

NOVADEL PHARMA INC  
Form S-3  
May 11, 2006

As filed with the Securities and Exchange Commission on May 11, 2006

Registration Statement No. 333-

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

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**FORM S-3**

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**REGISTRATION STATEMENT  
UNDER THE SECURITIES ACT OF 1933**

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**NovaDel Pharma Inc.**

(Exact name of Registrant as Specified in Its Charter)

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**Delaware**

**2834**

**22-2407152**

(State or other jurisdiction of incorporation or organization)

(Primary Standard Industrial Classification Code)  
25 Minneakoning Road  
Flemington, NJ 08822  
(908) 782-3431

(I.R.S. Employer Identification No.)

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

**Jan H. Egberts, M.D.**

**President, Chief Executive Officer and Chairman of the Board**

**NovaDel Pharma Inc.  
25 Minneakoning Road  
Flemington, NJ 08822  
(908) 782-3431**

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

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

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

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If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933 (the Securities Act ), other than securities offered only in connection with dividend or interest reinvestment plans, check the following box.  x

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

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

If this Form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box.  o

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box.  o

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## CALCULATION OF REGISTRATION FEE

Title of Shares To Be Registered	Amount To Be Registered	Proposed Maximum Aggregate Price Per Share	Proposed Maximum Aggregate Offering Price	Amount Of Registration Fee
Common Stock, \$0.001 par value	10,988,964(1)	\$1.64(2)	\$18,021,901	\$1,930

(1) Includes 2,896,168 shares of common stock that may be issued upon the exercise of warrants held by the selling stockholders. Pursuant to Rule 416 of the Securities Act of 1933, as amended, this registration statement shall also cover any additional shares of common stock by reason of any stock dividend, stock split, recapitalization or other similar transaction or to cover such additional shares as may hereinafter be offered or issued to prevent dilution resulting from stock splits, stock dividends, recapitalizations or certain other capital adjustments, effected without the registrant's receipt of consideration, which results in an increase in the number of the outstanding shares of registrant's common stock.

(2) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(c). Such price is based upon the average of the high and low prices of the registrant's common stock as reported on the American Stock Exchange on May 8, 2006.

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

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

**Subject to Completion, dated May 11, 2006**

**Prospectus**

**10,988,964**

**SHARES OF COMMON STOCK**

This prospectus covers resales by certain of our stockholders of up to 10,988,964 shares of our common stock, par value \$0.001 per share, for their own accounts. Of those shares, 2,896,168 are issuable upon the exercise of warrants held by the stockholders at an exercise prices of \$1.60 per share. Such stockholders are referred to throughout this prospectus as selling security holders.

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

Our common stock is listed for trading on the American Stock Exchange ( AMEX ) under the symbol NVD. On May 8, 2006, the closing sales price for our common stock on the AMEX was \$1.63 per share.

INVESTING IN OUR COMMON STOCK INVOLVES A HIGH DEGREE OF RISK. YOU SHOULD READ THE RISK FACTORS SECTION BEGINNING ON PAGE 6 BEFORE YOU DECIDE TO PURCHASE ANY SHARES OF OUR COMMON STOCK.

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

**The date of this Prospectus is \_\_\_\_\_, 2006**

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## PROSPECTUS SUMMARY

### *About This Prospectus*

This prospectus is a part of a registration statement on Form S-3 filed by us with the Securities and Exchange Commission, referred to herein as the SEC, to register 10,988,964 shares of our common stock. This prospectus does not contain all of the information set forth in the registration statement, certain parts of which are omitted in accordance with the rules and regulations of the SEC. Accordingly, you should refer to the registration statement and its exhibits for further information about us and our common stock. Copies of the registration statement and its exhibits are on file with the SEC. Statements contained in this prospectus concerning the documents we have filed with the SEC are not intended to be comprehensive, and in each instance we refer you to the copy of the actual document filed as an exhibit to the registration statement or otherwise filed with the SEC.

We have not authorized anyone to provide you with information different from that contained or incorporated by reference in this prospectus. The selling stockholders are offering to sell, and seeking offers to buy, shares of our common stock only in jurisdictions where offers and sales are permitted. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or of any sale of common stock.

