NOVADEL PHARMA INC
Form 424B3
September 15, 2003

Filed Pursuant to Rule 424(b)(3)
Registration No. 333-107122

PROSPECTUS

4,257,242 SHARES OF COMMON STOCK

OF

NOVADEL PHARMA INC.

We are registering up to 4,257,242 shares of our common stock for sale by certain shareholders of our company identified in this prospectus. These shareholders are referred to throughout this prospectus as "selling securityholders."

These individuals who wish to sell their shares of our common stock may offer and sell their shares on a continuous or delayed basis in the future. These sales may be conducted in the open market or in privately negotiated transactions and at market prices, fixed prices or negotiated prices. We will not receive any of the proceeds from the sale of the shares owned by the selling securityholders but will receive funds from the exercise of their warrants. Such proceeds will be used for working capital and general corporate purposes.

Our common stock is traded on the OTC Electronic Bulletin Board under the symbol "NVDL.OB". On September 9, 2003, the closing sales price for the common stock on the OTC Electronic Bulletin Board was $1.85 per share.

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

Our common stock being offered by this prospectus involves a high degree of risk. You should read the "Risk Factors" section beginning on page 7 before you decide to purchase any common stock.

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Neither the Securities and Exchange Commission nor any state commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Nor have they made, nor will they make, any determination as to whether anyone should buy these securities. Any representation to the contrary is a criminal offense.

The date of this Prospectus is September 11, 2003

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



PROSPECTUS SUMMARY

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

OUR COMPANY

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

system as Immediate-Immediate Release (I2RTM) because our delivery system is designed to provide therapeutic benefits within minutes of administration. Our development efforts for our novel drug delivery system are concentrated on drugs which are already available and proven in the marketplace. In addition to increasing bioavailability by avoiding metabolism by the liver before entry into the bloodstream, we believe that our proprietary delivery system offers the following significant advantages: (i) improved drug safety profile by reducing the required dosage, including possible reduction of side-effects; (ii) improved dosage reliability; (iii) allowing medication to be taken without water; and (iv) improved patient convenience and compliance.

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

At its inception in 1982, Novadel, then known as Pharmaconsult, was a consultant to the pharmaceutical industry, focusing on product development activities of various European pharmaceutical companies. Since 1992 NovaDel has used its consulting revenues to fund its own product development activities. Our focus on developing our own products evolved naturally out of our consulting experience for other pharmaceutical companies. Substantially all of our revenues previously were derived from our consulting activities. Consulting activities are no longer a material part of our business. In 1991, we changed our name to Flemington Pharmaceutical Corporation. Effective October 1, 2002, we changed our name to NovaDel Pharma Inc. Our principal business address is 25 Minneakoning Road, Flemington, New Jersey, 08822, and our telephone number is (908) 782-3431.

RECENT PRIVATE OFFERING

In April and May 2003, we sold Units (consisting of common stock and warrants) to accredited investors. Investors were issued one warrant for each four shares purchased. The warrants are exercisable for five years, at an exercise price of $2.00 per share. The securities were sold through Paramount Capital, Inc., a NASD broker- dealer. The gross proceeds of the private offering were approximately $4.8 million. For its services as placement agent, we paid Paramount a 7.5% commission fee of the aggregate amount raised (approximately $360,000) and also issued to Paramount warrants to purchase 160,017 shares of common stock at an exercise price of $1.65 and 40,004 shares of common stock at



an exercise price of $2.00. In connection with the offering, we agreed to file a registration statement with the Securities and Exchange Commission to register the resale of the shares of common stock and the shares underlying the warrants (as well as the shares underlying Paramount's warrants). We also agreed that if, at any time following the closing of the offering and continuing for a period of two (2) years thereafter, we offer shares of our common stock for sale in a capital raising transaction, we will permit the investors to purchase such number of shares of common stock to maintain their pro rata ownership percentages of NovaDel. We also agreed that if, at any time following the closing of the offering for a period of one year, we sold shares of common stock

in a capital raising transaction (of at least $1 million) at a per share price less than $1.50, we will issue to the investors additional shares of common stock (so that they would receive their original shares at such lower price).



THE OFFERING

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|---|---|
| Shares outstanding before offering/1/..... | 17,968,389 shares of common stoc |
| Shares outstanding offered by selling securityholders | 3,257,126 shares of common stock |
| Shares underlying warrants offered by selling securityholders | 1,000,116 shares of common stock |
| Plan of distribution..... | The offering of our shares of co is being made by shareholders of company who wish to sell their s Sales of our common stock may be the selling securityholders in t market or in privately negotiate transactions and at market price prices or negotiated prices. |
| Use of proceeds..... | We will not receive any of the p from the sale of the shares owne selling securityholders. However will receive funds from the exer warrants, if warrants are exerci cash. Such funds, if any, will b for working capital and general corporate purposes. |

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/1/ As of June 30, 2003.

SELECTED FINANCIAL DATA

The following selected financial data is qualified by reference to, and should be read in conjunction with, "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this Prospectus. The financial information set forth below is audited with respect to the annual period ended July 31, 2002 and unaudited for the nine month period ended April 30, 2003, and has been prepared by our management.

| | 9 Mos. Ended Apr. 30 | Years Ende July 31 |
|---|---|---|
| | 2003 | 2002 |
| SUMMARY OPERATING DATA | | |
| Consulting Revenues. . . . . | $-0- | $339,000 |
| Interest Income . . . . . | 40,000 | 44,000 |
| Total Revenues . . . . . | 40,000 | 383,000 |
| Expenses . . . . . | 4,478,000 | 4,791,000 |
| Net Loss Before Taxes. . . . . | (4,438,000) | (4,378,000) |
| Deferred Income Tax Benefit . . . . . | 84,000 | 88,000 |
| Net Loss. . . . . | (4,354,000) | (4,290,000) |
| Net Loss Per Common Share . . . . . | $(.30) | $(.38) |
| BALANCE DATA SHEET | | |
| Working Capital . . . . . | 1,980,000 | 3,095,000 |
| Total Assets . . . . . | 3,642,000 | 3,839,000 |
| Total Liabilities . . . . . | 747,000 | 316,000 |
| Shareholders' equity. . . . . | 2,895,000 | 3,523,000 |

SAFE HARBOR STATEMENTS UNDER THE PRIVATE SECURITIES LITIGATION REFORM ACT OF 1995

This prospectus includes "forward-looking statements" as that term is defined in the Private Securities Litigation Reform Act of 1995. The safe harbor provisions of the Securities Exchange Act of 1934 and the Securities Act of 1933 apply to forward-looking statements made by us. These statements can be identified by the use of forward-looking terminology such as "believes," "expects," "may," "will," "should," "plans," "future," "intends," "continue," "estimate" or "anticipates" or the negatives or variations of these terms, and other comparable terminology. In addition, any statements discussing strategy that involve risks and uncertainties are forward-looking.

Forward-looking statements involve risks and uncertainties, including those risks and uncertainties identified in the section of this prospectus beginning on page 7 titled "Risk Factors" and those risks and uncertainties identified elsewhere in, or incorporated by reference into, this prospectus. Due to these risks and uncertainties, the actual results that we achieve may differ materially from these forward-looking statements. These forward-looking



statements are based on current expectations, and we assume no obligation to update this information. In preparing this prospectus, we may have made a number of assumptions and projections about the future of our business. These assumptions and projections could be wrong for several reasons including, but not limited to, those factors identified in the "Risk Factors" section.

You are urged to carefully review and consider the various disclosures that we make in this prospectus, any subsequent prospectus supplement and in our other reports filed with the Commission. These disclosures attempt to advise interested parties of the risk factors that may affect our business and the market price of our shares of common stock.

## RISK FACTORS

You 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 and results of operations and could result in a complete loss of your investment. The risks and uncertainties described below are not the only ones we may face.

