, 2003 through July 31, 2003)         | \$2.20             |
| FISCAL YEAR 2002   |                    |
| First Quarter (August 1, 2001 through October 31, 2001)    | \$0.60             |
| Second Quarter (November 1, 2001 through January 31, 2002) | \$2.30             |
| Third Quarter (February 1, 2002 through April 30, 2002)    | \$3.79             |
| Fourth Quarter (May 1, 2002 through July 31, 2002)         | \$3.62             |

The closing bid price of our common stock as reported by the OTCBB on February 6, 2004, was \$1.75. As of February 6, 2004, there were approximately 65 record holders of our common stock.

We have never declared or paid a dividend on our common stock, and management expects that all or a substantial portion of our future earnings will be retained for expansion or development of our business. The decision to pay dividends, if any, in the future is within the discretion of the Board and will depend upon our earnings, capital requirements, financial condition and other

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relevant factors such as contractual obligations. Management does not anticipate that we will pay dividends on our common stock in the foreseeable future, if at all.

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### Securities Authorized for Issuance Under Equity Compensation Plans

#### 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 | Num<br>re<br>fo<br>co |
|--|---|---|-----------------------|
| Equity compensation plans approved by security holders (1) | 1,623,500   | \$1.24  |                       |
| Equity compensation plans not approved by security holders | 3,983,333   | \$1.72  |                       |
| <b>Total</b>   | <b>5,606,833</b>  | <b>\$1.58</b>   |                       |

#### Executive Compensation

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

#### SUMMARY COMPENSATION TABLE

| Name and Principal Position              | Fiscal Year | Annual Compensation |            |                                | Long-Term Awards               |              |
|--|-------------|---------------------|------------|--------------------------------|--------------------------------|--------------|
|  |             | Salary (\$)         | Bonus (\$) | Other Annual Compensation (\$) | Restricted Stock Award(s) (\$) | Sec Und Op S |
| Gary A. Shangold, M.D. President and CEO | 2003        | 210,900             | 200,000    | 0                              | 0                              | 1,           |
| Harry A. Dugger, III, Ph.D.              | 2003        | 246,900             | 0          | 0                              | 0                              | 2            |

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Chief Scientific Officer, formerly  
President and CEO

|   |      |         |   |   |   |    |
|---|------|---------|---|---|---|----|
|   | 2002 | 347,000 | 0 | 0 | 0 |    |
|   | 2001 | 182,974 | 0 | 0 | 0 |    |
| John H. Klein<br>Chairman   | 2003 | 300,000 | 0 | 0 | 0 |    |
|   | 2002 | 150,000 | 0 | 0 | 0 | 1, |
| Donald J. Deitman<br>Chief Financial Officer                              | 2003 | 124,200 | 0 | 0 | 0 |    |
|   | 2002 | 104,400 | 0 | 0 | 0 |    |
|   | 2001 | 70,800  | 0 | 0 | 0 |    |
| Robert C. Galler<br>Vice President<br>Corporate Development               | 2003 | 186,900 | 0 | 0 | 0 | 3  |
|   | 2002 | 143,600 | 0 | 0 | 0 | 7  |
| Mohammed Abd El-Shafy, Ph.D., Vice<br>President - Formulation Development | 2003 | 144,000 | 0 | 0 | 0 | 1  |
|   | 2002 | 24,000  | 0 | 0 | 0 | 1  |

(1) No stock appreciation rights have been issued.

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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 year 2003:

| Option/SAR Grants in Last Fiscal Year |  |   |                 |
|---------------------------------------|--|---|-----------------|
| Individual Grants                     |  |   |                 |
| (a)                                   | (b)  | (c)   |                 |
| Name                                  | Number of Securities<br>Underlying Options/SARs<br>Granted (#) | % of Total Options/SARs<br>Granted to Employees in<br>Fiscal Year | Exercis<br>Pric |
| Gary A. Shangold, M.D.                | 1,000,000  | 54%   | \$              |
| Harry A Dugger III, Ph.D              | 275,000  | 15%   | \$              |

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|                              |         |     |    |
|------------------------------|---------|-----|----|
| John H. Klein                | 0       | N/A | \$ |
| Donald J. Deitman            | 0       | N/A |    |
| Robert Galler                | 350,000 | 19% | \$ |
| Mohammed Abd El-Shafy, Ph.D. | 50,000  | 3%  | \$ |
| Barry Cohen                  | 75,000  | 4%  | \$ |

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

| Name of Executive Officer    | Number of Shares Acquired on Exercise | Value Realized (\$) | Number of Securities Underlying Unexercised Options at Fiscal Year End; (Exercisable/Unexercisable) |
|------------------------------|---------------------------------------|---------------------|---|
| Harry A. Dugger, III, Ph.D.  | 0                                     | --                  | 920,000/0   |
| John H. Klein                | 0                                     | --                  | 333,333/666,667   |
| Gary A. Shangold, M.D.       | 0                                     | --                  | 0/1,000,000   |
| Donald J. Deitman            | 0                                     | --                  | --  |
| Mohammed Abd El-Shafy, Ph.D. | 0                                     | --                  | 150,000/50,000  |
| Robert Galler                | 0                                     | --                  | 1,050,000/0   |
| Barry Cohen                  | 0                                     | --                  | 0/75,000  |

Stock Option Plans

We have three stock option plans, adopted in 1992, 1997 and 1998, respectively. The 1992 and 1997 Plans provide for the issuance of options to purchase 500,000 shares of common stock, and the 1998 Plan provides for the issuance of options to purchase 1,800,000 shares of common stock, for a total of 2,800,000 shares. The 1997 Stock Option Plan is administered by Messrs. Hamilton and Kessel, who constitute the Compensation Committee of the Board, and the 1992 Stock Option Plan and 1998 Stock Option Plan are administered by the entire Board. The Compensation Committee has sole discretion and authority, consistent with the provisions of the Plans, to select the eligible participants to whom options will be granted under the Plans, the number of shares which will be covered by each option and the form and terms of the agreement to be used. All of our employees and officers are eligible to participate in the Plans.

At February 6, 2004, 300,000, 250,000 and 1,595,000 shares of our common stock were reserved for issuance pursuant to the 1992, 1997 and 1998 Plans, respectively. The exercise prices for the outstanding options reserved under the 1992 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 \$2.69 per share.

Our Compensation Committee is empowered to determine the exercise price of options granted under the Plans, but the exercise price of ISOs must be equal to or greater than the fair market value of a share of common stock on the date the option is granted (110% with respect to optionees who own at least 10% of our outstanding common stock). Our Compensation 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 10 years from the date of grant (five years with respect to optionees who own at least 10% of our outstanding common stock). Options are nontransferable, other than by will and the laws of descent, and generally may be exercised only our employees during their employment 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 of our plans) exceeds \$100,000. The Plans do not confer upon any employee any right with respect to the continuation of employment by us, nor do the Plans interfere in any way with the employee's right or our right to terminate the employee's employment at any time.

#### Non-Plan Options

As of February 6, 2004, we had 3,983,333 non-plan options outstanding as follows: 1,000,000 options exercisable at \$1.93 per share; 600,000 options exercisable at \$1.84 per share; 1,050,000 options exercisable at \$.75 per share; 333,333 options exercisable at \$2.40 per share; 250,000 options exercisable at \$3.18 per share; 150,000 options exercisable at \$3.02 per share; 200,000 options exercisable at \$1.30 per share; 200,000 options at \$1.51 per share; 100,000 options at \$2.15 per share; and 100,000 options at \$1.85 per share.

#### Compensation Committee Interlocks and Insider Participation

Messrs. Hamilton and Kessel serve as the members of our Board's Compensation Committee, which reviews and makes recommendations with respect to compensation of officers, employees and consultants, including the granting of options under our 1997 Stock Option Plan. The 1992 and 1998 Plans are administered by the entire Board.

#### Compensation Committee Report on Executive Compensation

Compensation of our executives is intended to attract, retain and award persons who are essential to the enterprise. The fundamental policy of our executive compensation program is to offer competitive compensation to executives that appropriately rewards the individual executive's contribution to corporate performance. The Board utilizes subjective criteria for evaluation of individual performance. The Board focuses on two primary components of our executive compensation program, each of which is intended to reflect individual and corporate performance: base salary compensation and long-term incentive compensation. We have not paid cash incentive bonuses during fiscal year 2003.