### *About NovaDel*

NovaDel Pharma Inc., referred to herein as we, us and our, is engaged in the development of novel application drug delivery systems for presently marketed prescription, over-the-counter ( OTC ) and veterinary drugs. Our patented and patent-pending delivery system is an oral spray potentially enabling drug absorption through the oral mucosa and more rapid absorption into the bloodstream than presently available oral delivery systems. We currently have seven patents issued in the United States and eight patents which have been issued outside the United States. Additionally, we have approximately 120 patents pending worldwide. Our proprietary delivery system potentially enhances and greatly accelerates the onset of the therapeutic benefits within minutes of administration. Our development efforts for our proprietary novel drug delivery system are concentrated on making such delivery system available for drugs that are already available and proven in the marketplace. In addition to increasing the bioavailability of a drug by avoiding metabolism by the liver before entry into the bloodstream, we believe that our proprietary drug delivery system potentially offers the following significant advantages: (i) more rapid delivery of drugs to the bloodstream allowing for quicker onset of therapeutic effects compared to conventional oral dosage forms; (ii) improved drug safety profile by reducing the required dosage, including possible reduction of side-effects; (iii) improved dosage reliability; (iv) allowing medication to be taken without water; and (v) improved patient convenience and compliance.

Our strategy is to concentrate our product development activities primarily on pharmaceutical products for which there already are significant prescription sales, where the use of our proprietary novel drug delivery technology will greatly enhance speed of onset of therapeutic effect, reduce side effects through a reduction of the amount of active drug substance required to produce a given therapeutic effect and/or improve patient convenience or compliance.

We are devoting the majority of our internal research and development resources to the following product candidates:

**NitroMist** (nitroglycerin lingual aerosol). This product candidate is indicated for acute relief of an attack or acute prophylaxis of angina pectoris due to coronary artery disease. We have partnered with Par Pharmaceutical Companies, Inc., (Par) who has exclusive rights to market, sell and distribute NitroMist in the United States and Canada.

**Zolpidem oral spray**. Zolpidem is the active ingredient in Ambien®, the leading hypnotic marketed by Sanofi-Aventis.

**Sumatriptan oral spray**. Sumatriptan is the active ingredient in Imitrex® which is the largest selling migraine remedy marketed by GlaxoSmithKline ( GSK ).

**Additional Product Candidates**. We have identified a number of additional product candidates for which we have recently commenced preliminary development activities.

We are also supporting our partners, as necessary, with the following product candidates and opportunities although we are not devoting a significant amount of resources to such activities:

**Zensana** (ondansetron oral spray). Ondansetron is the active ingredient in Zofran®, the leading anti-emetic marketed by GSK. Our partner for this product, Hana Biosciences, is overseeing all clinical development and regulatory approval activities for this product in the United States and Canada.

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Propofol oral spray. Propofol is the active ingredient in Diprivan®, the world's leading intravenous anesthetic marketed by AstraZeneca. Our partner for this product, Manhattan Pharmaceuticals, is overseeing all clinical development and regulatory activities for approval of this product.

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Our veterinary initiatives are being carried out largely by our partner, Velcera Pharmaceuticals, Inc. At our inception in 1982, NovaDel, then known as Pharmaconsult, consulted to the pharmaceutical industry, focusing on product development activities of various European pharmaceutical companies. Since 1992, we have used our consulting revenues to fund our 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.



**THE OFFERING**

Number of shares of our common stock offered by the selling stockholders 10,988,964<sup>(1)</sup> shares

Number of shares of our common stock outstanding after the offering 51,770,791<sup>(2)</sup> shares

Use of proceeds We will not receive any proceeds from the sale of common stock by the selling security holders. We may receive the proceeds from the exercise of warrants held by the selling security holders, if any are exercised. Any such proceeds will be used primarily for increased or additional research and development and general working capital. However, the selling security holders have the right to exercise the warrants pursuant to a cashless exercise provision, in which case, we will not receive any proceeds from the exercise of the warrants from the selling security holders.