WE HAVE A HISTORY OF LOSSES AND OUR AUDITORS HAVE QUALIFIED THEIR AUDIT OPINION WITH REGARD TO OUR ABILITY TO CONTINUE AS A GOING CONCERN

We had an accumulated deficit at April 30, 2003 of approximately $14,167,000. We incurred operating losses in all of the last seven fiscal years ended July 31 including a net loss of approximately $4,290,000 for the year ended July 31, 2002 and $4,354,000 for the nine month period ended April 30, 2003. Because we increased our product development activities, we anticipate that we will incur substantial operating expenses in connection with continued development, testing and approval of our proposed products, and expect these expenses will result in continuing and, perhaps, significant operating losses until such time, if ever, that we are able to achieve adequate product sales levels. Because our rate of expenses is high, and our very limited resources, our auditors have qualified their audit opinion with regard to our ability to

continue as a going concern.

WE WILL REQUIRE SIGNIFICANT CAPITAL REQUIREMENTS FOR PRODUCT DEVELOPMENT AND COMMERCIALIZATION

We have significant capital requirements necessary to fund planned expenditures in connection with the research, development, testing and approval of our proposed products. We anticipate, based on our current proposed plans and assumptions relating to our operations (including the timetable of, and costs associated with, new product development), that the proceeds of our recent private placements and projected cash flow from operations will be sufficient to satisfy our contemplated cash requirements for the remainder of the calendar year 2003. Due to our small revenue base, low level of working capital and inability to increase the number of development agreements with pharmaceutical companies, we have been unable to aggressively pursue our product development strategy. We will require significant additional financing and/or a strategic alliance with a well-funded development partner to aggressively pursue our business plan. We have no current arrangements with respect to, or sources of, additional financing, and there can be no assurance that additional financing will be available to us on acceptable terms, if at all. Unless we raise additional financing or significantly reduce our expenses, we will not have sufficient funds and we will not be to complete development and commercialization of our proposed products or continue operating. See "Management's Discussion and Analysis of Financial Condition and Results of Operations."



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

Revenue received from our product development consists of payments by pharmaceutical companies for research and bioavailability studies, pilot clinical trials, and similar milestone-related payments. Our future growth and profitability will be dependent upon our ability successfully to raise additional funds to complete the development of, obtain regulatory approvals for, and license out or market, our proposed products. Accordingly, our prospects must be considered in light of the risks, expenses and difficulties frequently encountered in connection with the establishment of a new business in a highly competitive industry, characterized by frequent new product introductions. We anticipate that we will incur substantial operating expenses in connection with the development, testing and approval of our proposed products and expect these expenses to result in continuing and, perhaps, significant operating losses until such time, if ever, that we are able to achieve adequate levels of sales or license revenues. There can be no assurance that we will be able to raise additional financing, increase revenues significantly, or achieve profitable operations.

WE DO NOT HAVE COMMERCIALLY AVAILABLE PRODUCTS

Our principal efforts are the development of, and obtaining regulatory approvals for, our proposed products. We anticipate that marketing activities for our proprietary products, whether by us or one or more licensees, will not begin until 2004 at the earliest. Accordingly, it is not anticipated that we will generate any revenues from royalties or sales of proprietary products until regulatory approvals are obtained and marketing activities begin. There can be no assurance that any of the proposed proprietary products will prove to be commercially viable, or if viable, that they will reach the marketplace on the timetables desired by us. The failure or the delay of these products to achieve commercial viability would have a material adverse effect on us. See "Business -

Proposed Products" and " - Government Regulation."

WE HAVE NOT COMPLETED PRODUCT DEVELOPMENT

The development of our proposed products has not been completed and we will be required to devote considerable effort and expenditures to complete such development. In addition to obtaining adequate financing, satisfactory completion of development, testing, government approval and sufficient production levels of such products must be obtained before the proposed products will become available for commercial sale. We do not anticipate generating material revenue from product sales until perhaps 2004 or thereafter. Other potential products remain in the conceptual or very early development stage and remain subject to all the risks inherent in the development of pharmaceutical products, including unanticipated development problems, and possible lack of funds to undertake or continue development. These factors could result in abandonment or substantial change in the development of a specific formulated product. There can be no assurance that any of our proposed products will be successfully developed, be developed on a timely basis or be commercially accepted once developed. The inability to successfully complete development, or a determination by us, for financial or other reasons, not to undertake to complete development of any product, particularly in instances in which we have made significant capital expenditures, could have a material adverse effect on us.

WE DO NOT HAVE DIRECT CONSUMER MARKETING EXPERIENCE

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



can be no assurance that we will do so in the future or that any such products can be successfully marketed. Our strategy to rely on third party marketing arrangements could adversely affect our profit margins. See "Business - Marketing and Distribution."

WE MUST COMPLY WITH GOOD MANUFACTURING PRACTICES

The manufacture of our pharmaceutical products will be subject to current Good Manufacturing Practices ("cGMP") prescribed by the FDA, pre-approval inspections by the FDA or foreign authorities, or both, before commercial manufacture of any such products and periodic cGMP compliance inspections thereafter by the FDA. There can be no assurance that we or any third party manufacturer will be able to comply with cGMP or satisfy pre- or post-approval inspections in connection with the manufacture of our proposed products. Failure or delay by us or any such manufacturer to comply with cGMP or satisfy pre- or post-approval inspections would have a material adverse effect on us. See "Business-- Manufacturing."

WE ARE DEPENDENT ON OUR SUPPLIERS

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

We believe that certain raw materials, including inactive ingredients, are available from a limited number of suppliers and that certain packaging materials intended for use in connection with our spray products currently are available only from sole source suppliers. Although we do not believe we will encounter difficulties in obtaining the inactive ingredients or packaging materials necessary for the manufacture of our products, there can be no assurance that we will be able to enter into satisfactory agreements or arrangements for the purchase of commercial quantities of such materials. We have a written supply agreement with Dynamit Nobel for certain raw materials for the nitroglycerin lingual spray product. With respect to other suppliers, we operate primarily on a purchase order basis beyond which there is no contract memorializing our purchasing arrangements. The inability to enter into agreements or otherwise arrange for adequate or timely supplies of principal raw materials and the possible inability to secure alternative sources of raw material supplies could have a material adverse effect on our ability to arrange for the manufacture of formulated products. In addition, development and regulatory approval of our products are dependent upon our ability to procure active ingredients and certain packaging materials from FDA-approved sources. Since the FDA approval process requires manufacturers to specify their proposed suppliers of active ingredients and certain packaging materials in their applications, FDA approval of a supplemental application to use a new supplier would be required if active ingredients or such packaging materials were no longer available from the originally specified supplier, which could result in manufacturing delays. See "- Business- Raw Materials and Suppliers."

WE FACE INTENSE COMPETITION

The markets which we intend to enter are characterized by intense competition. We or our licensees may be competing against established pharmaceutical companies which currently market products which are equivalent or functionally similar to those we intend to market. Prices of drug products are significantly affected by competitive factors and tend to decline as competition increases. In addition, numerous companies are developing or may, in the future, engage in the development of products competitive with our proposed products. We expect that technological developments will occur at a rapid rate and that competition is likely to intensify as enhanced dosage from technologies gain greater acceptance. Additionally, the markets for formulated products which we have targeted for development are intensely competitive, involving numerous competitors and products. Most of our prospective competitors possess



substantially greater financial, technical and other resources than we do. Moreover, many of these companies possess greater marketing capabilities than we do, including the resources necessary to enable them to implement extensive advertising campaigns. There can be no assurance that we will have the ability to compete successfully. See "Business - Competition."

THE ABSENCE OF PRODUCT LIABILITY INSURANCE COVERAGE MAY AFFECT OUR BUSINESS

We may be exposed to potential product liability claims by consumers. We presently maintain no product liability insurance coverage. Although we will seek to obtain product liability insurance before the commercialization of any proprietary products, there can be no assurance that we will be able to obtain such insurance or, if obtained, that any such insurance will be sufficient to cover all possible liabilities to which we may be exposed. In the event of a successful suit against us, insufficiency of insurance coverage could have a material adverse effect on us. In addition, certain food and drug retailers require minimum product liability insurance coverage as a condition precedent to

purchasing or accepting products for retail distribution. Failure to satisfy such insurance requirements could impede the ability of us or our distributors to achieve broad retail distribution of our proposed products, which could have a material adverse effect on us. See "Business - Product Liability."