Except as set forth herein, we do not have any annuity, retirement, pension, deferred or incentive compensation plan or arrangement under which any executive officer is entitled to benefits, nor do we have any long-term incentive plan pursuant to which performance units or other forms of compensation are paid. Executive officers who qualify will be permitted to participate in our 1992, 1997 and 1998 Plans which were adopted in May 1992, February 1997 and June 1998, respectively. In December 2003 the Board adopted a 401(k) plan in which all of our employees are eligible to participate. Executive officers may participate in group life, health and hospitalization plans, if and when such plans are available generally to all of our employees. Our Compensation Committee is satisfied that the compensation and stock option plans provided to our officers are structured and operated to create strong alignment with our long-term best interests and the best interests of our stockholders.

The compensation of our Chief Scientific Officer, Dr. Dugger (who served as our President and Chief Executive Officer for fiscal year 2002), for fiscal year 2002 consisted of base salary of \$248,500. Because of an inadequacy of cash flow during the first and second quarters of fiscal year 2001, Dr. Dugger agreed to accrue all of his salary until the cash flow situation resolved itself. In May 2001, Dr. Dugger's salary was resumed and one-half of his accrued salary was paid out. The remaining half was paid out in January 2002. In October 2002, Dr. Dugger was granted options to purchase 275,000 shares of our common stock at an exercise price equal to \$1.30 per share.

The compensation of our Chief Executive Officer, Dr. Shangold, consists of a base annual salary equal to \$350,000 and a guaranteed bonus equal to \$150,000. In addition, Dr. Shangold's employment agreement provides for: (i) an annual discretionary bonus of up to \$262,500, which shall be determined at the sole discretion of the Board; and (ii) an investment and fee bonus equal to 5% of all amounts up to an aggregate of \$7,500,000 (i.e., \$375,000) invested in, or earned by, us during his term. We paid Dr. Shangold his guaranteed bonus, plus a portion of the investment and fee bonus (a total of \$200,000) during the fourth quarter of fiscal year 2003; the remainder of the investment and fee bonus (approximately \$50,000) was paid during December 2003. The investment and fee bonus was reduced by certain proceeds received by Dr. Shangold from his former employer. Upon execution of his employment agreement, Dr. Shangold was also granted non-plan options to purchase 1,000,000 shares of our common stock (at an exercise price equal to \$1.93 per share) which vest over a three year period beginning in December 2003.

The determination by the Compensation Committee of executive compensation is based upon methods consistent with those used for other senior executives. The Compensation Committee considers certain quantitative factors, including our financial, strategic and operating performance for the fiscal year. The qualitative criteria include the executive's leadership qualities and management skills, as exhibited by his innovations, time and effort devoted to us, and other general considerations. The Compensation Committee also takes note of comparable remuneration of other similar executive positions at similar companies. Based on our performance, the Compensation Committee believes that the compensation paid to these executives was appropriate.

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

Harry A. Dugger, III, Ph.D. Effective as of January 1, 2002, we entered into a new three-year employment agreement with Dr. Dugger at a base salary, for the first year, equal to \$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 H. Klein. In February 2002, we entered into a one-year consulting agreement with Mr. Klein (which was renewed in February 2003 for an additional one year) at a base compensation of \$300,000, plus certain fringe benefits of approximately \$72,000 per year. Pursuant to the agreement, we granted 1,000,000 non-plan options to Mr. Klein with an exercise price equal to \$2.40 per share. See "Certain Relationships and Related Transactions." Mr. Klein is also entitled to certain bonuses, in the form of stock, stock options or other rights or property, as determined by the Board. In addition, Mr. Klein is entitled to receive certain success fees (based upon a percentage of net revenues) upon completion of certain types of corporate transactions (i.e., strategic partnerships, licensing arrangements and the like) which are introduced us by Mr. Klein. The percentage of net revenue (which is between 4% - 10%) depends upon the share of profits that we are entitled to in such transactions. In December 2003, the Company determined not to renew Mr. Klein's agreement for an additional term. Therefore, it expired at the end of January 2004.

Donald J. Deitman. Effective as of January 1, 2002, we entered into a three year employment agreement with Mr. Deitman who serves as our Chief Financial Officer. The agreement provides for a base salary, for the first year, equal to \$125,000 per year (which increases each year by the greater of the CPI index or 5%). All other provisions of the agreement are the same as those in effect for our other executives.

Mohammed Abd El-Shafy, Ph.D. In May 2002, we entered into a three year employment agreement with Dr. El-Shafy, who was appointed Vice President-Formulation Development. Pursuant to the agreement, he received a base salary, for the first year, of \$110,000, which increased in April 2003 to \$180,000. In addition, we granted 150,000 non-plan options to Dr. El-Shafy at an exercise price equal to \$3.02 per share. Subsequently, in March 2003, we granted 50,000 options to Dr. El-Shafy under the 1998 Option Plan at an exercise price equal to \$1.51.

Barry Cohen. In May 2003, we entered into a three year employment agreement with Barry Cohen, who was appointed Vice President-New Business and Product Development. Pursuant to the agreement, Mr. Cohen receives a base salary of \$185,000, plus incentive bonuses. Pursuant to the agreement, we issued 75,000 options to Mr. Cohen at an exercise price equal to \$2.04 per share under the 1998 Plan. Sixty thousand of such options vest in three equal installments commencing May 2004 and expire in May 2008. The balance of such options vest

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upon achievement of certain objectives.

The foregoing agreements also provide for certain non-competition and non-disclosure covenants on the part of our executives. 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 we adopt any such benefit plans.

### Legal Matters

The validity of the common stock offered hereby will be passed upon for us by Dickstein Shapiro Morin & Oshinsky LLP, New York, New York.

### Experts

Certain of the financial statements of NovaDel included in this prospectus and elsewhere in the registration statement, to the extent and for the periods indicated in their reports, have been audited by Wiss & Company, LLP, independent certified public accountants, whose reports thereon appear elsewhere herein and in the registration statement.

### Available Information

We file annual, quarterly and special reports, proxy statements and other information with the Securities and Exchange Commission. You may read and copy any document we file at the Commission's public reference rooms at 450 Fifth Street, N.W., Washington, D.C. 20549. Please call the Commission at 1-800-SEC-0330 for further information on the public reference rooms. Many of our Commission filings are also available to the public from the Commission's Website at "<http://www.sec.gov>." We make available free of charge our annual, quarterly and current reports, proxy statements and other information upon request. To request such materials, please send an e-mail to [bwrubel@Novadel.com](mailto:bwrubel@Novadel.com) or contact Bernadine Wrubel, at our address as set forth above. We maintain a Website at "<http://www.NovaDel.com>" (this is not a hyperlink, you must visit this website through an Internet browser). Our Website and the information contained therein or connected thereto are not incorporated into this prospectus.

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We have filed with the Commission a registration statement (which contains this prospectus) on Form SB-2 under the Securities Act relating to the common stock we are offering by this prospectus. This prospectus does not contain all of the information set forth in the registration statement and the exhibits and schedules to the registration statement. Please refer to the registration statement and its exhibits and schedules for further information with respect to us and the common stock. Statements contained in this prospectus as to the contents of any contract or other document are not necessarily complete and, in each instance, we refer you to the copy of that contract or document filed as an exhibit to the registration statement. You may read and obtain a copy of the registration statement and its exhibits and schedules from the Commission, as described in the preceding paragraph.

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INDEPENDENT AUDITOR'S REPORT

To the Audit Committee of  
NOVADEL PHARMA INC.

We have audited the balance sheet of NOVADEL PHARMA INC., formerly known as Flemington Pharmaceutical Corporation as of July 31, 2003, and the related statements of operations, changes in stockholders' equity and cash flow for each of the two years in the period then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of NOVADEL PHARMA INC. at July 31, 2003, and the results of its operations and its cash flows for each of the two years in the period then ended, are in conformity with accounting principles generally accepted in the United States of America.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has had a recent history of recurring losses from operations, giving rise to an accumulated deficit through July 31, 2003, and is currently developing pharmaceutical products which will require substantial financing to fund anticipated product development costs. Resulting operating losses and negative cash flows from operations are likely to occur until, if ever, profitability can be achieved through successful marketing of newly developed products. These factors raise substantial doubt about the Company's ability to continue as going concern. Management's plans in regard to these matters are described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ Wiss & Company LLP  
-----  
WISS & COMPANY, LLP

Livingston, New Jersey  
September 8, 2003

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NOVADEL PHARMA INC.