American Stock Exchange symbol NVD

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(1) Includes warrants to purchase 2,896,168 shares of common stock.

(2) Based upon 48,874,623 shares of common stock issued and outstanding as of May 1, 2005, after giving effect to the exercise of warrants to purchase up to an aggregate of 2,896,168 shares of common stock, and excluding shares of common stock to be issued upon the exercise of outstanding warrants.

## RISK FACTORS

One should carefully consider the following risk factors and all other information contained in this prospectus before investing in our common stock. Investing in our common stock involves a high degree of risk. Any of the following risks could adversely affect our business, financial condition, results of operations, performance, achievements and industry and could result in a complete loss of one's investment. The risks and uncertainties described below are not the only ones we may face.

### **WE ARE A PRE-COMMERCIALIZATION COMPANY, HAVE A LIMITED OPERATING HISTORY AND HAVE NOT GENERATED ANY REVENUES FROM THE SALE OF PRODUCTS TO DATE.**

We are a pre-commercialization specialty pharmaceutical company. There are many uncertainties and complexities with respect to such companies. We have not generated any revenue from the commercial sale of our proposed products and do not expect to receive such revenue in the near future. We have no material licensing or royalty revenue or products ready for sale or licensing in the marketplace. This limited history may not be adequate to enable one to fully assess our ability to develop our technologies and proposed products, obtain FDA approval and achieve market acceptance of our proposed products and respond to competition.

We cannot be certain as to when to anticipate commercializing and marketing any of our proposed products in development, if at all, and do not expect to generate sufficient revenues from proposed product sales to cover our expenses or achieve profitability in the near future.

We had an accumulated deficit as of January 31, 2006 of approximately \$39.8 million. We incurred losses in each of our last nine fiscal years, including a net loss of approximately \$9.5 million for the fiscal year ended July 31, 2005, and a net loss of \$5.4 million for the six months ended January 31, 2006. Because we increased our product development activities, we anticipate that we will incur substantial operating expenses in connection with continued research and development, clinical trials, testing and approval of our proposed products, and expect these expenses will result in continuing and, perhaps, significant operating losses until such time, if ever, that we are able to achieve adequate product sales levels. Our ability to generate revenue and achieve profitability depends upon our ability, alone or with others, to complete the development of our proposed products, obtain the required regulatory approvals and manufacture, market and sell our proposed products.

### **WE WILL REQUIRE SIGNIFICANT CAPITAL FOR PRODUCT DEVELOPMENT AND COMMERCIALIZATION**

The research, development, testing and approval of our proposed products involve significant expenditures, and, accordingly, we require significant capital to fund such expenditures. Due to our small revenue base, low level of working capital and, until recently, our relative inability to increase the number of development agreements with pharmaceutical companies, we have been unable to pursue aggressively our product development strategy. Until and unless our operations generate significant revenues, we will attempt to continue to fund operations from cash on hand and through the sources of capital described below. Our long-term liquidity is contingent upon achieving sales and/or obtaining additional financing. The most likely sources of financing include private placements of our equity or debt securities or bridge loans from third party lenders. We can give no assurances that any additional capital that we are able to obtain will be sufficient to meet our needs. In our Annual Report on Form 10-KSB for the fiscal year ended July 31, 2005 and our Quarterly Report on Form 10-Q for the quarter ended October 31, 2005 and January 31, 2006, we stated that unless we received additional capital during the fiscal year ended July 31, 2006, we would have to significantly reduce our operating expenses in order to have sufficient cash to fund our operations through the end of fiscal 2006. As of April 19, 2006, we concluded an equity financing in which we received gross proceeds of \$11.7 million. Although we expect to have sufficient cash to fund our operations through the end of fiscal 2007, we would have to significantly reduce the pace of our ongoing development of our priority product candidates unless we can obtain additional working capital. Given the current and desired pace of product development of our priority product candidates, we estimate that we could need to raise additional capital during fiscal year 2007 in order to fully fund our development activities through July 31, 2007. This could include the securing of funds through new partnerships and/or the sale of our common stock or other securities, in order to fund our research and development activities. There can be no assurance that such capital will be available to us on favorable terms or at all. There are a number of risks and uncertainties related to our attempt to complete a financing or strategic partnering arrangement that are outside our control. We may not be able to successfully obtain additional financing on terms acceptable to us, or at all. If we are unsuccessful at obtaining additional financing as needed, we may be required to significantly curtail or cease operations. We will need additional financing thereafter until we achieve profitability, if ever.