EXTENSIVE GOVERNMENT REGULATION MAY AFFECT OUR BUSINESS

The development, manufacture and commercialization of pharmaceutical products are generally subject to extensive regulation by various federal and state governmental entities. The FDA, which is the principal United States regulatory authority, has the power to seize adulterated or misbranded products and unapproved new drugs, to request their recall from the market, to enjoin further manufacture or sale, to publicize certain facts concerning a product and to initiate criminal proceedings. As a result of federal statutes and FDA regulations, pursuant to which new pharmaceuticals are required to undergo extensive and rigorous testing, obtaining pre-market regulatory approval requires extensive time and expenditures. Under the "FDC Act", a new drug may not be commercialized or otherwise distributed in the United States without the prior approval of the FDA. The FDA approval processes relating to new drugs differ, depending on the nature of the particular drug for which approval is sought. With respect to any drug product with active ingredients not previously approved by the FDA, a prospective drug manufacturer is required to submit a new drug application ("NDA"), including complete reports of pre-clinical, clinical and laboratory studies to prove such product's safety and efficacy. The NDA process generally requires, before the submission of the NDA, submission of an IND pursuant to which permission is sought to begin preliminary clinical testing of the new drug. An NDA, based on published safety and efficacy studies conducted by others, may also be required to be submitted for a drug product with a previously approved active ingredient if the method of delivery, strength or dosage form is changed. Alternatively, a drug having the same active ingredient as a drug previously approved by the FDA may be eligible to be submitted under an ANDA, which is significantly less stringent than the NDA approval process. While the ANDA process requires a manufacturer to establish bioequivalence to the previously approved drug, it permits the manufacturer to rely on the safety and efficacy studies contained in the NDA for the previously approved drug. We believe that products developed in spray dosage form will require submission of an NDA. We estimate that the development of new formulations of pharmaceutical products, including formulation, testing and obtaining FDA approval, generally takes four to seven years for the NDA process. There can be no assurance that our determinations will prove to be accurate or that pre-marketing approval relating to our proposed products will be obtained on a timely basis, or at all. The failure by us to obtain necessary regulatory approvals, whether on a timely basis, or at all, would have a material adverse effect on our business.



WE MAY NOT BE ABLE TO PROTECT AND ENFORCE OUR INTELLECTUAL PROPERTY RIGHTS.

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

We rely on a combination of patents, trademarks, trade secrets, confidentiality agreements and licensing arrangements to establish and protect

our proprietary technology. Employees, consultants and customers have access to our proprietary and confidential information. Any misuse or misappropriation of this intellectual property could have an adverse impact on our business. We take steps to control access to, and the distribution of, our proprietary information. We cannot guarantee, however, that such safeguards will protect our intellectual property and other valuable competitive information. If we fail to successfully enforce our intellectual property rights, our competitive position will suffer.

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

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

WE ARE DEPENDENT ON EXISTING MANAGEMENT

Our success is substantially dependent on the efforts and abilities of our President and Chief Executive Officer, Gary A. Shangold, MD, our founder and Chief Scientific Officer, Harry A. Dugger, III, Ph.D., our Chairman, John Klein, our Chief Financial Officer, Donald Deitman, our Vice President - Formulation Development, Mohammed Abd El-Shafy, Ph.D., and our Vice President-New Business and Product Development, Barry Cohen. Mr. Klein is not required to devote full time to us. Decisions concerning our business and our management are and will continue to be made or significantly influenced by these individuals. The loss or interruption of their continued services would have a materially adverse effect on our business operations and prospects.

WE ARE CONTROLLED BY CURRENT STOCKHOLDERS, OFFICERS AND DIRECTORS

Our directors, executive officers and principal stockholders and certain of our affiliates have the ability to influence the election of our directors and most other stockholder actions. Management and our affiliates currently beneficially own (including shares they have the right to acquire) approximately 78% of our common stock. Specifically, Dr. Rosenwald has the ability to exert significant influence over the election of the Board of Directors and other matters submitted to our stockholders for approval. These arrangements may discourage or prevent any proposed takeover of NovaDel, including transactions in which stockholders might otherwise receive a premium for their shares over the then current market prices. Such stockholders may influence corporate actions, including influencing elections of directors and significant corporate events.



THERE IS A POTENTIAL ADVERSE EFFECT IF WE REDEEM OUR PUBLICLY TRADED WARRANTS

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

exercise price ($5.80), subject to adjustment. Redemption of the warrants could force the holders thereof to exercise the warrants and pay the exercise price at a time when it may be disadvantageous for the holders to do so, to sell the warrants at the then current market price when they might otherwise wish to hold the warrants, or to accept the redemption price, which is likely to be substantially less than the market value of the warrants at the time of redemption. The warrants expire on November 18, 2003.

THE LIMITED PRIOR PUBLIC MARKET AND TRADING MARKET MAY CAUSE POSSIBLE VOLATILITY IN OUR STOCK PRICE

There has only been a limited public market for our securities and there can be no assurance that an active trading market in our securities will be maintained. The OTC Bulletin Board is an unorganized, inter-dealer, over-the-counter market which provides significantly less liquidity than the Nasdaq Stock market, and quotes for stocks included on the OTC Bulletin Board are not listed in the financial sections of newspapers as are those for the Nasdaq Stock Market. In addition, the stock market in recent years has experienced extreme price and volume fluctuations that have particularly affected the market prices of many smaller companies. The trading price of our common stock is expected to be subject to significant fluctuations in response to variations in quarterly operating results, changes in analysts' earnings estimates, announcements of innovations by us or our competitors, general conditions in the industry in which we operate and other factors. These fluctuation, as well as general economic and market conditions, may have a material or adverse effect on the market price of our common stock.

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

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



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

- control of the market for the security by one or a few broker-dealers that are often related to the promoter or issuer;
- manipulation of prices through prearranged matching of purchases and sales and false and misleading press releases;
- "boiler room" practices involving high pressure sales tactics and unrealistic price projections by inexperienced sales persons;
- excessive and undisclosed bid-ask differentials and markups by selling broker-dealers; and
- the wholesale dumping of the same securities by promoters and broker-dealers after prices have been manipulated to a desired level, along with the inevitable collapse of those prices with consequent investor losses.

Our management is aware of the abuses that have occurred historically in the penny stock market. Although we do not expect to be in a position to dictate the behavior of the market or of broker-dealers who participate in the market, management will strive within the confines of practical limitations to prevent the described patterns from being established with respect to our common stock.

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

We are authorized to issue 50,000,000 shares of our common stock. As of June 30, 2003 there were 17,968,389 shares of our common stock issued and outstanding. However, the total number of shares of common stock issued and outstanding does not include the exercise of options or warrants. We have reserved up to 14,360,409 shares of our common stock for issuance upon exercise of stock options and warrants. Of the reserved shares, a total of 2,800,000 shares have been reserved among NovaDel's 1992, 1997 and 1998 Stock Option Plans, of which options to purchase an aggregate of 300,000, 450,000 and 1,152,500 shares have been issued under the respective Plans. Another 3,800,000 shares are reserved for issuance and available for the options granted pursuant to the terms of certain employment agreements. A significant number of such options and warrants contain provisions for cashless exercise.

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

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

stock.