BALANCE SHEET  
JULY 31, 2003

ASSETS

CURRENT ASSETS:

Cash and equivalents ..... \$ 3,086,000

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|  |              |           |
|--|--------------|-----------|
| Accounts receivable - trade .....                    | 2,000        |           |
| Prepaid expenses and other current assets .....      | 168,000      |           |
|  | -----        |           |
| Total Current Assets .....                           |              | \$ 3,256, |
| FURNITURE, FIXTURES, EQUIPMENT                       |              |           |
| and LEASEHOLD IMPROVEMENTS, LESS                     |              |           |
| ACCUMULATED DEPRECIATION OF \$252,000 .....          |              | 714,      |
| OTHER ASSETS .....                                   |              | 357,      |
|  |              | -----     |
|  |              | \$4,327,  |
|  |              | =====     |
| LIABILITIES AND STOCKHOLDERS' EQUITY                 |              |           |
| CURRENT LIABILITIES:                                 |              |           |
| Accounts payable-trade .....                         | \$ 139,000   |           |
| Accrued expenses and other current liabilities ..... | 318,000      |           |
|  | -----        |           |
| Total Current Liabilities .....                      |              | \$ 457,   |
| COMMITMENTS AND CONTINGENCIES                        |              |           |
| STOCKHOLDERS' EQUITY :                               |              |           |
| Preferred stock, \$.01 per value:                    |              |           |
| Authorized 1,000,000 shares, none issued             |              |           |
| Common stock \$.001 par value:                       |              |           |
| Authorized - 50,000,000 shares                       |              |           |
| Issued and outstanding - 17,972,760 shares .....     | 18,000       |           |
| Additional paid-in capital .....                     | 19,480,000   |           |
| Accumulated Deficit .....                            | (15,628,000) |           |
|  | -----        |           |
| Total Stockholders' Equity .....                     |              | 3,870,    |
|  |              | -----     |
|  |              | \$4,327,  |
|  |              | =====     |

See accompanying notes to financial statements.

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NOVADEL PHARMA INC.  
STATEMENT OF OPERATIONS

|  | Year Ended<br>July 31, |            |
|--|------------------------|------------|
|  | 2003                   | 2002       |
|  | -----                  | -----      |
| CONSULTING REVENUES .....                          | \$ 2,000               | \$ 339,000 |
| CONSULTING, RESEARCH AND DEVELOPMENT .....         | 1,048,000              | 962,000    |
| SELLING, GENERAL AND ADMINISTRATIVE EXPENSES ..... | 4,902,000              | 3,767,000  |
|  | -----                  | -----      |

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|  |                |                |
|--|----------------|----------------|
| LOSS FROM OPERATIONS .....                           | (5,948,000)    | (4,390,000)    |
| BUY-OUT OF CONSULTANT'S CONTRACT .....               | --             | (32,000)       |
| INTEREST INCOME .....                                | 49,000         | 44,000         |
|  | -----          | -----          |
| NET LOSS BEFORE TAXES .....                          | (5,899,000)    | (4,378,000)    |
| DEFERRED STATE INCOME TAX BENEFIT .....              | 84,000         | 88,000         |
|  | -----          | -----          |
| NET LOSS .....                                       | \$ (5,815,000) | \$ (4,290,000) |
|  | =====          | =====          |
| BASIC AND DILUTED LOSS                               |                |                |
| PER COMMON SHARE:                                    |                |                |
| Net Loss .....                                       | \$ (.38)       | \$ (.38)       |
|  | -----          | -----          |
| WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING | 15,419,000     | 11,361,000     |
|  | =====          | =====          |

See accompanying notes to financial statements.

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NOVADEL PHARMA INC.  
STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY

|                                       | Common Stock |           | Additional      | Accum    |
|---------------------------------------|--------------|-----------|-----------------|----------|
|                                       | Shares       | Par Value | Paid-in Capital | Def      |
|                                       | -----        | -----     | -----           | -----    |
| BALANCE, JULY 31, 2002                | 14,448,817   | \$ 14,000 | \$ 13,322,000   | \$ (9,8  |
|                                       | -----        | -----     | -----           | -----    |
| YEAR ENDED JULY 31, 2003              |              |           |                 |          |
| Common Shares Issued in connection    |              |           |                 |          |
| with private placements, net of costs | 3,200,345    | 3,000     | 4,333,000       |          |
| Shares issued for Options exercised   | 210,577      | --        | --              |          |
| Shares issued for Warrants exercised  | 113,021      | 1,000     | 19,000          |          |
| Options issued for services           | --           | --        | 1,674,000       |          |
| Warrants issued for services          | --           | --        | 7,000           |          |
| Equity investment from related party  | --           | --        | 125,000         |          |
| Net Loss                              | --           | --        | --              | (5,8     |
|                                       | -----        | -----     | -----           | -----    |
| BALANCE, JULY 31, 2003                | 17,972,760   | \$ 18,000 | \$ 19,480,000   | \$ (15,6 |
|                                       | =====        | =====     | =====           | =====    |

See accompanying notes to financial statements.

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NOVADEL PHARMA INC  
STATEMENT OF CASH FLOWS

|  | July 31<br>Year Ended |               |
|--|-----------------------|---------------|
|  | 2003                  | 2002          |
| <b>CASH FLOW FROM OPERATING ACTIVITIES:</b>                                    |                       |               |
| Net loss   | \$(5,815,000)         | \$(4,290,000) |
| Adjustments to reconcile net loss to net cash flows from operating activities: |                       |               |
| Options issued for services  | 1,674,000             | 1,947,000     |
| Warrants issued for services   | 7,000                 | 54,000        |
| Depreciation and amortization  | 81,000                | 77,000        |
| Allowances for Doubtful Accounts   | (88,000)              | 79,000        |
| Changes in operating assets and liabilities:                                   |                       |               |
| Accounts receivable  | 87,000                | 12,000        |
| Demand note receivable, Officer  | --                    | 60,000        |
| Prepaid expenses and other current assets                                      | (72,000)              | (39,000)      |
| Due from Joint Venture partner for reimbursable expenses                       | --                    | 6,000         |
| Other Assets   | (335,000)             | (5,000)       |
| Accounts payable - trade   | 14,000                | 114,000       |
| Accrued expenses and other current liabilities                                 | 127,000               | 114,000       |
| Net cash flows from operating activities                                       | (4,320,000)           | (1,871,000)   |
| <b>CASH FLOWS FROM INVESTING ACTIVITIES -</b>                                  |                       |               |
| Purchase of property and equipment   | (389,000)             | (316,000)     |
| Net cash flows from investing activities                                       | (389,000)             | (316,000)     |
| <b>CASH FLOWS FROM FINANCING ACTIVITIES -</b>                                  |                       |               |
| Proceeds received from the exercise of warrants                                | 20,000                | --            |
| Proceeds received from private placements                                      | 4,336,000             | 4,916,000     |
| Capital contributions from related party                                       | 125,000               | --            |
| Net cash flows from financing activities                                       | 4,481,000             | 4,916,000     |
| NET CHANGE IN CASH   | (228,000)             | 2,729,000     |
| CASH, BEGINNING OF YEAR  | 3,314,000             | 585,000       |
| CASH, END OF YEAR  | 3,086,000             | \$ 3,314,000  |
| <b>SUPPLEMENTAL CASH FLOW INFORMATION:</b>                                     |                       |               |
| Interest paid  | \$ --                 | \$ --         |
| Income taxes paid  | \$ --                 | \$ --         |

See accompanying notes to financial statements.

NOVADEL PHARMA INC.

NOTES TO FINANCIAL STATEMENTS

Note 1 - Nature of the Business and Summary of Significant Accounting Policies:

Nature of the Business - NOVADEL PHARMA INC. (the "Company"), which was formerly known as Flemington Pharmaceutical Corporation, is incorporated in the State of Delaware. The Company is engaged in the development of novel pharmaceutical products combining presently marketed drugs with patent-pending oral dosage delivery systems of the Company, designed to enhance and accelerate the onset of the therapeutic benefits which the drugs are intended to produce and is also engaged in domestic and international consulting activities. Management intends to develop the products in collaboration with pharmaceutical companies.

