NOVADEL PHARMA INC
Form S-8
June 18, 2004

AS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION ON JUNE 18, 2004

REGISTRATION NO. 333-

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

FORM S-8

REGISTRATION STATEMENT UNDER
THE SECURITIES ACT OF 1933

NOVADEL PHARMA INC.

(EXACT NAME OF REGISTRANT AS SPECIFIED IN ITS CHARTER)

DELAWARE	22-2407152
(STATE OR OTHER JURISDICTION OF INCORPORATION OR ORGANIZATION)	(I.R.S. EMPLOYER IDENTIFICATION NO.)

25 MINNEAKONING ROAD, FLEMINGTON, NEW JERSEY 08822

(ADDRESS OF PRINCIPAL EXECUTIVE OFFICES) (ZIP CODE)

NOVADEL PHARMA INC. 1998 STOCK OPTION PLAN
AND NON-PLAN EXECUTIVE, DIRECTOR AND CONSULTANT OPTIONS

(FULL TITLE OF THE PLAN)

GARY A. SHANGOLD, M.D., 25 MINNEAKONING ROAD, FLEMINGTON, NEW JERSEY 08822

(NAME AND ADDRESS OF AGENT FOR SERVICE)

(908) 782-3431

(TELEPHONE NUMBER, INCLUDING AREA CODE, OF AGENT FOR SERVICE)

CALCULATION OF REGISTRATION FEE

Title of securities to be registered	Amount to be registered (1)	Proposed maximum offering price per share(2)	Proposed maximum aggregate offering price	Amount of Registration Fee
Common Stock	6,950,000	$1.96	$13,622,000	$1,725.91

$.001 par value

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(1) The aggregate amount of securities registered hereunder is 6,950,000 shares of common stock issued in connection with, or issuable upon exercise of, non-plan stock options held by executives and other employees, consultants and directors, and options which were, or may be, granted pursuant to our 1998 Stock Option Plan. Pursuant to Rule 416 promulgated under the Securities Act of 1933, as amended, this registration statement covers such indeterminate additional shares of common stock to be offered or issued to prevent dilution as a result of future stock splits, stock dividends or other similar transactions.

(2) The fee with respect to these shares has been calculated pursuant to paragraphs (h) and (c) of Rule 457 upon the basis of $1.96, the average of the high and low prices for our common stock on June 15, 2004, a date within five (5) business days prior to the date of filing of this registration statement, as reported by the American Stock Exchange LLC.

EXPLANATORY NOTE

This Registration Statement contains two parts. The first part contains a "Reoffer Prospectus," which has been prepared in accordance with the requirements of Part I of Form S-3 (as required by Section C.1. of the General Instructions to Form S-8). The Reoffer Prospectus will be used for reoffers and resales by affiliates of NovaDel Pharma Inc. (the "Registrant") of shares of common stock of the Registrant to be issued upon exercise of options granted pursuant to the Registrant's 1998 stock option plan and non-plan executive, director and consultant options, and by non-affiliates of the Registrant of shares of common stock previously issued to them upon exercise of options . The second part contains information required in the registration statement pursuant to Part II of Form S-8. Pursuant to the introductory note to Part I of Form S-8, the plan information, which constitutes part of the "Plan Prospectus," is not being filed with the Securities and Exchange Commission.

PROSPECTUS

NOVADEL PHARMA INC.

6,950,000 Shares of

Common Stock

NovaDel Pharma Inc. 1998 Stock Option Plan and Non-plan Executive, Director and Consultant Options

This prospectus is being used in connection with the offering from time to time by certain selling stockholders of our company or their successors in interest of shares of the common stock which have been issued under, or may be acquired upon the exercise of, stock options pursuant to our 1998 Stock Option Plan and Non-plan Executive, Director and Consultant Options (collectively, the "Plans").