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

The additional financings we require may be obtained through one or more transactions which effectively dilute the ownership interests of our stockholders. Further, we may not be able to secure such additional financing on terms acceptable to us, if at all. We have the authority to issue additional shares of common stock, as well as additional classes or series of ownership interests or debt obligations which may be convertible into any one or more classes or series of ownership interests. We are authorized to issue a total of 100,000,000 shares of common stock and 1,000,000 shares of preferred stock. Such securities may be issued without the approval or other consent of our stockholders. See Risk Factors Additional Authorized Shares of Common Stock and Preferred Stock Available for Issuance May Adversely Affect the Market for a description of certain rights of Paramount BioCapital Inc. ( Paramount ) that may negatively impact our ability to raise additional capital.



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

Our strategy is to concentrate our product development activities primarily on pharmaceutical products for which there already are significant prescription sales, where the use of our proprietary, novel drug delivery technology will greatly enhance speed of onset of therapeutic effect, reduce side effects through a reduction of the amount of active drug substance required to produce a given therapeutic effect and improve patient convenience or compliance.

We filed an NDA for our nitroglycerin lingual spray, NitroMist<sup>®</sup>, on June 21, 2004, which was accepted for filing by the FDA on September 29, 2004. We received a Prescription Drug User Fee Act (PDUFA) date of June 4, 2005, for NitroMist<sup>®</sup>, and received an approvable letter from the FDA on June 1, 2005. We believe that the FDA is likely to give final approval of NitroMist<sup>®</sup> once we complete certain manufacturing process validation commitments which we had previously agreed to with the FDA. The FDA is not requiring us to complete any additional clinical studies for approval. Although we currently intend to complete the manufacturing process validation commitments, the FDA may not grant us final marketing approval for NitroMist<sup>®</sup> if we do not timely complete the manufacturing process validation commitments or for other reasons. On June 1, 2005, we received an approvable letter from the FDA regarding its NDA for NitroMist<sup>®</sup>. We are currently planning to complete our process validation commitments in the second calendar quarter of 2006; and, if this timeline is met, we may obtain final approval from the FDA by the end of the second calendar quarter of 2006. NitroMist<sup>®</sup> is a trademark of Par Pharmaceuticals, Inc.

We have initiated and completed pharmacokinetic studies of our priority products during late calendar year 2004 and early calendar year 2005. These products are oral spray formulations of ondansetron, sumatriptan, alprazolam, propofol and zolpidem. The goal of these pilot pharmacokinetic studies is to determine whether or not a specific oral spray can achieve therapeutic blood levels of an active ingredient via administration through the oral mucosa. If blood levels are not achieved, it could result in the need to reformulate the oral spray and/or to terminate work on a specific compound which would have a material adverse effect on our operations.

We have also completed pilot pharmacokinetic studies for two antihistamine oral sprays (loratadine and clemastine), an estradiol oral spray and a progesterone oral spray. In addition, we completed phase 2 clinical trials for the clemastine oral spray. However, additional development work on loratadine, clemastine, estradiol and progesterone has been put on hold due to changes in the marketplace which have significantly reduced the market potential for these compounds.