SHARES ELIGIBLE FOR FUTURE SALE MAY ADVERSELY AFFECT THE MARKET

Of the 17,968,389 shares of common stock (as of June 30, 2003) held by our present stockholders, 14,555,349 shares may be available for public sale by means of ordinary brokerage transactions in the open market pursuant to Rule 144, promulgated under the Act, subject to certain limitations. In general, under Rule 144, a person (or persons whose shares are aggregated) who has satisfied a one-year holding period may, under certain circumstances, sell within any three-month period a number of securities which does not exceed the greater of 1% of the then outstanding shares of common stock or the average weekly trading volume of the class during the four calendar weeks prior to such sale. Rule 144 also permits, under certain circumstances, the sale of securities, without any limitation, by a person who is not an affiliate of NovaDel and who has satisfied a two-year holding period. In addition, 3,257,126 shares of our outstanding common stock are being registered for resale by certain selling stockholders.

We have reserved up to 14,360,409 shares of common stock for issuance upon exercise of various stock options and warrants, of which 1,600,000 shares were registered under a Registration Statement on Form S-8 under the Act. Any substantial sale of common stock pursuant to Rule 144 may have an adverse effect on the market price of our securities.

LIMITATION ON DIRECTOR/OFFICER LIABILITY

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

WE HAVE NO HISTORY OF PAYING DIVIDENDS ON OUR COMMON STOCK

We have never paid any cash dividends on our common stock and do not anticipate paying any cash dividends on our common stock in the foreseeable future. We plan to retain any future earnings to finance growth. If we determine that we will pay dividends to the holders of our common stock, there is no assurance or guarantee that such dividends will be paid on a timely basis.

USE OF PROCEEDS

We will not receive any of the proceeds from the sale of the shares owned by the selling securityholders. However, we will receive funds from the exercise of warrants, if warrants are exercised. Some of the warrants contain provisions for cashless exercise. We intend to use all of such proceeds for working capital and general corporate purposes. Pending use of the proceeds, they will be invested in short-term, interest bearing securities or money market funds.

SELLING SECURITYHOLDERS

The following table sets forth the shareholders who are offering their shares for sale under this prospectus, the amount of shares owned by such shareholder prior to this offering, the amount to be offered by such shareholder and the amount to be owned by such shareholders following completion of the offering. The prior-to-offering figures are as of June 30, 2003. All share numbers are based on information that these shareholders supplied to us. This table assumes that each shareholder will sell all of its shares available for sale during the effectiveness of the registration statement that includes this prospectus. Shareholders are not required to sell their shares. Beneficial ownership is determined in accordance with SEC rules and includes voting or investment power with respect to the securities.

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

| NAME | POSITION WITH NOVADEL | NUMBER OF SHARES OWNED PRIOR TO OFFERING | PERCENTAGE OF SHARES OWNED |
|---|---|---|---|
| Mark Berg SEP IRA(1) | None | 250,000 | 1.39% |
| Smithfield Fiduciary, LLC (2) | None | 125,000 | * |
| Isaac R. Dweck (3) | None | 125,000 | * |
| Thomas J. Glennen (4) | None | 166,668 | * |
| Ewa Lipton (5) | None | 20,834 | * |
| Mark Mazzer (6) | None | 21,250 | * |
| Carmine Sanzo (7) | None | 41,668 | * |
| Hillel Weinberger (8) | None | 125,000 | * |
| Trevor Colby IRA (9) | None | 41,668 | * |
| Robert Falk (10) | None | 125,000 | * |
| Kash Family Trust (11) | None | 20,834 | * |
| Eli Levitin (12) | None | 20,834 | * |
| Howard Schain (13) | None | 12,500 | * |
| Edmund & Mary Shea Real Property Trust (14) | None | 125,000 | * |

| | | | |
|---|---|---|---|
| Aaron Wolfson (15) | None | 33,334 | * |
| South Ferry #2, LP (16) | None | 416,668 | 2.31% |
| Cornell Capital Partners, LP (17) | None | 83,334 | * |
| Ivette's Isaac Dabah 2002 Trust (18) | None | 245,834 | 1.36% |
| Leonard Grunstein (19) | None | 20,834 | * |
| The Mataponi Trust (20) | None | 20,834 | * |
| Riverside Contracting, LLC (21) | None | 41,668 | * |
| Ivan Kaufman (22) | None | 83,334 | * |
| Howard Gittis (23) | None | 208,334 | 1.16% |
| Harris R.L. Lydon, Jr. (24) | None | 20,834 | * |
| Bonnie B. Kazam (25) | None | 83,334 | * |
| Keys Foundation (26) | None | 565,568 | 3.13% |
| Burton I. Koffman (27) | None | 20,834 | * |



| NAME | POSITION WITH NOVADEL | NUMBER OF SHARES OWNED PRIOR TO OFFERING | PERCENTAGE OF SHARES OWNED |
|---|---|---|---|
| MHR Capital Partnership, LP (28) | (28) | 833,334 | 4.60% |
| Michael A. Mullen (29) | None | 20,834 | * |
| The Osterweis Revocable Trust (30) | None | 41,668 | * |
| Wolcot Capital, Inc (31) | None | 37,500 | * |
| Dr. Tis Prager (32) | None | 145,168 | * |
| David W. Ruttenberg (33) | None | 20,000 | * |
| Gary. J Strauss (34) | None | 41,668 | * |
| Bruno Widmer (35) | None | 41,668 | * |

| | | | |
|---|---|---|---|
| William Corcoran (36) | None | 1,938 | * |
| Timothy McInerney (37) | None | 23,534 | * |
| Peter M. Kash (38) | None | 52,588 | * |
| Scott Katzmann (39) | None | 34,238 | * |
| Joshua Kazam (40) | None | 49,494 | * |
| Michael Rosenman (41) | None | 8,250 | * |
| David M. Tanen (42) | None | 10,616 | * |
| Stephen C. Rocamboli (43) | None | 10,616 | * |
| John Knox (44) | None | 1,250 | * |
| Basil Christakos (45) | None | 1,250 | * |
| JS & Co. (46) | None | 6,250 | * |
| John Moroney (47) | None | 543,706 | 2.97% |

* Less than one percent (1%).

(1) Includes 50,000 warrants exercisable at $2.00 per share which expire in May, 2008.
(2) Includes 25,000 warrants exercisable at $2.00 per share which expire in May, 2008.
(3) Includes 25,000 warrants exercisable at $2.00 per share which expire in May, 2008.
(4) Includes 33,334 warrants exercisable at $2.00 per share which expire in May, 2008.
(5) Includes 4,167 warrants exercisable at $2.00 per share which expire in May, 2008.
(6) Includes 4,250 warrants exercisable at $2.00 per share which expire in May, 2008.
(7) Includes 8,334 warrants exercisable at $2.00 per share which expire in May, 2008.
(8) Includes 25,000 warrants exercisable at $2.00 per share which expire in May, 2008.
(9) Includes 8,334 warrants exercisable at $2.00 per share which expire in May, 2008.
(10) Includes 25,000 warrants exercisable at $2.00 per share which expire in May, 2008.
(11) Includes 4,167 warrants exercisable at $2.00 per share which expire in May, 2008.
(12) Includes 4,167 warrants exercisable at $2.00 per share which expire in May, 2008.
(13) Includes 2,500 warrants exercisable at $2.00 per share which expire in May, 2008.
(14) Includes 25,000 warrants exercisable at $2.00 per share which expire in May, 2008.
(15) Includes 6,667 warrants exercisable at $2.00 per share which expire in May, 2008.
(16) Includes 83,334 warrants exercisable at $2.00 per share which expire in May, 2008.
(17) Includes 16,667 warrants exercisable at $2.00 per share which expire in April, 2008.
(18) Includes 49,167 warrants exercisable at $2.00 per share which expire in April, 2008.
(19) Includes 4,167 warrants exercisable at $2.00 per share which expire in April, 2008.
(20) Includes 4,167 warrants exercisable at $2.00 per share which expire in April, 2008.
(21) Includes 8,334 warrants exercisable at $2.00 per share which expire in April, 2008.
(22) Includes 16,667 warrants exercisable at $2.00 per share which expire in April, 2008.
(23) Includes 41,667 warrants exercisable at $2.00 per share which expire in April, 2008.