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

Consulting contract costs normally consist of fees paid to outside clinics for studies and an allocable portion of the Company's operating expenses. General and administrative costs pertaining to contracts are charged to expense as incurred.

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

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

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

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

Research and Development Costs - All research and development costs are expensed as incurred. These include all internal costs, external costs related to services contracted by the Company and research services conducted for others. Research and development costs consist primarily of salaries and benefits, contractor fees, clinical drug supplies of preclinical and clinical development programs, consumable research supplies and allocated facility and administrative costs. The Company has incurred research and development expenses that totaled \$660,000 and \$606,000 for 2003 and

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2002, respectively.

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Income Taxes - Temporary differences between financial statement and income tax reporting result primarily from net operating losses. As a result of these temporary differences, the Company has recorded a deferred tax asset with an offsetting valuation allowance for the same amount. The Company received \$84,000 and \$88,000 in 2003 and 2002, respectively from the transfer of New Jersey Net operating losses (See Note 8).

Defined Contribution Retirement Plans - The Company has a Simple IRA retirement plan, available to all employees, providing for contributions at management's discretion. During the years ended July 2003 and July 2002, the Company made contributions to the retirement plan of approximately \$15,000 and approximately \$11,000, respectively.

### Risk Concentrations:

- (a) Credit Risk - The Company maintains its cash balances in financial institutions that are insured by the Federal Deposit Insurance Corporation (FDIC) up to \$100,000 each. Such balances during the fiscal year ended 2003 have exceeded the FDIC limits.
- (b) Major Customers - During fiscal 2003, the Company had revenue from one customer located in the USA approximating 100% of the Company's total revenue.

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

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

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

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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.

|  | Year e               |
|--|----------------------|
|  | 2003                 |
| Numerator:   |                      |
| Net loss applicable to common shareholders - basic and diluted     | (5,815,000)<br>===== |
| Denominator:   |                      |
| Denominator for basic earnings (loss) per common share:            |                      |
| Weighted average shares  | 15,419,000           |
| Effect of dilutive securities                                      | --<br>-----          |
| Denominator for basic and diluted earnings (loss) per common share | 15,419,000<br>=====  |
| Earnings (loss) per common share:                                  |                      |
| Basic and Diluted  | (.38)                |

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

Recent Accounting Pronouncements - In November 22, 2002, the FASB issued FASB Interpretation (FIN) No. 45, Guarantor's Accounting and Disclosure Requirements for Guarantees, including Indirect Guarantees of Indebtedness of Others. FIN 45 requires that a liability be recorded in the guarantor's balance sheet upon issuance of a guarantee. In addition, FIN 45 requires disclosures about the guarantees that an entity has issued, including a rollforward of the entity's product warranty liabilities. The Company does not expect FIN 45 to have a material impact on its financial position, results of operations or cash flows.

In December 2002, the FASB issued SFAS No. 148, Accounting for Stock-Based Compensation, Transition and Disclosure. SFAS No. 148 provides alternative methods of transition for a voluntary change to the fair value base method of accounting for stock-based employee compensation. SFAS No. 148 also requires that disclosures of the pro forma effect of using the fair value method of accounting for stock-based employee compensation be displayed more prominently and

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in tabular format. Additionally, SFAS No. 148 requires disclosure of the pro forma effect in interim financial statements. The transition and annual disclosure requirements are effective for our 2003 fiscal year. The interim disclosure requirements are not effective. The Company does not expect the adoption of SFAS No. 148 to have a material impact on its financial position, results of operations or cash flow.

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

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

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

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

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

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

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

### Note 3 - Other assets and Accrued expenses:

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

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

### Note 4 - Furniture, Fixtures and Equipment and Leasehold Improvements

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

|                                    |                  |
|------------------------------------|------------------|
|                                    | July 31,<br>2003 |
|                                    | -----            |
| Equipment                          | \$713,000        |
| Furniture and fixtures             | 122,000          |
| Leasehold improvements             | 131,000          |
|                                    | -----            |
|                                    | 966,000          |
| <br>Less: Accumulated depreciation | <br>252,000      |
|                                    | =====            |
|                                    | \$714,000        |
|                                    | =====            |

### Note 5 - Stockholders' equity:

Private Placement - In May 2003, the Company completed a private placement and received net proceeds of approximately \$4,336,000 from the placement of a total of 48.01 Units of the Company's securities. Each Unit consisted of sixty six thousand, six hundred, sixty six and two thirds (66,666?) common shares, par value \$.001, and sixteen thousand, six hundred, sixty six and two thirds (16,666?) warrants. Each warrant entitles the holder to purchase an additional share of the Company's common stock at an exercise price of \$2.00 within five (5) years. The sale price of each Unit was \$100,000 (\$1.50 per share).

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

### Note 6 - Related Party Transactions:

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

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

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

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

### Note 7 - Commitments and Contingencies:

Employment Agreements - In December 2002, Dr. Shangold entered into a three-year employment agreement with NovaDel pursuant to which he agreed to serve as its President and Chief Executive Officer. We agreed to pay Dr. Shangold an annual base salary of \$350,000 and a guaranteed bonus of \$150,000. In addition, Dr. Shangold is eligible to receive: (i) an annual discretionary bonus of up to \$262,500, which shall be determined at the sole discretion of the Board; and

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(ii) an investment and fee bonus equal to 5% of all amounts up to an aggregate of \$7,500,000 (i.e., \$375,000) invested in, or earned by, NovaDel during his term. We paid Dr. Shangold a contractual bonus of \$200,000 during the fourth quarter. The investment bonus shall be

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reduced by certain proceeds received by Dr. Shangold from his former employer. Pursuant to the agreement, Dr. Shangold was also granted non-plan options to purchase 1,000,000 shares of our common stock (at an exercise price of \$1.93 per share) which vest over a three year period.

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

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

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

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

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

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employee 150,000 non plan options to purchase shares of the Company's common stock at an exercise price of \$3.02 per share; as of the date of this report none of such options had vested.

In May 2003, the Company entered into a three-year employment agreement with Barry Cohen pursuant to which he agreed to serve as the Company's Vice President, New Business & New Product Development. The Company agreed to pay Mr. Cohen an annual base salary of \$185,000. Pursuant to the agreement, Mr. Cohen was also granted Plan options to purchase up to 75,000 shares of the Company's common stock at an exercise price of \$2.20 per share (110% of the fair market value on the grant date) which vest, subject to conditions, over a three year period. Such options have a term of ten (10) years.

License and Development Agreement - In April 2003, the Company entered into a license and development agreement with Manhattan Pharmaceuticals, Inc. for the worldwide, exclusive rights to the Company's proprietary lingual spray technology to deliver Propofol for pre-procedural sedation. The terms of the agreement calls for certain milestone and other payments, the first of which was partially received during June 2003 (See Note 6).

Leases - In August 2000, the Company entered into a 5-year lease agreement, effective October 2000, for approximately 4,500 square feet of office, laboratory and manufacturing space. Annual rent is approximately \$63,000 plus real estate taxes, currently estimated to be approximately \$11,000 annually. Previously, the Company rented office space on a month to month basis. Rent expense for the Company totaled approximately \$92,000 and \$75,000 for the years ended July 31, 2003, and 2002 respectively.

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

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Future minimum rental payments as follows:

Year Ending July 31,

|                     |             |
|---------------------|-------------|
| 2004                | \$ 480,000  |
| 2005                | \$ 461,000  |
| 2006                | \$ 443,000  |
| 2007                | \$ 443,000  |
| 2008                | \$ 443,000  |
| 2009 and thereafter | \$ 443,000  |
|                     | -----       |
|                     | \$2,713,000 |
|                     | =====       |

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

### Note 8 - Income Taxes:

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

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

|                                  | July 31     |             |
|----------------------------------|-------------|-------------|
|                                  | 2003        | 2002        |
| Net operating loss carryforwards | \$5,300,000 | \$2,890,000 |
|                                  | 5,300,000   | 2,890,000   |
| Valuation allowance              | 5,300,000   | 2,890,000   |
| 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:

|   | 2003         | 2002         |
|---|--------------|--------------|
| Federal Tax at statutory rate .....         | \$ 1,977,000 | \$ 1,459,000 |
| State Income Tax .....                      | 349,000      | 257,000      |
| Non deductible; options issued for services | (670,000)    | (802,000)    |
| Valuation allowance .....                   | (1,656,000)  | (914,000)    |
|   | \$ --        | \$ --        |
|   | =====        | =====        |

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

At July 31, 2003, the Company has federal and state net operating loss carryforwards for financial reporting and income tax purposes of approximately \$15,500,000 and \$10,031,000, respectively, which can be used to offset current and future taxable income through the year 2024.