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

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

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

**THERE ARE CERTAIN INTERLOCKING RELATIONSHIPS AND POTENTIAL CONFLICTS OF INTEREST.**

Lindsay A. Rosenwald, M.D., a significant stockholder, directly and indirectly, of us, is the Chairman and sole shareholder of Paramount BioCapital Inc. In the regular course of its business and the business of its affiliates, and outside of its arrangement with us, Paramount and/or its affiliates identify, evaluate and pursue investment opportunities in biomedical and pharmaceutical products, technologies and companies. Dr. Rosenwald beneficially owns approximately 22% of our outstanding common stock (assuming exercise of certain warrants beneficially owned by Dr. Rosenwald). As such, Dr. Rosenwald and Paramount may be deemed to be our affiliates. Dr. Rosenwald has the ability to designate an individual to serve on our Board of Directors ( Board ) and has exercised such ability by designating Mr. J. Jay Lobell to serve on the Board. On December 14, 2005 based upon the recommendation of the Corporate Governance and Nominating Committee, the Board elected Mr. Lobell as a member of the Board. Pursuant to the listing standards of the AMEX, Mr. Lobell is not deemed to be an independent director. Dr. Rosenwald and Paramount may also be deemed to be affiliates of Manhattan Pharmaceuticals, Velcera Pharmaceuticals and Hana Biosciences. Generally, Delaware corporate law requires that any transactions between us and any of our affiliates be on terms that, when taken as a whole, are substantially as favorable to us as those then reasonably obtainable in an arms length transaction from a person who is not an affiliate. Nevertheless, neither Dr. Rosenwald nor Paramount, nor their affiliates, are obligated pursuant to any agreement or understanding with us to make any additional products or technologies available to us, nor can there be any assurance, and we do not expect and our stockholders should not expect, that any biomedical or pharmaceutical product or technology identified by Dr. Rosenwald nor Paramount, or their affiliates, in the future will be made available to us. In addition, certain of our current officers and directors or any officers or directors hereafter appointed by us may from time to time serve as officers or directors of other biopharmaceutical or biotechnology companies. Such other companies may have interests in conflict with our interests.

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

Revenue received from our product development efforts consists of payments by pharmaceutical companies for research and bioavailability studies, pilot clinical trials and similar milestone-related payments. Our future growth and profitability will be dependent upon our ability successfully to raise additional funds to complete the development of, obtain regulatory approvals for and license out or market our proposed products. Accordingly, our prospects must be considered in light of the risks, expenses and difficulties frequently encountered in connection with the establishment of a new business in a highly competitive industry, characterized by frequent new product introductions. We anticipate that we will incur substantial operating expenses in connection with the development, testing and approval of our proposed products and expect these expenses to result in continuing and significant operating losses until such time, if ever, that we are able to achieve adequate levels of sales or license revenues. We may not be able to raise additional financing, increase revenues significantly, or achieve profitable operations. See Risk Factors - We Will Require Significant Capital For Product Development And Commercialization And - Our Strategy Is To Enter Into Collaboration Agreements With Third Parties And We May Require Additional Collaboration Agreements . If We Fail To Enter Into These Agreements Or If We Or The Third Parties Do Not Perform Under Such Agreements, It Could Impair Our Ability To Commercialize Our Proposed Products .

**WE DO NOT HAVE COMMERCIALY AVAILABLE PRODUCTS.**

Our principal efforts are the development of, and obtaining regulatory approvals for, our proposed products. We anticipate that marketing activities for our proprietary products, whether by us or one or more of our licensees, if any, will not begin until the third calendar quarter of 2006 at the earliest. Accordingly, it is not anticipated that we will generate any revenues from royalties or sales of proprietary products until regulatory approvals are obtained and marketing activities begin. Any one or more of our proposed proprietary products may not prove to be commercially viable, or if viable, may not reach the marketplace on a basis consistent with our desired timetables. The failure or the delay of any one or more of our proposed products to achieve commercial viability would have a material adverse effect on us.

**WE HAVE NOT COMPLETED PRODUCT DEVELOPMENT.**

We have not completed the development of our proposed products and we will be required to devote considerable effort and expenditures to complete such development. In addition to obtaining adequate financing, satisfactory completion of development, testing, government approval and sufficient production levels of such products must be obtained before the proposed products will become available for commercial sale. We do not anticipate generating material revenue from product sales until perhaps in calendar year 2006 or thereafter. Other potential products remain in the conceptual or very early development stage and remain subject to all the risks inherent in the development of pharmaceutical products, including unanticipated development problems and possible lack of funds to undertake or continue development. These factors could result in abandonment or substantial change in the development of a specific formulated product. We may not be able to successfully develop any one or more of our proposed products or develop such proposed products on a timely basis. Further, such proposed products may not be commercially accepted if developed. The inability to successfully complete development, or a determination by us, for financial or other reasons, not to undertake to complete development of any proposed product, particularly in instances in which we have made significant capital expenditures, could have a material adverse effect on our business and operations.