(24) Includes 4,167 warrants exercisable at $2.00 per share which expire in April, 2008.
(25) Includes 16,667 warrants exercisable at $2.00 per share which expire in April, 2008.
(26) Includes 83,334 warrants exercisable at $2.00 per share which expire in April, 2008.
(27) Includes 4,167 warrants exercisable at $2.00 per share which expire in April, 2008.
(28) Includes 166,667 warrants exercisable at $2.00 per share which expire in April, 2008. MH Capital Partnership, L.P. is controlled by Mark H. Rachesky, a director of Novadel.
(29) Includes 4,167 warrants exercisable at $2.00 per share which expire in April, 2008.
(30) Includes 8,334 warrants exercisable at $2.00 per share which expire in April, 2008.
(31) Includes 7,500 warrants exercisable at $2.00 per share which expire in April, 2008.
(32) Includes 8,334 warrants exercisable at $2.00 per share which expire in April, 2008.
(33) Includes 5,000 warrants exercisable at $2.00 per share which expire in April, 2008.
(34) Includes 8,334 warrants exercisable at $2.00 per share which expire in April, 2008.
(35) Includes 8,334 warrants exercisable at $2.00 per share which expire in April, 2008.
(36) Includes 1,550 warrants exercisable at $1.65 per share and 388 warrants exercisable $2.00 per share, which each expire in 2008.
(37) Includes 18,827 warrants exercisable at $1.65 per share and 4,707 warrants exercisabl $2.00 per share, which each expire in 2008.
(38) Includes 42,070 warrants exercisable at $1.65 per share and 10,518 warrants exercisabl $2.00 per share, which each expire in 2008.
(39) Includes 27,390 warrants exercisable at $1.65 per share and 6,848 warrants exercisabl $2.00 per share, which each expire in 2008.
(40) Includes 39,595 warrants exercisable at $1.65 per share and 9,899 warrants exercisabl $2.00 per share, which each expire in 2008.
(41) Includes 6,600 warrants exercisable at $1.65 per share and 1,650 warrants exercisabl $2.00 per share, which each expire in 2008.
(42) Includes 8,493 warrants exercisable at $1.65 per share and 2,123 warrants exercisabl $2.00 per share, which each expire in 2008.
(43) Includes 8,493 warrants exercisable at $1.65 per share and 2,123 warrants exercisabl $2.00 per share, which each expire in 2008.
(44) Includes 1,000 warrants exercisable at $1.65 per share and 250 warrants exercisable $2.00 per share, which each expire in 2008.
(45) Includes 1,000 warrants exercisable at $1.65 per share and 250 warrants exercisable $2.00 per share, which each expire in 2008.
(46) Includes 5,000 warrants exercisable at $1.65 per share and 1,250 warrants exercisabl $2.00 per share, which each expire in 2008.

(47) Includes options to purchase 300,000 shares of common stock (exercisable at $1.84 per share), which expire in November 2007 and options to purchase 37,500 shares of common stock (exercisable at $2.69 per share), which expire in February 2012.

## PLAN OF DISTRIBUTION

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

The common stock offered by this prospectus may be sold from time to time directly by the selling securityholders. Alternatively, the selling securityholders may from time to time offer those shares through underwriters, brokers, dealers, agents or other intermediaries. The selling securityholders as of the date of this prospectus have advised us that at that time 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 securityholders may be effected in one or more transactions that may take place on the OTC Electronic Bulletin Board (including one or more block transaction) through customary brokerage channels, either through brokers acting as agents for the selling securityholders, or through market makers, dealers or underwriters acting as principals who may resell these shares on the OTC Electronic Bulletin Board; 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 securityholders in connection with sales of the common stock.

The selling securityholder 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 in the course of hedging the positions they assume with the selling securityholder. The selling securityholder also may sell shares short and redeliver the shares to close out such short positions. The selling securityholder may enter into option or other transactions with broker-dealers which require the delivery to the broker-dealer of the shares. The broker-dealer may then resell or otherwise transfer such shares pursuant to this prospectus.

The selling securityholders also may lend or pledge the shares to a broker-dealer. The broker-dealer may sell the shares so lent, or upon a default the broker-dealer may sell the pledged shares pursuant to this prospectus. Any securities covered by this prospectus which qualify for sale pursuant to Rule 144 promulgated under the Securities Act may be sold under Rule 144 rather than pursuant to this prospectus. The selling securityholders 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 by the selling securityholders.

Although the common stock covered by this prospectus are not currently being underwritten, the selling securityholders or their underwriters, brokers, dealers or other agents or other intermediaries that may participate with the selling securityholders in any offering or distribution of common stock may be deemed "underwriters" within the meaning of the Securities Act of 1933, as amended (the "Securities Act"), and any profits realized or commissions received by them may be deemed underwriting compensation thereunder.

At the time a particular offer of common stock is made by or on behalf of a selling securityholder, to the extent required under applicable rules of the SEC, we will prepare a prospectus supplement setting forth the number of shares being offered and the terms of the offering, including the name or names of any underwriters, dealers, brokers, agents or other intermediaries, if any, the purchase price paid by any underwriter for securities purchased from the selling securityholders and any discounts, commissions or concessions allowed or reallowed or paid to others, and the proposed selling price to the public.

Under applicable rules and regulations under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), any person engaged in a distribution 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 securityholders 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 securityholders.

In order to comply with certain state securities laws, 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.

All costs, expenses and fees in connection with the registration of the common stock offered hereby will be borne by NovaDel. However, any brokerage or underwriting commissions and similar selling expenses, if any, attributable to the sale of the common stock will be borne by the selling securityholders.

We have agreed to indemnify certain of the selling securityholders against certain liabilities, including liabilities under the Securities Act of 1933, or to contribute to payments to which any of those securityholders may be required to make in respect thereof.



## DIRECTORS, EXECUTIVE OFFICERS, PROMOTERS AND CONTROL PERSONS

### Officers and directors

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

| Name | Age | Position with NovaDel |
|---|---|---|
| Gary A. Shangold, M.D. | 49 | President, Chief Executive Officer and Directo |
| Harry A. Dugger, III, Ph.D. | 66 | Chief Scientific Officer and Director |
| John Klein | 56 | Chairman of the Board |
| Donald Deitman | 60 | Chief Financial Officer |
| Robert F. Schaul, Esq. | 64 | Secretary and Director |
| William F. Hamilton, Ph.D. | 63 | Director |
| Lawrence J. Kessel, M.D., FACP | 49 | Director |
| Robert C. Galler | 42 | Vice President - Corporate Development |
| Mohammed Abd El-Shefy, Ph. D. | 49 | Vice President - Formulation Development |
| Barry Cohen | 40 | Vice President - New Business and Product Deve |
| Mark H. Rachesky, M.D. | 44 | Director |

### Background of Executive Officers and Directors

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

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

JOHN H. KLEIN, Chairman of the Board. Mr. Klein joined NovaDel in February 2002 as a consultant and as Chairman of its Board of Directors. From April 1996 to the present Mr. Klein has been affiliated with a number of enterprises, including True North Capital (Chairman/ Managing Director ), Kindred Healthcare (Director), US Interactive, Inc. (Director), America's Plan (Director and Chairman), Coleman Co., Inc. (Director), Sunbeam Corp. (Director), Bi Logix, Inc. (Director), Strategic Business and Technology Solutions, LLC (Chairman),



Cybear (Director and Chairman) and Image Vision (Director and Vice Chairman). From 1996 to 1998, Mr. Klein was Chairman and CEO of Mim Corp. From 1989 to 1996, he was President, CEO and Director of Zenith Laboratories, Inc., which in 1995 merged into IVAX, Inc., of which Mr. Klein is an Executive Officer and President of its IVAX North American Multi-Source Pharmaceutical Group. Mr. Klein holds BS and MBA degrees from Roosevelt University, Chicago, Illinois.

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

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

and a JD from Harvard University in 1964.