The common stock may be sold from time to time by the selling stockholders or by their pledgees, donees, transferees or other successors in interest. Such sales may be made in the over-the-counter market or otherwise at prices and at terms then prevailing or at prices related to the then current market price, or in negotiated transactions. The common stock may be sold by one or more of the

following: (a) block trades in which the broker or dealer so engaged will attempt to sell the shares as agent but may position and resell portions of the block as principal to facilitate the transaction; (b) purchases by a broker or dealer as principal and resale by such broker or dealer for its account pursuant to this prospectus; (c) an exchange distribution in accordance with the rules of such exchange; and (d) ordinary brokerage transactions and transactions in which the broker solicits purchases. In effecting sales, brokers or dealers engaged by the selling stockholders may arrange for other brokers or dealers to participate. Brokers or dealers will receive commissions or discounts from selling stockholders in amounts to be negotiated immediately prior to the sale. Such brokers or dealers and any other participating brokers or dealers may be deemed to be "underwriters" within the meaning of the Securities Act of 1933, as amended (the "Act") in connection with such sales. In addition, 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. We will not receive any of the proceeds from the sale of these shares, although we have paid the expenses of preparing this prospectus and the related registration statement.

The closing sales price of our common stock on June 15, 2004 as reported by the American Stock Exchange LLC ("AMEX") was $1.98.

THESE SECURITIES HAVE NOT BEEN APPROVED OR DISAPPROVED BY THE SECURITIES AND EXCHANGE COMMISSION OR ANY STATE SECURITIES COMMISSION NOR HAS THE COMMISSION OR ANY STATE SECURITIES COMMISSION PASSED UPON THE ACCURACY OR ADEQUACY OF THIS PROSPECTUS. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.

The date of this Prospectus is June 18, 2004.

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NO PERSON HAS BEEN AUTHORIZED TO GIVE ANY INFORMATION OR TO MAKE ANY REPRESENTATIONS, OTHER THAN THOSE CONTAINED IN THIS PROSPECTUS, IN CONNECTION WITH THE OFFERING MADE HEREBY, AND, IF GIVEN OR MADE, SUCH INFORMATION OR REPRESENTATION MUST NOT BE RELIED UPON AS HAVING BEEN AUTHORIZED BY THE COMPANY OR ANY OTHER PERSON. NEITHER THE DELIVERY OF THIS PROSPECTUS NOR ANY SALE MADE HEREUNDER SHALL UNDER ANY CIRCUMSTANCES CREATE ANY IMPLICATION THAT THERE HAS BEEN NO CHANGE IN THE AFFAIRS OF THE COMPANY SINCE THE DATE HEREOF. THIS PROSPECTUS DOES NOT CONSTITUTE AN OFFER TO SELL OR A SOLICITATION OF AN OFFER TO BUY ANY SECURITIES OFFERED HEREBY BY ANYONE IN ANY JURISDICTION IN WHICH SUCH OFFER OR SOLICITATION IS NOT AUTHORIZED OR IN WHICH THE PERSON MAKING SUCH OFFER OR SOLICITATION IS NOT QUALIFIED TO DO SO OR TO ANY PERSON TO WHOM IT IS

UNLAWFUL TO MAKE SUCH OFFER OR SOLICITATION.

PROSPECTUS SUMMARY

The following summary contains basic information about Novadel Pharma Inc. and this prospectus. It may not contain all of the information that is important to you. For a more complete understanding, we encourage you to read the entire prospectus and the documents incorporated by reference into this prospectus. In this prospectus, the words "Novadel," "Company," "we," "our" and "us" refer to Novadel Pharma Inc.

Common Stock outstanding before the offering	32,943,699 Shares (1)
Common Stock outstanding which may be offered pursuant to this prospectus	34,060 Shares
Common Stock issuable upon exercise of outstanding options which may be offered pursuant to this prospectus	6,915,940 Shares
AMEX Symbol for Common Stock	"NVD"
Use of Proceeds	We will not receive any proceeds from the sales of these shares. We will receive proceeds to the extent that currently outstanding options are exercised for cash. We will use the exercise proceeds, if any, for working capital and general corporate purposes.
Risk Factors	There are risks associated with an investment in the common stock offered by this prospectus. You should carefully consider the risk factors described in this prospectus in the "Risk Factors" section before making a decision to invest.

(1) As of June 9, 2004. Does not include shares of common stock issuable upon exercise of options or warrants.

WHERE YOU CAN FIND MORE INFORMATION

We file annual, quarterly and current reports, proxy statements and other information with the Securities and Exchange Commission (the "SEC"). You may read and copy, upon payment of a fee set by the SEC, any documents that we file with the SEC as its public reference room at 450 Fifth Street, N.W., Washington, D.C. You may also call the SEC at 1-800-432-0330 for more information on the public reference rooms. Our filings are also available to the public on the Internet through the SEC's EDGAR database. You may access the EDGAR database at the SEC's website at www.sec.gov.