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

### Note 9 - Stock Options:

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

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The Company follows the intrinsic method of Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees" (APB 25) and related interpretations in accounting for its employee stock options because, as discussed below, Financial Accounting Standards Board Statement No. 123, "Accounting for Stock-Based Compensation" (FAS 123) requires use of option valuation models that were not developed for use in valuing employee stock options. FAS 123 permits a company to elect to follow the intrinsic method of APB 25 rather than the alternative fair value accounting provided under FAS 123, but requires pro forma net income and earnings per share disclosures as well as various other disclosures not required under FAS 123 for companies following APB 25. The Company has adopted the disclosure provisions required under Financial Accounting Standards Board Statement No. 148, "Accounting for Stock-Based Compensation - Transition and Disclosure" (FAS 148). Under APB 25, because the exercise price of the Company's stock options equals the market price of the underlying stock on the date of grant, no compensation expense was recognized.

Pro forma information regarding net income and earnings per share is required by FAS 123 and FAS 148, and has been determined as if the Company had accounted for its employee stock options under the fair value method of that Statement.

The fair value of options granted in 2003 and 2002 were estimated at the date of grant using a Black-Scholes option pricing model with the following weighted-average assumptions, respectively: risk-free interest rates of 4.0%, dividend yield of 0.0%, volatility factors of the expected market price of the Company's common stock of 74% in 2003 and 72% in 2002, and a weighted-average expected life of the

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options of five years.

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

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

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|   | Fiscal Year Ended |                |
|---|-------------------|----------------|
|   | June 30           | June 30        |
|   | 2003              | 2002           |
|   | -----             | -----          |
| Net income (loss) as reported   | \$ (5,815,000)    | \$ (4,290,000) |
| Stock-based employee compensation expense under fair value method, net of related tax effects | 486,000           | 1,440,000      |
|   | -----             | -----          |
| Pro forma net loss  | \$ (6,301,000)    | \$ (5,730,000) |
|   | =====             | =====          |
| Income / (Loss) per share:  |                   |                |
| Basic and diluted, as reported  | \$ (.38)          | \$ (.38)       |
| Basic and diluted, pro forma  | \$ (.41)          | \$ (.50)       |

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

|                            | Outstanding Options            |                      |                                    |
|----------------------------|--------------------------------|----------------------|------------------------------------|
|                            | Options Available<br>For Grant | Number of<br>Options | Weighted Average<br>Exercise Price |
|                            | -----                          | -----                | -----                              |
| Balance at August 1, 2001  | --                             | 2,300                | \$ 1.53                            |
| Additional Shares reserved | 2,475                          | --                   | --                                 |
| Grants .....               | 3,378                          | 3,378                | 1.60                               |
| Exercises .....            | --                             | 10                   | .63                                |
| Cancellations .....        | 1,190                          | 1,190                | 1.42                               |
|                            | -----                          | -----                | -----                              |
| Balance at July 31, 2002 . | 287                            | 4,478                | 1.61                               |

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|                            |       |       |         |
|----------------------------|-------|-------|---------|
| Additional Shares Reserved | 2,575 | --    | --      |
| Grants .....               | 2,159 | 2,159 | 1.60    |
| Exercises .....            | --    | 445   | .94     |
| Cancellations .....        | --    | --    | --      |
| Balances at July 31, 2003  | 703   | 6,192 | \$ 1.66 |

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

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

| Range of Exercise Prices | Outstanding Options |  |                                 | Options Exercisable |                                 |
|--------------------------|---------------------|--|---------------------------------|---------------------|---------------------------------|
|                          | Options             | Weighted Average Remaining Life in Years | Weighted Average Exercise Price | Options             | Weighted Average Exercise Price |
| \$0.01 - \$1.00 .....    | 2,035               | 6.9                                      | \$ .75                          | 2,035               | \$ .75                          |
| \$1.01 - \$2.00 .....    | 2,395               | 4.1                                      | 1.77                            | 1,195               | 1.68                            |
| \$2.01 - \$3.00 .....    | 1,362               | 8.3                                      | 2.40                            | 520                 | 2.51                            |
| \$3.01 - \$4.00 .....    | 400                 | 8.7                                      | 3.12                            | 350                 | 3.13                            |
|                          | 6,192               | 6.2                                      | \$ 1.66                         | 4,100               | \$ 1.45                         |

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

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

- A. 680,000 Class A Warrants, issued in connection with the Public Offering, exercisable until November 2003, to purchase a like number of shares of Common Stock at an exercise price of \$5.80 per share. These warrants were originally scheduled to expire during November 2002. Before expiration, the Company extended the expiration date by one year, to November 2003. The Company has not yet made any decision as to whether the expiration date might be further extended.
- B. 4,550,000 stock options, not issued under any of the plans, as follows:
  - o 300,000 options issued on November 19, 1997, vesting immediately, to the Company's then President, having an exercise price of \$1.84 per share, issued in connection

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with his employment agreement in June 1997, exercisable until November 2007.

- o 300,000 options issued on November 19, 1997, vesting immediately, to the Company's then Chairman, having an exercise price of \$1.84 per share, issued in connection with his employment agreement in June 1997, exercisable until November 2007.
- o 700,000 options issued in December 2001, and 350,000 options issued in July 2003, for a total of 1,050,000, vesting immediately, to the Company's Vice President for Corporate Development, in connection with his employment agreement, exercisable until December 2011.
- o 1,000,000 options issued in February 2002, vesting in three equal installments beginning in February 2003, to the Company's present Chairman in connection with his consulting agreement, having an exercise price of \$2.40 per share, exercisable until January 2012.
- o 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.
- o 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.

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- o 200,000 options issued in October 2002, to the Company's Chief Scientific Officer, having an exercise price of \$1.30 per share, exercisable until October 2007.
  - o 1,000,000 options issued in December 2002, vesting in three equal installments beginning in December 2003, to the Company's present President, having an exercise price of \$1.93 per share, issued in connection with his employment agreement, exercisable until December 2007.
  - o 100,000 options issued in March 2003, to each of two directors, for a total of 200,000, having an exercise price of \$1.51 per share, exercisable until March 2008.
  - o 100,000 options issued in June 2003, to a director, having an exercise price of \$2.15 per share, exercisable until June 2008.
- C. 60,000 warrants issued to a public relations company, exercisable until January 2007 at a price of \$2.00.
- D. 4,000,000 warrants issued to an investor, in connection with the fiscal year 2002 private placement, exercisable until December 2008 at a price of \$.75.

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- E. 2,666,667 warrants issued to an investor, in connection with the fiscal year 2002 private placement, exercisable until December 2009 at a price of \$.75.
- F. 200,000 warrants issued to a consulting company, exercisable until January 2010 at a price of \$1.00.
- G. 200,000 warrants issued to each of two consulting companies, for a total of 400,000, exercisable until November 2010 at a price of \$.75.
- H. 76,533 warrants at \$.75 per share issued to broker/dealers in connection with the fiscal year 2001 private placement. 5,000 of such warrants expire in December 2008, and remaining warrants (71,533) expire in May 2011.
- I. 210,017 warrants at \$1.50 per share issued to broker/dealers in connection with the fiscal year 2003 private placement. 93,167 of such warrants expire in April 2008, and remaining warrants (116,850) expire in May 2008.

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- J. 40,004 warrants at \$2.00 per share issued to broker/dealers in connection with the fiscal year 2003 private placement. 23,292 of such warrants expire in April 2008, and remaining warrants (16,712) expire in May 2008.
- K. 800,095 warrants at \$1.50 per share issued to investors in connection with the fiscal year 2003 private placement. 465,841 of such warrants expire in April 2008, and remaining warrants (334,254) expire in May 2008.

Note 10 - Subsequent Events:

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

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NOVADEL PHARMA INC.