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

LAWRENCE J. KESSEL, M.D., FACP, Director. Dr. Kessel was elected to the Board in March 2003. Dr. Kessel is president of a five physician practice specializing in Internal Medicine and Geriatrics since 1984. He graduated Magna Cum Laude with a B.S. degree from the University of Pittsburgh as an honors major in Biology and subsequently graduated with an MD degree from Temple Medical School. He completed a formal residency in Internal Medicine at Abington Memorial Hospital, and is Board Certified in Internal Medicine with added qualification as a diplomate in Geriatric Medicine. He is an active staff attending and Clinical Instructor at Chestnut Hill Hospital (University of Pennsylvania affiliate) and Roxborough Memorial Hospital in Philadelphia, Pennsylvania. Dr. Kessel is a Board Reviewer for the American Board of Internal Medicine, as well as a Fellow of the American College of Physicians. He also serves on the advisory board of Independence Blue Cross. Dr. Kessel presently serves as a director to Cypress Biosciences, Inc. of San Diego, California, a publicly traded biotechnology company and Dor BioPharma, Inc. of Lake Forest, Illinois, a publicly traded biotechnology company. He previously served on the board of Genta, Inc., a publicly traded biopharmaceutical company. Mr. Kessel is a member of the Board's Audit Committee and Compensation Committee.



ROBERT C. GALLER, Vice President, Corporate Development. Mr. Galler has been an employee of NovaDel since September, 2001. He was also a director from December 2001 to March 2003. From 1992 to the present, Mr. Galler has been the President and Chairman of the Lois Joy Galler Foundation for Hemolytic Uremic Syndrom, a non-profit charity. From 1999 to 2001, Mr. Galler was Vice President, Corporate Development and Director of Select Therapeutics, Inc. From 1994 to 1998 Mr. Galler was a Director and advisor of Synsorb Biotech, Inc. From 1992 to 1994 Mr. Galler was an equity coordinator at Gallers Financial Group, Inc., and from 1984 to 1992 he was Vice President of Investments with Gruntal & Co. Mr. Galler attended Hofstra University, Hempstead, N. Y.

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

BARRY COHEN, Vice President of New Business and Product Development. Mr. Cohen joined Novadel in May 2003. Before joining Novadel, he was Vice President-Business Development at Keryx, and before that held several executive marketing and business development positions at Novartis Consumer Health. Mr.

Cohen holds a BBA in Marketing from Hofstra University and an MBA in Marketing from Pace University.

MARK H. RACHESKY, M.D., Director. Dr. Rachesky joined the Board in June 2003. Dr. Rachesky is the founder and President of MHR Fund Management LLC and affiliates, investment managers of various private investment funds that invest in inefficient market sectors, including special situation equities and distressed investments. Dr. Rachesky is currently on the board of directors of Neose Technologies, Inc. a company developing a drug manufacturing process and proprietary drugs. Dr. Rachesky is a graduate of Stanford University School of Medicine, and Stanford University School of Business. Dr. Rachesky graduated from the University of Pennsylvania with a major in Molecular Aspects of Cancer.

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

Section 16(a) of the Securities Exchange Act of 1934 requires our directors and executive officers, and persons who own more than ten percent (10%) of a registered class of our equity securities, to file with the Securities and Exchange Commission initial reports of ownership and reports of changes in ownership of common stock and other equity securities of NovaDel. Officers, directors and greater than ten percent shareholders are required by SEC regulation to furnish us with copies of all Section 16(a) forms they file.

To our knowledge, based solely upon its review of the copies of such reports furnished to us during the year ended July 31, 2002, all Section 16(a) filing requirements applicable to its officers and directors and greater than ten percent beneficial owners were satisfied.

DIRECTOR COMPENSATION

The Directors of NovaDel are elected annually and serve until the next annual meeting of stockholders and until a successor shall have been duly elected and qualified. Effective February 2002, Directors of NovaDel, who are not employees or consultants, receive for each Board and committee meeting attended fees of $1,000 (telephone meetings are compensated at the rate of $750 per meeting). Such Directors are also reimbursed for expenses incurred in



connection with their attendance at meetings of the Board of Directors. Directors may be removed with or without cause by a vote of the majority of the stockholders then entitled to vote. There were no other arrangements pursuant to which any Director was compensated during fiscal 2002 for any services provided as a Director. Directors who are members of the Compensation and Audit Committees receive $1,000 per committee meeting. The Chairman of each of the Audit and Compensation Committees receives an annual fee of $5,000 for serving as such; other members of the Committees receive an annual fee of $3,000.



SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth information, as of June 30, 2003 with respect to the beneficial ownership of the outstanding shares of our common

stock (17,968,389 as of such date plus, where relevant for particular beneficial owners, shares which such beneficial owner has the right to acquire), by (i) any holder known to us owning more than five percent (5%) of the outstanding shares; (ii) our officers and directors; and (iii) the directors and officers of NovaDel as a group:

| TITLE OF CLASS | NAME AND ADDRESS OR NUMBER IN GROUP(1) | AMOUNT AND NATURE OF BENEFICIAL OWNERSHIP |
|---|---|---|
| Common Stock | Harry A. Dugger, III, Ph.D. | 2,104,003(2) |
| Common Stock | Gary A. Shangold, M.D. | 0(3) |
| Common Stock | John Klein | 666,666(4) |
| Common Stock | Donald Deitman | 0 |
| Common Stock | Robert C. Galler | 700,000(5) |
| Common Stock | Robert F. Schaul, Esq. | 274,286(6) |
| Common Stock | Mohammed Abd El-Shafy | 150,000(7) |
| Common Stock | William F. Hamilton, Ph.D. | 0(8) |
| Common Stock | Lawrence J. Kessel, M.D., FACP | 0(8) |
| Common Stock | Barry Cohen | 0(9) |
| Common Stock | Mark H. Rachesky | 833,334(10) |
| Common Stock | Lindsay Rosenwald | 13,233,334(11) |
| Common Stock | Biomedical Investment Group, LLC | 5,333,334(11)(12) |
| Common Stock | All Executive Officers and Directors as a group (11 persons) | 4,728,289(2)(3)(4)(5)(6)(7)(8)(9)(10) |

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

(2) Includes options to purchase 200,000 shares of common stock (exercisable at $.70 per share) issued under the 1992 Stock Option Plan which expire in July 2006; options to purchase 50,000 shares of common stock (exercisable at $.70 per share) under the 1997 Stock Option Plan which expire in December 2006; options to purchase 95,000 shares of common stock (exercisable at $.70 per share) issued under the 1998 Stock Option Plan which expire in January 2005; options to purchase 300,000 shares of common stock issued outside of the Plans (exercisable at $1.84 per share) which expire November 2007; options to purchase 200,000 shares of common stock issued outside of the Plans (exercisable at $1.30 per share) which expire October 2007; options to purchase 75,000 shares of common stock (exercisable at $1.30 per share) issued under the 1998 Stock Option Plan, which expire in October 2007; 142,000 shares owned by his daughter Christina Dugger; and 142,000 shares owned by his son Andrew Dugger.

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

(4) Represents 666,666 Non-Plan Options exercisable at $2.40 per share. Does not include additional Non-Plan options to purchase 333,334 shares of common stock at an exercise price of $2.40 per share. These additional options vest in February 2004. All of the options expire in 2012.

(5) Mr. Galler was granted Non-Plan options to purchase 1,050,000 shares of common stock, at an exercise price of $0.75 per share. 700,000 of these options are vested; the remaining 350,000 options are subject to a condition precedent which has not yet been met. The vested options expire in September 2011.

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

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

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

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

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

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

(12) Includes warrants to purchase 2,666,667 shares of common stock at an

exercise price of $.75 per share which expire in March 2009.

## DESCRIPTION OF SECURITIES

### GENERAL

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



We are authorized to issue up to 50,000,000 shares of common stock, $.001 par value per share, of which 17,968,389 shares were issued and outstanding as of June 30, 2003. Our certificate of incorporation authorizes 1,000,000 shares of "blank check" preferred stock, none of which are outstanding.