This prospectus is part of registration statement on Form S-8 that we have filed with the SEC to register the common stock offered hereby under the Act. As permitted by SEC rules, this prospectus does not contain all of the information contained in the registration statement and accompanying exhibits and schedules that we file with the SEC. You may refer to the registration statement, the exhibits and schedules for more information about us and our common stock. The registration statement, exhibits and schedules are available at the SEC's public reference rooms or through its EDGAR database on the Internet.

You should rely only on the information contained in this prospectus or any supplement to this prospectus. We have not authorized anyone to provide you with different information.

Our common stock is quoted on the AMEX under the symbol "NVD."

DOCUMENTS INCORPORATED BY REFERENCE

The following documents filed with the SEC (File No. 000-23399) pursuant to the Securities Exchange Act of 1934, as amended, (the "Exchange Act") are incorporated herein by reference:

1. The description of the common stock contained in our Registration Statement (File No. 333-112852) on Form SB-2/A filed with the SEC on March 25, 2004.

2. Annual Report on Form 10-KSB for the fiscal year ended July 31, 2003, as amended.

3. Quarterly Report on Form 10-QSB for the period ended October 31, 2003.

4. Quarterly Report on Form 10-QSB for the period ended January 31, 2004.

5. Quarterly Report on Form 10-QSB for the period ended April 30, 2004.

6. Definitive Proxy Statement on Schedule 14A dated March 5, 2004 in connection with our annual meeting of stockholders held on April 19, 2004.

7. Current Reports on Form 8-K filed on December 3 and December 30, 2003 and on January 6, January 12 and May 11, 2004.

All documents subsequently filed by the Company pursuant to Section 13(a), 13(c), 14 or 15(d) of the Exchange Act prior to the termination of this offering shall be deemed to be incorporated by reference in this prospectus and to be a part of this prospectus from the date of filing thereof.

Any statement contained in a document incorporated by reference herein shall be deemed to be modified or superseded for purposes of this prospectus to the extent that a statement contained herein or in any other subsequently filed document which also is or is deemed to be incorporated by reference herein modifies or supersedes such statement. Any such statement so modified or superseded shall not be deemed, except as so modified or superseded, to constitute part of this prospectus.

We will provide without charge to each person to whom this prospectus is delivered, upon written or oral request of that person, a copy of all documents incorporated by reference into the registration statement of which this prospectus is a part, other than exhibits to those documents (unless such exhibits are specifically incorporated by reference into such documents). Requests for such documents should be directed to Jean W. Frydman, Esq., General Counsel, NovaDel Pharma Inc., 25 Minneakoning Road, Flemington, New Jersey, 08822, telephone: (908) 782-3431.

THE COMPANY

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, 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 our license agreement with Manhattan Pharmaceuticals, Inc., in connection with propofol, 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. Our principal business address is 25 Minneakoning Road, Flemington, New Jersey, 08822, and our telephone number is (908) 782-3431.

FORWARD LOOKING STATEMENTS

The statements set forth 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 Act and Section 21E of the Exchange Act, including statements regarding the expectations, beliefs, intentions or strategies for the future. These statements can be identified by the use of forward-looking terminology such as "believes," "expects," "may," "will," "should," "plans," "future," "intends," "continue," "estimate" or "anticipates" or the negatives or variations of these terms, and other comparable terminology. 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.

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.

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. See also "Forward Looking Statements."

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.

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.

We had an accumulated deficit as of April 30, 2004, of approximately $20,499,000. We incurred operating losses in each of our last eight fiscal years, including a net loss of approximately $5,815,000 for the fiscal year ended July 31, 2003 and $4,871,000 for the nine months ended April 30, 2004. Because we increased our product development activities, we anticipate that we will incur substantial operating expenses in connection with continued research and development, clinical trials, testing and approval of our proposed products, and expect these expenses will result in continuing and, perhaps, significant operating losses until such time, if ever, that we are able to achieve adequate product sales levels. Our ability to generate revenue and achieve profitability depends upon our ability, alone or with others, to complete the development of our proposed products, obtain the required regulatory approvals and manufacture, market and sell our proposed products.

WE WILL REQUIRE SIGNIFICANT CAPITAL 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 third 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.