CONDENSED BALANCE SHEETS

October 31,  
2003

-----  
(Unaudited)

ASSETS

CURRENT ASSETS:  
Cash

\$ 1,316,000

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|  |              |
|--|--------------|
| Accounts receivable - trade  | --           |
| Prepaid expenses and other current assets                            | 268,000      |
|  | -----        |
| Total Current Assets   | 1,584,000    |
|  | -----        |
| FURNITURE, FIXTURES, AND EQUIPMENT, LESS<br>ACCUMULATED DEPRECIATION | 1,054,000    |
| OTHER ASSETS   | 355,000      |
|  | -----        |
|  | \$ 2,993,000 |
|  | =====        |
| LIABILITIES AND STOCKHOLDERS' EQUITY                                 |              |
| CURRENT LIABILITIES:   |              |
| Accounts payable-trade   | \$ 365,000   |
| Accrued expenses and other current liabilities                       | 404,000      |
| Current portion of capitalized lease obligation                      | 25,000       |
|  | -----        |
| Total Current Liabilities  | 794,000      |
|  | -----        |
| Non current portion of capitalized lease obligation                  | 56,000       |
|  | -----        |
| Total Liabilities  | 850,000      |
|  | -----        |
| COMMITMENTS AND CONTINGENCIES  |              |
| STOCKHOLDERS' EQUITY:  |              |
| Preferred stock, \$.01 par value:                                    |              |
| Authorized 1,000,000 shares, none issued                             |              |
| Common stock, \$.001 par value:                                      |              |
| Authorized - 50,000,000 shares                                       |              |
| Issued and outstanding 17,972,760                                    | 18,000       |
| Additional paid-in capital   | 19,480,000   |
| Accumulated deficit  | (17,355,000) |
|  | -----        |
| Total Stockholders' Equity   | 2,143,000    |
|  | -----        |
|  | \$ 2,993,000 |
|  | =====        |

See accompanying notes to condensed financial statements.

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NOVADEL PHARMA INC.

CONDENSED STATEMENTS OF OPERATIONS  
(Unaudited)

Three Months Ended  
October 31

-----  
2003

-----  
2002

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|   |                |                |
|---|----------------|----------------|
| CONSULTING, SELLING, GENERAL AND<br>ADMINISTRATIVE EXPENSES AND LOSS<br>FROM OPERATIONS | \$ 1,733,000   | \$ 1,729,000   |
| INTEREST INCOME   | 6,000          | 15,000         |
| NET LOSS  | \$ (1,727,000) | \$ (1,714,000) |
| BASIC AND DILUTED LOSS PER SHARE  | \$ (.10)       | \$ (.12)       |
| SHARES USED IN COMPUTATION OF BASIC<br>AND DILUTED LOSS PER SHARE                       | 17,972,760     | 14,509,523     |

See accompanying notes to condensed financial statements.

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NOVADEL PHARMA INC.

CONDENSED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY  
(Unaudited)

|                           | Common Stock |              |                    |                        |     |
|---------------------------|--------------|--------------|--------------------|------------------------|-----|
|                           | Shares       | Par<br>Value | Paid-in<br>Capital | Accumulated<br>Deficit | Sto |
| BALANCE, August 1, 2003   | 17,972,760   | \$ 18,000    | \$ 19,480,000      | \$(15,628,000)         | \$  |
| Net Loss                  | --           | --           | --                 | (1,727,000)            | (   |
| BALANCE, October 31, 2003 | 17,972,760   | \$ 18,000    | \$ 19,480,000      | \$(17,355,000)         | \$  |

See accompanying notes to condensed financial statements.

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NOVADEL PHARMA INC.

CONDENSED STATEMENT OF CASH FLOWS  
(Unaudited)

Three Months Ended

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|   | October 31    |               |
|---|---------------|---------------|
|   | 2003          | 2002          |
| CASH FLOW FROM OPERATING ACTIVITIES:  |               |               |
| Net loss  | \$(1,727,000) | \$(1,714,000) |
| Adjustments to reconcile net loss to net cash used in operating activities: |               |               |
| Options issued for services   | --            | 573,000       |
| Warrants issued for services  | --            | 7,000         |
| Depreciation and amortization   | 49,000        | 37,000        |
| Changes in operating assets and liabilities:                                |               |               |
| Accounts receivable   | 2,000         | 1,000         |
| Prepaid expenses and other current assets                                   | (100,000)     | (15,000)      |
| Other assets  | 2,000         | --            |
| Accounts payable - trade  | 226,000       | 58,000        |
| Accrued expenses and other current liabilities                              | 86,000        | 60,000        |
| Net cash used in operating activities                                       | (1,462,000)   | (993,000)     |
| CASH FLOWS FROM INVESTING ACTIVITIES -                                      |               |               |
| Purchase of property and equipment  | (308,000)     | (110,000)     |
| NET DECREASE IN CASH  | (1,770,000)   | (1,103,000)   |
| CASH, BEGINNING OF PERIOD   | 3,086,000     | 3,314,000     |
| CASH, END OF PERIOD   | \$ 1,316,000  | 2,211,000     |
| SUPPLEMENTAL DISCLOSURE OF INVESTING AND FINANCING ACTIVITIES:              |               |               |
| Equipment acquired under capitalized lease obligation                       | \$ 81,000     | \$ --         |

See accompanying notes to condensed financial statements.

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NOVADEL PHARMA INC.  
NOTES TO CONDENSED FINANCIAL STATEMENTS

Note 1 - Basis of Presentation:

The balance sheet at the end of the preceding fiscal year has been derived from the audited balance sheet contained in the previously filed Form 10-KSB of NovaDel Pharma Inc. (The Company) for the year ended July 31, 2003 and is presented for comparative purposes. All other financial statements are unaudited. In the opinion of management, all adjustments, which include only normal recurring adjustments necessary to present fairly the financial position, results of operations and cash flows for all periods presented, have been made in the interim statements. Results of operations for interim periods are not necessarily indicative of the operating results to be expected for a full year.

The accompanying financial statements have been prepared assuming

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that the Company will continue as a going concern. Before December 31, 2003, it will be necessary for the Company to obtain additional financing and/or consummate 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. The Company 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.

Certain footnote disclosures normally included in financial statements prepared in accordance with generally accepted accounting principles have been omitted in accordance with the published rules and regulations of the Securities and Exchange Commission. The financial statements in this report should be read in conjunction with the financial statements and notes thereto included in the Form 10-KSB for the year ended July 31, 2003.

Loss per common share is computed pursuant to SFAS No. 128, "Earnings Per Share." Basic loss per share is computed as net income (loss) available to common shareholders divided by the weighted average number of common shares outstanding for the period. Diluted loss per share reflects the potential dilution that could occur from common shares issuable through stock options, warrants and convertible debt. As of October 31, 2003, 15,506,755 of options and warrants were excluded from the diluted loss per share computation, as their effect would be anti-dilutive.

### Note 2 - Capitalized Lease Obligation:

In October 2003, the Company entered into a capital lease for laboratory equipment. This lease requires 36 monthly payments of \$2,827 each.

### Note 3 - Contracts:

In August 2003, Mr. Robert C. Galler agreed to change from an employee of the Company as Vice President - Corporate Development to a consultant and entered into a consulting agreement with the Company at a base compensation of \$180,000 per year. The consulting agreement terminates in February 2005.

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### Note 4 - Stock Options:

The Company follows the intrinsic value method of Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees" (APB 25) and related interpretations in accounting for its employee stock options because, in the opinion of management, as discussed below, Financial Accounting Standards Board Statement No. 123, "Accounting for Stock-Based Compensation" (FAS 123) requires use of option valuation models that were not developed for use in valuing employee stock options. FAS 123 permits a company to elect to follow the intrinsic value method of APB 25 rather than the alternative fair value accounting provided under FAS 123, but requires pro forma net income (loss) and earnings (loss) per share disclosures as well as various other disclosures. The Company has adopted the disclosure provisions required under Financial

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Accounting standards Board Statement No. 148, "Accounting for Stock-Based Compensation Transition and Disclosure" (FAS 148). Under APB 25, because the exercise price of the Company's stock options has equaled the market price of the underlying stock on the date of grant, no compensation expense was recognized.

Pro forma information regarding net loss and loss per share is required by FAS 123 and FAS 148, and has been determined as if the Company had accounted for its employee stock options under the fair value method of Statement 123.

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, options valuation models require the input of highly subjective input assumptions including the expected stock price volatility. Because the Company's employee stock options have characteristics significantly different from those of traded options, and because changes in the subjective input assumptions can materially affect the fair value estimate, in management's opinion, the existing models do not necessarily provide a reliable measure of the fair value of its employee stock options.