### COMMON STOCK

Subject to the rights of holders of preferred stock, if any, holders of shares of our common stock are entitled to share equally on a per share basis in such dividends as may be declared by our Board of Directors out of funds legally available therefore. There are presently no plans to pay dividends with respect to the shares of our common stock. Upon our liquidation, dissolution or winding up, after payment of creditors and the holders of any of our senior securities, including preferred stock, if any, our assets will be divided pro rata on a per share basis among the holders of the shares of our common stock. The common stock is not subject to any liability for further assessments. There are no conversion or redemption privileges nor any sinking fund provisions with respect to the common stock and the common stock is not subject to call. The holders of common stock do not have any pre-emptive or other subscription rights.

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

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

### PREFERRED STOCK

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

### WARRANTS

As of June 30, 2003, we had 9,034,835 warrants outstanding as follows: 680,000 publicly traded warrants exercisable at $5.80 per share; 200,000 warrants exercisable at $1.00 per share; 60,000 warrants exercisable at $2.00 per share; 840,099 warrants exercisable at $2.00 per share; 160,017 warrants exercisable at $1.65 per share; and the balance at $.75 per share. All of such warrants, except the publicly traded warrants and the warrants issued to the investors in the 2003 private placement, contain provisions for cashless exercise.

The exercise price of the warrants and the number of shares issuable upon exercise of the warrants are subject to adjustment to protect against dilution in certain events such as stock splits, combinations, subdivisions and reclassifications.



PUBLICLY TRADED CLASS A WARRANTS

The following statements are summaries of the Warrant Agreement (defined below) and are qualified in their entirety by reference to the Warrant Agreement, which is incorporated herein in its entirety by reference.

In connection with our initial public offering, 680,000 of our publicly traded warrants were issued pursuant to a warrant agreement (the "Warrant Agreement") between NovaDel and American Stock Transfer and Trust Company, as Warrant Agent, and are evidenced by warrant certificates in registered form.

Each warrant entitles the holder to purchase one share of common stock at an exercise price, subject to adjustment, of $5.80 at any time during the period ending at 5:00 P.M., New York City time, on November 18, 2003 (the "Expiration Date"), unless previously redeemed.

The warrants are subject to redemption by NovaDel upon 30 days written notice at $.10 per Warrant, if the last sale price of the common stock has been at least 200% of the current warrant exercise price, subject to adjustment, for at least twenty consecutive trading days ending within three days prior to the date on which notice of redemption is given. The right to purchase common stock will be forfeited unless exercised before the date of notice.

The exercise price of the warrants and the number of shares issuable upon exercise of the warrants are subject to adjustment to protect against dilution in certain events such as stock splits, combinations, subdivisions and reclassifications.

Warrants may be exercised upon surrender of the warrant certificate on or prior to the Expiration Date (or earlier redemption date) at the office of American Stock Transfer & Trust Company, the Warrant Agent, with the Subscription Form on the reverse side of the warrant certificate completed and executed as indicated, accompanied by payment of the full exercise price (by certified or bank check payable to the order of NovaDel) for the number of shares with respect to which the warrants are being exercised. Shares issued upon exercise of warrants and payment in accordance with the terms of the warrants will be fully paid and non-assessable.

The warrants do not confer upon the warrant holder any voting or other rights of a stockholder of NovaDel. Upon notice to the warrant holders, NovaDel has the right to reduce the exercise price or extend the Expiration Date of the warrants.

Upon the exercise of the warrants, NovaDel may pay NASD members a fee of 5% of the aggregate exercise price if (i) the market price of our common stock on the date the warrant is exercised is greater than the then exercise price of the warrants; (ii) the exercise of the warrant was solicited by a member of NASD and the customer states in writing that the transaction was solicited and designates in writing the broker-dealer to receive compensation for the exercise; (iii) the warrant is not held in a discretionary account; (iv) disclosure of compensation arrangements were made both at the time of the offering and at the time of exercise of the warrants; and (v) the solicitation of exercise of the warrant was not in violation of Regulation M promulgated under the Exchange Act.

LIMITATION ON LIABILITY OF DIRECTORS

Our certificate of incorporation provides that a director of NovaDel will not be personally liable to NovaDel or its stockholders for monetary damages for breach of the fiduciary duty of care as a director, including breaches which constitute gross negligence. By its terms and in accordance with the Delaware General Corporation Law, however, this provision does not eliminate or limit the liability of a director of NovaDel (i) for breach of the director's duty of loyalty to NovaDel or its stockholders, (ii) for acts or omissions not



in good faith or which involve international misconduct or a knowing violation of law, (iii) under Section 174 of the Delaware General Corporation Law (relating to unlawful payments or dividends or unlawful stock repurchases or redemptions)or (iv) for any improper benefit.

DIVIDEND POLICY

We have not paid any dividends on our common stock since our inception and do not intend to pay dividends on our common stock in the foreseeable future. Any earnings which we may realize in the foreseeable future will be retained to finance the growth of NovaDel.

SHARES ELIGIBLE FOR FUTURE RESALE

Of the 17,968,389 shares of common stock held by our present stockholders, 14,555,349 shares may be available for public sale by means of ordinary brokerage transactions in the open market pursuant to Rule 144, promulgated under the Act, subject to certain limitations. In general, under Rule 144, a person (or persons whose shares are aggregated) who has satisfied a one-year holding period may, under certain circumstances, sell within any three-month period a number of securities which does not exceed the greater of 1% of the then outstanding shares of common stock or the average weekly trading volume of the class during the four calendar weeks prior to such sale. Rule 144 also permits, under certain circumstances, the sale of securities, without any limitation, by a person who is not an affiliate of NovaDel and who has satisfied a two-year holding period. In addition, 3,257,126 shares of our outstanding common stock have been registered for resale hereunder by the selling securityholders.

TRANSFER AGENT AND REGISTRAR

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

DISCLOSURE OF COMMISSION POSITION ON INDEMNIFICATION FOR SECURITIES ACT LIABILITIES

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

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 Securities Act may be permitted to directors, officers or persons controlling NovaDel pursuant to the foregoing provisions, we have been informed that in the opinion of the Commission, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.



## OUR BUSINESS

SUMMARY

NovaDel (formerly known as Flemington Pharmaceutical Corporation), is engaged in the development of novel application drug delivery systems for presently marketed prescription and over-the-counter ("OTC") drugs. Our (both patented and patent-pending) delivery systems are lingual sprays, enabling drug absorption through the oral mucosa and more rapid absorption into the bloodstream than presently available oral delivery systems. Our proprietary delivery system enhances and greatly accelerates the onset of the therapeutic benefits which the drugs are intended to produce. We refer to our delivery system as Immediate-Immediate Release (I2RTM) because our delivery system is designed to provide therapeutic benefits within minutes of administration. Our development efforts for our novel drug delivery system are concentrated on drugs which are already available and proven in the marketplace. In addition to increasing bioavailability by avoiding metabolism by the liver before entry into the bloodstream, we believe that our proprietary delivery system offers the following significant advantages: (i) improved drug safety profile by reducing the required dosage, including possible reduction of side-effects; (ii) improved dosage reliability; (iii) allowing medication to be taken without water; and (iv) improved patient convenience and compliance.

In light of the material expense and delays associated with independently developing and obtaining approval of pharmaceutical products, we will seek to develop such products through collaborative arrangements with major

pharmaceutical companies, which will fund that development. Due to our small revenue base, low level of working capital and the inability to conclude development agreements with major pharmaceutical companies, we have been unable aggressively to pursue our product development strategy. We will require significant additional financing and/or a strategic alliance with a well-funded development partner to undertake our business plan. See "Management Discussion and Analysis."