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

The additional financings we require may be obtained through one or more transactions which effectively dilute the ownership interests of our stockholders. Further, we may not be able to secure such additional financing on terms acceptable to us, if at all. We have the authority to issue additional shares of common stock, as well as additional classes or series of ownership interests or debt obligations which may be convertible into any one or more

classes or series of ownership interests. We are authorized to issue 100,000,000 shares of common stock and 1,000,000 shares of preferred stock. Such securities may be issued without the approval or other consent of our stockholders.

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

- the number of clinical sites;
- the size of the patient population;
- the proximity of patients to the clinical sites;
- the eligibility criteria for the study;

- the existence of competing clinical trials; and
- the existence of alternative available products.

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

THERE ARE CERTAIN INTERLOCKING RELATIONSHIPS AND POTENTIAL CONFLICTS OF INTEREST.

Lindsay A. Rosenwald, M.D., a significant stockholder of NovaDel, is the Chairman of Paramount Capital, the placement agent for the private placements we completed during calendar year 2003. 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 10,838,901 of our outstanding common stock (assuming exercise of certain warrants beneficially owned by Dr. Rosenwald) and 5,075,664 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 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."

WE DO NOT HAVE COMMERCIALLY AVAILABLE PRODUCTS.

Our principal efforts are the development of, and obtaining regulatory approvals for, our proposed products. We anticipate that marketing activities for our proprietary products, whether by us or one or more of our licensees, if any, will not begin until 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.

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 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.

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.

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 registered with the FDA and foreign regulatory authorities.

WE FACE INTENSE COMPETITION.

The markets which we intend to enter are characterized by intense competition. We or our licensees may be competing against established pharmaceutical companies which currently market products which are equivalent or functionally similar to those we intend to market. Prices of drug products are significantly affected by competitive factors and tend to decline as competition increases. In addition, numerous companies are developing or may, in the future, engage in the development of products competitive with our proposed products. We expect that

technological developments will occur at a rapid rate and that competition is likely to intensify as enhanced dosage from technologies gain greater acceptance. Additionally, the markets for formulated products which we have targeted for development are intensely competitive, involving numerous competitors and products. Most of our prospective competitors possess substantially greater financial, technical and other resources than we do. Moreover, many of these companies possess greater marketing capabilities than we do, including the resources necessary to enable them to implement extensive advertising campaigns. We may not be able to compete successfully with such competitors.

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

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

Generex Biotechnology Corporation, based in Toronto, Canada, is developing an insulin formulation that is delivered directly into the mouth via their RapidMist(TM) device. They also state that they have begun research on four specific target molecules for their RapidMist delivery system: morphine, fentanyl, heparin and flu vaccine. Sirus Pharmaceuticals Ltd., based in the United Kingdom, also claims to be developing drugs to be delivered sublingually via an aerosol spray. Sirus is working in the areas of pain and emesis. There are several other companies that we are aware of that market lingual spray products containing vitamins and homeopathic ingredients.

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

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.

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 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 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.

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

We seek patent protection for our technology so as to prevent others from commercializing equivalent products in substantially less time and at substantially lower expense. The pharmaceutical industry places considerable importance on obtaining patent and trade secret protection for new technologies,

products and processes. Our success will depend in part on our ability and that of parties from whom we license technology to:

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

The patent position of firms relying upon biotechnology is highly uncertain and involves complex legal and factual questions for which important legal principles are unresolved. To date, the United States Patent and Trademark Office has not adopted a consistent policy regarding the breadth of claims that the United States Patent and Trademark Office allows in biotechnology patents or the degree of protection that these types of patents afford. As a result, there are risks that we may not develop or obtain rights to products or processes that are or may seem to be patentable.

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

We, and the parties licensing technologies to us, have filed various United States and foreign patent applications with respect to the products and technologies under our development, and the United States Patent and Trademark

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

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

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

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

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

We depend 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, 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., and our Vice President of New Business and Product Development, Barry Cohen. 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 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.

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 37% 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. 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.

WE MAY BE DE-LISTED FROM THE AMEX IF WE DO NOT MEET CONTINUED LISTING REQUIREMENTS.

Our common stock commenced trading on the AMEX on May 11, 2004. The AMEX (Part 10, Section 1003) requires stockholders' equity (for continued listing) of at least $6,000,000 if a listed company has sustained net losses in its five most recent fiscal years. We have sustained net losses in each of our last eight fiscal years. As of April 30, 2004, our stockholders' equity was approximately $11,984,000.