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

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|  | 3 Months Ended<br>October 31, |                |
|--|-------------------------------|----------------|
|  | 2003                          | 2002           |
| Net Loss, as reported  | \$ (1,727,000)                | \$ (1,714,000) |
| Stock-based employee compensation expense<br>under fair value method, net of related tax effects | (10,000)                      | --             |
| Pro forma net loss   | \$ (1,737,000)                | \$ (1,714,000) |
| Loss per share:  |                               |                |
| Basic and diluted, as reported   | \$ (.10)                      | \$ (.12)       |
| Basic and diluted, pro forma   | \$ (.10)                      | \$ (.12)       |

In August 2003, the Company issued 75,000 options under the 1998 Option Plan to a new employee. These options vest equally over 3 years, beginning August 1, 2004, have an exercise price of \$2.23 and expire during July 2013.

In August 2003, the Company issued 6,000 options under the 1998 Option Plan to a new employee. These options vest equally over 3 years, beginning September 1, 2004, have an exercise price of \$1.99

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and expire during August 2013.

### Note 5 - Related Party Transactions:

In April 2003, the Company entered into a license and development agreement with Manhattan Pharmaceuticals, Inc. for the worldwide, exclusive rights to the Company's proprietary lingual spray technology. One of the Company's major shareholders is also a significant shareholder of Manhattan Pharmaceuticals, Inc.

During the Company's first fiscal quarter ended October 31, 2003, the Company invoiced Manhattan Pharmaceuticals, Inc. approximately \$93,000 for the Company's reimbursable expenses. In November 2003, the Company received \$375,000, from Manhattan Pharmaceuticals, Inc., for license fees. The Company expects to recognize these license fees over the 20 year term of the license.

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### Note 6 - Subsequent Events:

On November 18, 2003, the Company's publicly traded warrants expired.

On November 14, 2003, the Company engaged Paramount Capital, a related party, to assist the Company in the private placement of common stock and warrants. In January 2004, the Company issued 13,333,330 shares of common stock pursuant to the private placement and received net proceeds of approximately \$13,000,000. In connection with the private placement, the Company paid Paramount Capital and/or its designees, approximately \$1,000,000, and other consideration for its services.

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You should rely only on the information contained in this document. We have not authorized anyone to provide you with information that is different. This document may only be used where it is legal to sell these securities. The information in this document may only be accurate on the date of this document.

Additional risks and uncertainties not presently known or that are currently deemed immaterial may also impair our business operations. The risks and uncertainties described in this document and other risks and uncertainties which we may face in the future will have a greater impact on those who purchase our common stock. These purchasers will purchase our common stock at the market price or at a privately negotiated price and will run the risk of losing their entire investment.

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NovaDel Pharma Inc.

20,484,217  
shares of

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common stock

-----  
PROSPECTUS

-----  
February 13, 2004  
-----

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 24. Indemnification of Directors and Officers

Section 145 of the Delaware General Corporation Law (the "DGCL") empowers a corporation to indemnify its directors and officers and to purchase insurance with respect to liability arising out of the performance of their duties as directors and officers. The DGCL provides further that the indemnification permitted thereunder shall not be deemed exclusive of any other rights to which the directors and officers may be entitled under the corporation's by-laws, any agreement, vote of stockholders or otherwise.

Article Ninth of our Certificate of Incorporation eliminates the personal liability of directors to the fullest extent permitted by Section 102 of the DGCL. Article Tenth provides for indemnification of all persons whom we shall have the power to indemnify pursuant to Section 145 of the DGCL.

The effect of the foregoing is to require us, to the extent permitted by law, to indemnify our officers and directors for any claims arising against such persons in their official capacities if such persons acted in good faith and in a manner that they reasonably believed to be in or not opposed to our best interests, and, with respect to any criminal action or proceeding, had no reasonable cause to believe their conduct was unlawful. Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers or persons controlling us pursuant to the foregoing provisions, we have been informed that in the opinion of the Commission, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

We currently have liability insurance coverage for our officers and directors.

Item 25. Other Expenses of Issuance and Distribution.

The following table sets forth the costs and expenses payable by the registrant in connection with the sale of the securities being registered. All amounts are estimates except the SEC registration fee:

|  |              |
|--|--------------|
| SEC registration fee .....               | \$ 4,817.51  |
| Printing and engraving expenses .....    | \$ 10,000.00 |
| Accounting fees and expenses .....       | \$ 7,500.00  |
| Attorneys' fees and expenses .....       | \$ 90,000.00 |
| Transfer agent's fees and expenses ..... | \$ 7,500.00  |
| Miscellaneous .....                      | \$ 5,182.49  |
| Total .....                              | \$125,000.00 |

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### Item 26. Recent Sales of Unregistered Securities.

Set forth below is information regarding the issuance and sales of our securities without registration during the last three years. Other than as set forth below, no such sales involved the use of an underwriter and no commissions were paid in connection with the sale of any securities.

In December 2003, we sold units (consisting of common stock and warrants) to accredited investors. The units contained 95,238 shares of common stock and warrants to purchase 28,571 shares of common stock. The warrants are exercisable for five years, at an exercise price of \$1.40 per share. The units were sold through Paramount. We paid Paramount approximately \$1,000,000 in commissions and issued to Paramount or its designees 14 unit purchase options. Upon full exercise of such unit purchase options, we shall issue 1,333,332 shares of our common stock and warrants to purchase 399,994 shares of our common stock for a purchase price equal to \$1.40 per share. Upon the closing of the transaction, we issued 1,371,549 shares of Common Stock to investors in the offerings consummated by us in April and May of 2003 in connection with certain preemption rights extended to such investors. These sales were made in reliance on Section 4(2) and on Regulation D of the Securities Act.

In June 2003, we issued 206,206 shares to a former employee upon cashless exercise of outstanding options. The sale was made in reliance on Section 3(a)(9) of the Securities Act.

In April and May 2003, we sold units consisting of four shares of common stock and warrants to purchase one share of common stock to accredited investors. We issued a total of 3,200,345 shares (at \$1.50 per share) and 800,095 warrants exercisable at \$2.00 per share. The securities were sold through Paramount. We paid Paramount approximately \$360,000 in fees and issued to Paramount or its designees 160,017 warrants exercisable at \$1.65 per share and 40,004 warrants exercisable at \$2.00 per share. These sales were made in reliance on Section 4(2) and on Regulation D of the Securities Act.

In May 2003, we issued 13,329 shares of our common stock to First Montauk Securities Corp., upon exercise of warrants held by it. The sale was made in reliance on Section 4(2) of the Securities Act.

In December 2002, we issued 13,770 shares of our common stock to employees and/or principals of First Montauk, upon exercise of warrants held by them. The sales were made in reliance of Section 4(2) of the Securities Act.

In August 2002, we issued 85,922 shares of our common stock to employees and/or principals of Shipley Raidy Capital Partners LLC (via cashless exercise of warrants to purchase 136,482 shares). The issuance was made in reliance on Section 3(a)(9) of the Securities Act.

In July 2002, we issued 7,765 shares of our common stock to a former employee upon cashless exercise of outstanding options. The issuance was made in reliance on Section 3(a)(9) of the Securities Act.

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During July 2002, we issued 35,106 shares of our common stock to employees and/or principals of Adolph Komorsky Investments (via cashless exercise of warrants to purchase 48,142 shares). The issuance were made in reliance on

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Section 3(a)(9) of the Securities Act.

During June 2002, we issued 14,379 shares of our common stock to employees and/or principals of Adolph Komorsky (via cashless exercise of warrants to purchase 19,216 shares). The issuance was made in reliance on Section 3(a)(9) of the Securities Act.

During March 2002, we issued 2,666,667 units (each consisting of one share of common stock and one warrant to purchase a share of our common stock at \$.75 per share) at \$.75 per unit, to an accredited investor pursuant to Section 4(2) of the Securities Act.

During December 2001, we issued 4,000,000 units (each consisting of one share of common stock and one warrant to purchase a share of our common stock at \$.75 per share) at \$.75 per unit, to an accredited investor pursuant to Section 4(2) of the Securities Act.

In May 2001, we issued 1,843,663 shares of our common stock, at \$.75 per share, to accredited investors. The sales were made in reliance of Section 4(2) of the Securities Act. We paid \$138,275 in commissions in connection with that transaction.