At its inception in 1982, Novadel, then known as Pharmaconsult, was a consultant to the pharmaceutical industry, focusing on product development activities of various European pharmaceutical companies. Since 1992 NovaDel has used its consulting revenues to fund its own product development activities. Our focus on developing our own products evolved naturally out of our consulting experience for other pharmaceutical companies. Substantially all of our revenues previously were derived from our consulting activities. Consulting activities are no longer a material part of our business. In 1991, we changed our name to Flemington Pharmaceutical Corporation. Effective October 1, 2002, we changed our name to NovaDel Pharma Inc. Our principal business address is 25 Minneakoning Road, Flemington, New Jersey, 08822, and our telephone number is (908) 782-3431.

PRODUCT DEVELOPMENT

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

CARDIOVASCULAR (NITROGLYCERIN)

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



LORATADINE LINGUAL SPRAY

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

CLEMASTINE LINGUAL SPRAY

The formulation of clemastine lingual spray that was terminated by Novartis in 1998 was revised and a Pre-IND meeting with FDA was held in the third quarter of 2000. Based on the results of that meeting a plan for further

development was prepared and an IND was filed. A pilot nasal challenge efficacy study was initiated in the second quarter of 2000. This study tested the relative response of subjects challenged with allergy producing substances to an OTC tablet (1.34 mg) and a lingual spray dose of 0.68 mg. The antihistamine was administered 15 minutes prior to the challenge. The results showed that the spray had the same antihistaminic effect as the tablet when compared to placebo at 45 minutes after dosing even though the dose was only half that of the tablet. Eight of the parameters measured in the study showed a clear trend that the spray was better than the tablet and the tablet was better than placebo. Even though the study was only a pilot study, the results appear to support the concept that a clemastine lingual spray could be a non-sedating antihistamine product in that there were two cases of drowsiness when the tablet was given and one with the placebo but none when the lingual spray was administered. A pharmacokinetic dose-ranging study has been completed and other pilot studies are planned. NovaDel is seeking a partner to complete development of this product.

ESTRADIOL SPRAYS

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

AGREEMENT WITH MANHATTAN PHARMACEUTICALS

In April 2003, we entered into a license and development agreement with Manhattan Pharmaceuticals, Inc. for the worldwide, exclusive rights to our lingual spray technology to deliver Pro-pofol for pre-procedural sedation. The terms of the agreement call for certain milestones and other payments, the first of which was received during June 2003.

BUSINESS STRATEGY

NovaDel's strategy is to concentrate its product development activities primarily on those pharmaceuticals for which there already are significant prescription and OTC sales, where the use of NovaDel's innovative delivery system will greatly enhance speed of onset of therapeutic effect, reduce side effects through a reduction of the amount of active drug substance required to



produce a given therapeutic effect, and improve patient convenience or compliance.

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

PATENTED AND PATENT PENDING DELIVERY SYSTEMS

NovaDel has certain patents and pending patent applications for its Lingual (Oral) Spray delivery system. FDA approval is not a prerequisite for patent approval. The expected year of marketability of a given product will vary depending upon the specific drug product with which the delivery system will be utilized. Each individual use of the delivery system will require registration with and/or approval by the FDA prior to marketability, and the amount of

regulatory oversight required by the FDA will also depend on the specific type of drug product for which the delivery system is implemented. The following is a description of the oral dosage delivery system for which patent applications are either granted or pending:

LINGUAL (ORAL) SPRAY. NovaDel's aerosol and pump spray formulations release the drug in the form of a fine mist into the mouth for immediate absorption into the bloodstream via the mucosal membranes. NovaDel believes that this delivery system offers certain advantages, including improving the safety profile of certain drugs by lowering the required dosage, improving dose reliability, and allowing medication to be taken without water. Drug absorption through the mucosal membranes of the mouth is rapid and minimizes the first-pass metabolism effect (i.e., total or partial inactivation of a drug as it passes through the gastrointestinal tract and liver).

PROPOSED PRODUCTS

NovaDel's proposed products described below are subjected to laboratory testing and stability studies and tested for therapeutic comparison to the originators' products by qualified laboratories and clinics. To the extent that two drug products with the same active ingredients are substantially identical in terms of their rate and extent of absorption in the human body (bioavailability), they are considered bioequivalent. If the accumulated data demonstrates bioequivalency, submission is then made to the FDA (through the filing of an ANDA) for its review and approval to manufacture and market. If the accumulated data demonstrates that there are differences in the two drugs' rate and extent of absorption into the human body, or if it is intended to make additional or different claims regarding therapeutic effect for the newly developed product, submission is made to the FDA via a NDA for its review and approval under Section 505(b)(1) or Section 505(b)(2) of the FDC Act. An NDA submitted under section 505(b)(2) of the FDC Act is generally less complex than an ordinary NDA. It is NovaDel's expectation that the majority of its products in development will require the filing of these shorter versions of an NDA because the products are known chemical entities, but NovaDel or its licensees will be making new claims as to therapeutic effects or lessened side effects, or both.

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



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

o CARDIOVASCULAR (NITROGLYCERIN)

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

o ANTIHISTAMINE (LORATADINE) LINGUAL SPRAY

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

o ANTIHISTAMINE (CLEMASTINE) LINGUAL SPRAY

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

MARKETING AND DISTRIBUTION

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

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



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

Strategies relating to marketing of NovaDel's other proposed formulated

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

MANUFACTURING

NovaDel has determined to internalize the manufacturing of its proposed products. Presently, NovaDel has established a pilot manufacturing facility at its present location, which it believes is adequate for its needs in manufacturing our requirements for formulation development, stability testing and clinical supplies. It has also leased a new, larger facility which will have adequate space for its future foreseeable requirements for production manufacturing and warehouse space. This new space is presently being prepared for occupancy, the first phase of which began in third quarter of 2003. There can be no assurance, however, that NovaDel will be successful in constructing and maintaining such a manufacturing and warehousing facility in compliance with cGMP. If it is unable to do so, it will become necessary for NovaDel to make arrangements with a third party contract manufacturer to satisfy NovaDel's requirements. There can be no assurance that, if necessary, NovaDel will be able to do so, or be able to do so on commercially satisfactory terms. Failure of NovaDel to complete successfully the internalization of its manufacturing requirements, or to conclude an alternative contract manufacturing arrangement, could have an adverse effect on NovaDel's efforts to obtain regulatory approval for or to commercialize its products.

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

The manufacture of NovaDel's pharmaceutical products will be subject to current Good Manufacturing Processes ("cGMP") prescribed by the FDA, and pre-approval inspections by the FDA and foreign authorities prior to the commercial manufacture of any such products. See "Government Regulation" and "Raw Materials and Suppliers."

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

Accordingly, NovaDel may be subject to various import duties applicable to both finished products and raw materials and may be affected by various other import and export restrictions as well as other developments impacting upon international trade. These international trade factors will, under certain circumstances, have an impact on the manufacturing cost (which will, in turn, have an impact on the cost to NovaDel of the manufactured product). To the extent that transactions relating to the purchase of raw materials involve currencies other than United States dollars (e.g., Swiss francs and Euros), the operating results of NovaDel will be affected by fluctuations in foreign currency exchange rates.

RAW MATERIALS AND SUPPLIERS

NovaDel believes that the active ingredients used in the manufacture of its proposed pharmaceutical products are presently available from numerous suppliers located in the United States, Europe and Japan. Generally, certain raw materials, including inactive ingredients, are available from a limited number of suppliers and certain packaging materials intended for use in connection with NovaDel's lingual spray products may be only available from sole source suppliers. Although NovaDel believes that it will not encounter difficulties in obtaining the inactive ingredients or packaging materials necessary for the manufacture of its products, there can be no assurance that NovaDel will be able to enter into satisfactory agreements or arrangements for the purchase of commercial quantities of such materials. The failure to enter into agreements or otherwise arrange for adequate or timely supplies of principal raw materials and the possible inability to secure alternative sources of raw material supplies could have a material adverse effect on the ability to manufacture formulated products.

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

GOVERNMENT REGULATION

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

Under the Food, Drug and Cosmetic (FDC) Act, a new drug may not be comm