If our common stock is de-listed by the AMEX, trading of our common stock would thereafter likely be conducted on the OTC Bulletin Board. In such case, the market liquidity of our common stock would likely be negatively affected, which may make it more difficult for holders of our common stock to sell their securities in the open market and we could face difficulty raising capital necessary for our continued operations.

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

We are authorized to issue 100,000,000 shares of our common stock. As of June 9, 2004, there were 32,943,699 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 June 9, 2004, we had outstanding stock options and warrants to purchase approximately 20,289,221 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 2,053,000 shares are currently reserved for issuance in connection with our 1992, 1997 and 1998 Stock

Option Plans, respectively, of which options to purchase an aggregate of 300,000 (500,000 authorized under such plan and 200,000 exercised to date), 250,000 (500,000 authorized under such plan and 250,000 exercised to date) and 1,503,000 (3,400,000 authorized under such plan and 265,000 exercised to date) shares have been issued under the respective stock option plans. Another 2,900,000 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.

POSSIBLE FUTURE SALES OF SHARES BY THE SELLING STOCKHOLDERS MAY BE ADVERSELY AFFECT THE MARKET.

Subject to the restrictions described under "Risk Factors - Shares eligible for future sale may adversely affect the market" and applicable law, the selling stockholders could cause the sale of any or all the shares of common stock they own upon the effectiveness of the registration statement of which this prospectus forms a part. The selling stockholders may determine to sell shares of common stock from time to time for any reason. Although we can make no prediction as to the effect, if any, that sales of shares of common stock owned by selling stockholders would have on the market price prevailing from time to time, sales of substantial amounts of common stock, or the availability of such shares for sale in the public market, could adversely affect prevailing market

prices of common stock.

SHARES ELIGIBLE FOR FUTURE SALE MAY ADVERSELY AFFECT THE MARKET.

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

LIMITATION ON DIRECTOR/OFFICER LIABILITY.

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

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

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

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

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

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USE OF PROCEEDS

The shares which may be sold under this prospectus will be sold for the respective accounts of each of the selling stockholders. Accordingly, NovaDel will not realize any proceeds from the sale of the shares, except that it will derive proceeds if all of the options currently outstanding are exercised for cash. However, a substantial number of such options contain certain provisions for cashless exercise. If exercised for cash, such funds will be available to NovaDel for working capital and general corporate purposes. No assurance can be given, however, as to when or if any or all of the options will be exercised. All expenses of the registration of the shares will be paid for by NovaDel. See "Selling Stockholders" and "Plan of Distribution."

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SELLING STOCKHOLDERS

The following table sets forth the name and relationship to NovaDel and its affiliates (within the past three years) of each selling stockholder, the number of shares of common stock which each selling stockholder (1) owned of record before the offering; (2) may acquire pursuant to the exercise of a previously granted option or options which hereafter may be granted under the Plans, all of which shares may be sold pursuant to this prospectus; and (3) the amount of common stock to be owned by each selling stockholder and (if one percent or more) the percentage of the class to be owned by such stockholder assuming the grant of the maximum number of shares issuable under the Plans, the exercise of all options granted under the Plans, and the sale of all shares acquired upon exercise of such options.

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 June 9, 2004, the Company had 32,943,699 shares of common stock outstanding. Beneficial ownership information reflected in the table includes shares issuable upon the exercise of outstanding options/warrants issued by the Company at their initial exercise prices.

Name and Relationship to the Company Within the Past Three Years	Amount of Common Stock Beneficially Owned As of June 9, 2004	Amount Offered Hereby	Amount of Common Sto Percentage of Class Owned After the Off
Harry A. Dugger Founder, Officer Former Chairman	2,154,003(1)	420,000(2)	1,734,003 (5.18%
Gary A. Shangold CEO/President, Director	1,125,000(3)	1,125,000	0
Robert F. Schaul Officer, Director	324,286(4)	240,000(5)	84,286 (*

Mohammed Abd El-Shafy Officer	250,000(6)	250,000	0
Jean W. Frydman Officer	100,000(7)	100,000	0
William F. Hamilton Director	150,000(8)	150,000	0
Lawrence J. Kessel Director	176,265(9)	150,000(10)	26,265 (*)
Barry Cohen Officer	150,000(11)	150,000	0
Mark H. Rachesky Director	150,000(12)	150,000	0
Charles Nemeroff Director	150,000(13)	150,000	0
Robert G. Savage Director	150,000(14)	150,000	0