### Item 27. Exhibits

Exhibits are listed on the Exhibit Index at the end of this Registration Statement. The exhibits required by Item 601 of Regulation S-B, listed on such Exhibit Index in response to this Item, are incorporated herein by reference.

### Item 28. Undertakings.

The undersigned registrant hereby undertakes to:

(1) File, during any period in which it offers or sells securities, a post-effective amendment to this registration statement to:

(i) Include any prospectus required by section 10(a)(3) of Securities Act;

(ii) Reflect in the prospectus any facts or events which, individually or together, represent a fundamental change in the information in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(B) if, in the aggregate, the changes in volume and price represent no more than 20% change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement; and

(iii) Include any additional or changed material information on the plan of distribution.

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(2) For determining liability under the Securities Act treat each post-effective amendment as a new registration statement of the securities offered, and the offering of the securities at that time to be the initial bona fide offering.

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(3) File a post-effective amendment to remove from registration any of the securities that remain unsold at the end of the offering.

(4) Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the small business issuer pursuant to the foregoing provisions, or otherwise, the small business issuer has been advise that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore unenforceable.

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SIGNATURES

In accordance with the requirements of the Securities Act of 1933, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements of filing on Form SB-2 and authorized this registration statement to be signed on its behalf by the undersigned, in the City of Flemington, State of New Jersey, on February 13, 2004.

NOVADEL PHARMA INC.

By: /s/ Gary A. Shangold

-----  
Gary A. Shangold, M.D.  
President and  
Chief Executive Officer

In accordance with the requirements of the Securities Act of 1933, this registration statement was signed by the following persons in the capacities and on the dates indicated.

| Name<br>-----   | Title<br>-----  | Date<br>-----     |
|---|---|-------------------|
| /s/ Gary A. Shangold<br>-----<br>Gary A. Shangold, M.D. | President, Chief Executive Officer (Principal Executive Officer) and Director | February 13, 2004 |
| /s/ Donald J. Deitman<br>-----<br>Donald J. Deitman     | Chief Financial Officer<br>(Principal Financial Officer)                      | February 13, 2004 |
| /s/ John H. Klein<br>-----<br>John H. Klein             | Chairman of the Board   | February 13, 2004 |
| /s/ Robert F. Schaul<br>-----<br>Robert F. Schaul       | Secretary and Director  | February 13, 2004 |

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|  |          |                   |
|--|----------|-------------------|
| /s/ William F. Hamilton<br>-----<br>William F. Hamilton        | Director | February 13, 2002 |
| /s/ Lawrence J. Kessel<br>-----<br>Lawrence J. Kessel          | Director | February 13, 2002 |
| /s/ Mark H. Rachesky<br>-----<br>Mark H. Rachesky              | Director | February 13, 2002 |
| /s/ Charles Nemeroff<br>-----<br>Charles Nemeroff, M.D., Ph.D. | Director | February 13, 2002 |

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EXHIBIT INDEX

| Exhibit No.<br>----- | Description<br>-----   |
|----------------------|--|
| 2.1 (4)              | Agreement of Merger dated as of October 29, 1998                         |
| 3.1 (4)              | Certificate of Incorporation of the Registrant, as amended               |
| 3.2 (4)              | Bylaws of the Registrant, as amended                                     |
| 4.1 (3)              | Form of Warrant Agreement relating to Public Warrants                    |
| 4.3 (3)              | Form of Class A Warrant Certificate                                      |
| 4.4 (3)              | Form of Underwriters' Option Agreement                                   |
| 4.5(14)              | Form of Class C Warrant Certificate                                      |
| 5.1*                 | Opinion of Dickstein Shapiro Morin & Oshinsky LLP                        |
| 10.1 (8)             | Employment Agreement with Harry A. Dugger, III, Ph.D.                    |
| 10.2 (2)             | Employment Agreement with John J. Moroney                                |
| 10.3 (1)             | Agreement dated December 7, 1996 between the Registrant and Altana, Inc. |
| 10.4 (1)             | Registrant's 1992 Stock Option Plan                                      |
| 10.5 (2)             | Form of Option Agreement under the 1992 Stock Option Plan                |
| 10.6 (1)             | Registrant's 1997 Stock Option Plan                                      |
| 10.7 (2)             | Form of Option Agreement under the 1997 Stock Option Plan                |
| 10.8 (1)             | Agreement with Rapid Spray (Clemastine) dated June 2, 1992               |

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10.9 (1) Agreement with Rapid Spray (Nitroglycerin) dated June 2, 1992

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| Exhibit No.<br>----- | Description<br>-----  |
|----------------------|---|
| 10.10 (2)            | Agreement with Creative Technologies, Inc. dated December 26, 1996  |
| 10.11 (4)            | Registrant's 1998 Stock Option Plan   |
| 10.12 (5)            | Employment Agreement with Donald P. Cox, Ph.D.  |
| 10.13 (5)            | Employment Agreement with Kenneth Cleaver, Ph.D.  |
| 10.14 (5)            | Amendment to Consulting Agreement with Saggi Capital Corp. dated March 25, 1998   |
| 10.15 (6)            | Agreement with Altana, Inc., dated December 7, 1996   |
| 10.16 (6)            | Agreement with CLL Pharma dated February 12, 1998   |
| 10.17 (6)            | 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 |
| 10.18 (6)            | Agreement with PolyMASC Pharmaceuticals plc, dated July 25, 2000  |
| 10.19 (6)            | Authorization to proceed with Innovex, Inc. and Novartis Pharmaceuticals Corp., dated June 15, 2000   |
| 10.20 (8)            | Consulting Agreement with John Klein  |
| 10.21 (8)            | Employment Agreement with Robert Galler   |
| 10.22 (8)            | Employment Agreement Amendment No. 1 with Robert Galler   |
| 10.23 (8)            | Employment Agreement with Donald Deitman  |
| 10.24 (7)            | Common Stock and Warrant Purchase Agreement dated December 12, 2001   |
| 10.25 (8)            | Amendment No. 1 Common Stock and Warrant Purchase Agreement   |
| 10.26 (9)            | Employment Agreement with Mohammed Abd El-Shafy, Ph.D.  |
| 10.27 (10)           | Employment Agreement with Gary A. Shangold, M.D.  |
| 10.28 (10)           | Amendment No. 1 to Employment Agreement with Gary A. Shangold, M.D.   |
| 10.29 (11)           | Lease Agreement with Macedo Business Park, II, LLC  |

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- 10.30 (11) Amendment No. 1 to Lease Agreement with Macedo Business Park, II, LLC
- 10.31 (11) Employment Agreement with Barry C. Cohen
- 10.32 (13) Agreement with Manhattan Pharmaceuticals, Inc. dated April 4, 2003
- 11.1 (12) Computation of earnings per share
- 23.1\* Consent of Wiss & Company LLP

\* Filed herewith

- (1) As filed with the Registrant's Form SB-2, on August 8, 1997, File No. 333-33201.
- (2) As filed with the Registrant's Form SB-2, on October 3, 1997, File No. 333-33201.
- (3) As filed with the Registrant's Form SB-2, on October 31, 1997, File No. 333-33201.
- (4) As filed with the Registrant's Preliminary Proxy Statement on October 20, 1998, File No. 000-23399.
- (5) As filed with the Registrant's Form 10-KSB for the fiscal year ended July 31, 1999.
- (6) As filed with the Registrant's Form 10-KSB/A for the fiscal year ended July 31, 2001.
- (7) Incorporated by Reference to Schedule 13D filed on December 21, 2001 by Lindsay A. Rosenwald, M.D.
- (8) As filed with the Registrant's Form SB-2 on April 15, 2002, File No. 333-86262.
- (9) As filed with the Registrant's Form SB-2 on September 3, 2002, File No. 333-86262.
- (10) As filed with the Registrant's Quarterly Report of Form 10-QSB for the fiscal quarter ended January 31, 2003.
- (11) As filed with the Registrant's Quarterly Report on Form 10-QSB for the fiscal quarter ended April 30, 2003.
- (12) As filed with the Registrant's Form SB-2, on July 17, 2003, File No. 333-107122.
- (13) As filed with the Registrant's Form 10-KSB for the fiscal year ended July 31, 2003.
- (14) As filed with the Registrant's Form 8-K on January 12, 2004.