Name and Relationship to the Company Within the Past Three Years	Amount of Common Stock Beneficially Owned As of June 9, 2004	Amount Offered Hereby	Amount of Common Sto Percentage of Class Owned After the Off
D. Cox Former Employee	4,371(15)	4,371	0
Robert Galler Consultant, Former Officer	1,050,000(16)	1,050,000	0
Bernadine Wrubel Former Employee	29,689(17)	29,689	0

(*) Less than 1%.

(1) Represents 852,003 shares of common stock; options to purchase 200,000 shares of common stock (exercisable at $.70 per share) issued under the 1992 stock plan which expire in November 2006; options to purchase 50,000 shares of common stock (exercisable at $.70 per share) under the 1997 stock plan which expire in November 2006; options to purchase 300,000 shares of common stock issued outside of the 1998 Plan (exercisable at $1.84 per share) which expire November 2007; 166,000 shares owned by his daughter Christina Dugger; 166,000 shares owned by his son Andrew Dugger; and the options described in footnote 2 below.

(2) Represents options to purchase 95,000 shares of common stock (exercisable at $.70 per share) issued under the 1998 Plan which expire in November 2006; options to purchase 200,000 shares of common stock issued outside of the 1998 Plan (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 and options to purchase 50,000 shares of common stock issued under the 1998 Plan (exercisable at $1.82 per share) which expire in February 2009.

(3) Represents 1,000,000 options issued outside of the 1998 Plan, in December 2002 (exercisable at $1.93 per share) which expire in December 2007; and options to purchase 125,000 shares of common stock issued under the 1998 Plan (exercisable at $1.82 per share) which expire in February 2009.

(4) Represents 39,286 shares of common stock; 20,000 options, issued under the 1992 stock plan, to purchase common stock at an exercise price of $.63 per share, expiring in July, 2006; 25,000 options issued under the 1997 stock plan, to purchase common stock at an exercise price of $.63 per share, expiring in March 2008; and the options described in footnote 5 below.

(5) Represents 10,000 options issued under the 1998 Plan, to purchase common stock at an exercise price of $.63 per share, expiring in September 2009; 95,000 options issued under the 1998 Plan, to purchase common stock at an exercise price of $.63 per share, expiring in January 2010; 75,000 options issued under the 1998 Plan, to purchase common stock at an exercise price of $2.69 per share, expiring in February 2012; 10,000 options issued under the 1998 Plan to purchase common stock at an exercise price of $1.51 per share, expiring in March 2008 and 50,000 options issued outside of the 1998 Plan to purchase common stock at an exercise price of $1.95 per share expiring in April 2009.

(6) Represents options issued outside of the 1998 Plan to purchase 150,000 shares of common stock at an exercise price of $3.02 per share expiring in May 2012; 50,000 options issued under the 1998 Plan to purchase common stock at an exercise price of $1.51 per share, expiring in March 2008; and 50,000 options issued under the 1998 Plan to purchase common stock at an exercise price of $1.65 per share, expiring in February 2009.

(7) Represents 100,000 options issued outside the 1998 Plan to purchase shares of common stock at an exercise price of $1.98 per share, which expire in May 2014.

(8) Represents 100,000 options issued outside of the 1998 Plan, exercisable at $1.51 per share which expire in March 2008 and 50,000 options issued outside of the 1998 Plan, exercisable at $1.95 per share which expire in April 2009.

(9) 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 the options described in footnote 10 below.

(10) Represents 100,000 options issued outside of the 1998 Plan exercisable at $1.51 per share which expire in March 2008 and 50,000 options issued outside of the 1998 Plan exercisable at $1.95 per share which expire in April 2009.

(11) Represents 75,000 options issued under the 1998 Plan, to purchase common stock at an exercise price of $1.65 per share which expire in February 2009 and 75,000 options issued under the 1998 Plan to purchase common stock at an exercise price of $2.04 per share, which expire in May 2013.

(12) Represents 100,000 options issued outside of the 1998 Plan to purchase shares of common stock at an exercise price of $2.15 per share, which expire in June 2008 and 50,000 options issued outside of the 1998 Plan exercisable at $1.95 per share which expire in April 2009.

(13) Represents 100,000 options issued outside of the 1998 Plan to purchase shares of common stock at an exercise price of $1.85 per share, which expire in February 2009 and 50,000 options issued outside of the 1998 Plan exercisable at $1.95 per share which expire in April 2009.

(14) Represents 100,000 options issued outside of the 1998 Plan to purchase shares of common stock at an exercise price of $1.65 per share, which expire in September 2008 and 50,000 options issued outside of the 1998 Plan exercisable at $1.95 per share which expire in April 2009.

(15) Represents shares of common stock acquired upon exercise of stock options issued under the 1998 Plan.

(16) Represents 1,050,000 options issued outside of the 1998 Plan to purchase shares of common stock at an exercise price of $0.75 per share expiring in December 2011.

(17) Represents shares of common stock acquired upon exercise of stock options issued under the 1998 Plan.

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 Stockholders; 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 AMEX (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 principals who may resell these shares on the AMEX; 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.

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 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 prospectus.

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

There can be no assurance that the selling securityholders will sell any or all of the securities offered by them hereby.

LEGAL MATTERS

The legality of the common stock to be offered hereby has been passed upon for NovaDel by Ellenoff Grossman & Schole LLP.

EXPERTS

The balance sheet of NovaDel as of July 31, 2003 and the statements of operations, changes in capital deficiency and cash flows for each of the years in the two-year period ended July 31, 2003 incorporated by reference in this registration statement have been audited by Wiss & Company, LLP. These financial statements have been incorporated herein by reference in reliance upon the report of Wiss & Company, LLP, and upon their authority as experts in accounting and auditing.

NO PERSON HAS BEEN AUTHORIZED TO GIVE ANY INFORMATION OR TO MAKE ANY REPRESENTATIONS, OTHER THAN THOSE CONTAINED IN THIS PROSPECTUS, IN CONNECTION WITH THE OFFERING MADE HEREBY, AND, IF GIVEN OR MADE, SUCH INFORMATION OR REPRESENTATION MUST NOT BE RELIED UPON AS HAVING BEEN AUTHORIZED BY THE COMPANY OR ANY OTHER PERSON. NEITHER THE DELIVERY OF THIS PROSPECTUS NOR ANY SALE MADE HEREUNDER SHALL UNDER ANY CIRCUMSTANCES CREATE ANY IMPLICATION THAT THERE HAS BEEN NO CHANGE IN THE AFFAIRS OF THE COMPANY SINCE THE DATE HEREOF. THIS PROSPECTUS DOES NOT CONSTITUTE AN OFFER TO SELL OR A SOLICITATION OF AN OFFER TO BUY ANY SECURITIES OFFERED HEREBY BY ANYONE IN ANY JURISDICTION IN WHICH SUCH OFFER OR SOLICITATION IS NOT AUTHORIZED OR IN WHICH THE PERSON MAKING SUCH OFFER OR SOLICITATION IS NOT QUALIFIED TO DO SO OR TO ANY PERSON TO WHOM IT IS UNLAWFUL TO MAKE SUCH OFFER OR SOLICITATION.

6,950,000 SHARES

NOVADEL PHARMA INC.

COMMON STOCK

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P R O S P E C T U S

JUNE 18, 2004

PART II

INFORMATION REQUIRED IN REGISTRATION STATEMENT

ITEM 3 INCORPORATION OF DOCUMENTS BY REFERENCE

Included in Part I of this registration statement.

ITEM 4 DESCRIPTION OF SECURITIES

The description of the common stock contained in our Registration Statement (File No. 333-112852) on Form SB-2/A filed with the Commission on March 25, 2004 and declared effective by the Commission on March 29, 2004 is hereby incorporated by reference.

ITEM 5 INTERESTS OF NAMED EXPERTS AND COUNSEL

N/A

ITEM 6 INDEMNIFICATION OF DIRECTORS AND OFFICERS

Section 145 of the Delaware General Corporation Law (the "GCL") 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 GCL 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 GCL. Article Tenth provides for indemnification of all persons whom we shall have the power to indemnify pursuant to Section 145 of the GCL.

The effect of the foregoing is to require NovaDel to the extent permitted by law to indemnify the officers and directors of NovaDel for any claim arising against such persons in their official capacities if such person acted in good

faith and in a manner that he reasonably believed to be in or not opposed to the best interests of NovaDel, and, with respect to any criminal action or proceeding, had no reasonable cause to believe his conduct was unlawful. Insofar as indemnification for liabilities arising under the 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 Act and is therefore unenforceable. We currently have liability insurance coverage for our officers and directors.

In addition to such other rights of indemnification as they may have as directors or as members of the committee (the "Committee") administering our 1998 Stock Option Plan (the "Plan"), under the terms of the Plan the members of the Committee shall be indemnified by NovaDel against the reasonable expenses, including attorney's fees, actually and necessarily incurred in connection with the defense of any action, suit or proceeding, or in connection with any appeal therein, to which they or any of them may be a party by reason of any action taken or failure to act under or in connection with the Plans or any option granted thereunder, and against all amounts paid by them in settlement thereof (provided such settlement is approved by independent legal counsel selected by NovaDel) or paid by them in satisfaction of a judgment in any such action, suit or proceeding, except in relation to matters as to which it shall be adjudged in such action, suit or proceeding that such Board member is liable for negligence or misconduct in the performance of his duties.

Insofar as indemnification for liabilities arising under the Act may be permitted to directors, officers or persons controlling NovaDel pursuant to the foregoing provisions, NovaDel has been informed that in the opinion of the Commission such indemnification is against public policy as expressed in the Act and is therefore unenforceable.

ITEM 7 EXEMPTION FROM REGISTRATION CLAIMED

All shares of common stock registered hereunder for reoffer or resale, have been or will be issued upon exercise of options granted pursuant to the Registrant's 1998 Stock Option Plan, and its Non-Plan Executive, Consultant and Director Options. The options are non-transferable and the underlying shares were and will be issued in transactions not involving a public offering. Upon exercise of an option, the optionee is required to execute an undertaking not to resell such shares except pursuant to an effective registration statement or other exemption under the Act, a restrictive legend is placed on the certificates for the shares of common stock purchased and transfer stops are placed against such certificates. Such shares may only be reoffered and sold pursuant to registration under the Act or pursuant to an applicable exemption under the Act. As a result, such offers and sales are exempt from the registration requirements of the Act pursuant to the provisions of Section 4(2) of the Act.

ITEM 8 EXHIBITS

NUMBER	DESCRIPTION
4.1	Registrant's 1998 Stock Option Plan, as amended to date
4.2	Form of Stock Option Agreement for 1998 Stock Option Plan
4.3	Form of Non-Plan Stock Option Agreement

5.1	Opinion of Ellenoff Grossman & Schole LLP
23.1	Consent of Wiss & Company, LLP
23.2	Consent of Ellenoff Grossman & Schole LLP (included in Exhibit 5.1)

ITEM 9: UNDERTAKINGS

The undersigned Registrant hereby undertakes that, for purposes of determining any liability under the Securities Act of 1933, each filing of the Registrant's annual report pursuant to Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the Registration Statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the Registrant pursuant to the foregoing provisions, or otherwise, the Registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer or controlling person of the Registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

SIGNATURES

Pursuant to 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 for filing on Form S-8 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Flemington, New Jersey, on June 18, 2004.

NOVADEL PHARMA INC.

By: /s/ Gary A. Shangold

Name: Gary A. Shangold, M.D.
Title: President and Chief Executive Officer

Pursuant to the requirements of the Securities Act of 1933, this Registration Statement on Form S-8 has been signed by the following persons in the capacities and on the dates indicated.

NAME	TITLE	DATE
/s/ Gary A. Shangold --- Gary A. Shangold, M.D.	President, Chief Executive Officer (Principal Executive Officer) and Director	June 18, 2004

/s/ Donald J. Deitman Donald J. Deitman	Chief Financial Officer (Principal Financial Officer)	June 18, 2004
/s/ Robert F. Schaul Robert F. Schaul	Secretary and Director	June 18, 2004
/s/ William F. Hamilton William F. Hamilton	Director	June 18, 2004
/s/ Lawrence J. Kessel Lawrence J. Kessel	Director	June 18, 2004
/s/ Charles Nemeroff Charles Nemeroff, M.D., Ph.D.	Director	June 18, 2004
/s/ Robert G. Savage Robert G. Savage	Director	June 18, 2004

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