**WE DO NOT HAVE DIRECT CONSUMER MARKETING EXPERIENCE.**

We have no experience in marketing or distribution at the consumer level of our proposed products. Moreover, we do not have the financial or other resources to undertake extensive marketing and advertising activities. Accordingly, we intend generally to rely on marketing arrangements, including possible joint ventures or license or distribution arrangements with third parties. Except for our agreements with Par Pharmaceutical, Manhattan Pharmaceuticals, Velcera Pharmaceuticals and Hana Biosciences, we have not entered into any significant agreements or arrangements with respect to the marketing of our proposed products. We may not be able to enter into any such agreements or similar arrangements in the future and we may not be able to successfully market our products. If we fail to enter into these agreements or if we or the third parties do not perform under such agreements, it could impair our ability to commercialize our products.

We have stated our intention to market our own products in the future, although we have no such experience to date. Substantial investment will be required in order to build infrastructure and provide resources in support of marketing our own products, particularly the establishment of a marketing force. If we do not develop a marketing force of our own, then we will depend on arrangements with corporate partners or other entities for the marketing and sale of our remaining products. The establishment of our own marketing force, or a strategy to rely on third party marketing arrangements, could adversely affect our profit margins.

**WE MUST COMPLY WITH GOOD MANUFACTURING PRACTICES.**

The manufacture of our pharmaceutical products under development will be subject to current Good Manufacturing Practices (cGMP) prescribed by the FDA, pre-approval inspections by the FDA or comparable foreign authorities, or both, before commercial manufacture of any such products and periodic cGMP compliance inspections thereafter by the FDA. We, or any of our third party manufacturers, may not be able to comply with cGMP or satisfy pre- or post-approval inspections by the FDA or comparable foreign authorities in connection with the manufacture of our proposed products. Failure or delay by us or any such manufacturer to comply with cGMP or satisfy pre- or post-approval inspections would have a material adverse effect on our business and operations.

**WE ARE DEPENDENT ON OUR SUPPLIERS.**

We believe that the active ingredients used in the manufacture of our proposed pharmaceutical products are presently available from numerous suppliers located in the United States, Europe, India and Japan. We believe that certain raw materials, including inactive ingredients, are available from a limited number of suppliers and that certain packaging materials intended for use in connection with our spray products currently are available only from sole source suppliers. Although we do not believe we will encounter difficulties in obtaining the inactive ingredients or packaging materials necessary for the manufacture of our proposed products, we may not be able to enter into satisfactory agreements or arrangements for the purchase of commercial quantities of such materials. We have a written supply agreement with Dynamit Nobel for certain raw materials for our nitroglycerin lingual spray and a written supply agreement in place with INyX USA, Ltd., who intends to manufacture our nitroglycerin lingual spray in its Manatee, Puerto Rico facility. With respect to other suppliers, we operate primarily on a purchase order basis beyond which there is no contract memorializing our purchasing arrangements. The inability to enter into agreements or otherwise arrange for adequate or timely supplies of principal raw materials and the possible inability to secure alternative sources of raw material supplies, or the failure of Dynamit Nobel or INyX USA, Ltd. to comply with their supply obligations to us, could have a material adverse effect on our ability to arrange for the manufacture of formulated products. In addition, development and regulatory approval of our products are dependent upon our ability to procure active ingredients and certain packaging materials from FDA-approved sources. Since the FDA approval process requires manufacturers to specify their proposed suppliers of active ingredients and certain packaging materials in their applications, FDA approval of a supplemental application to use a new supplier would be required if active ingredients or such packaging materials were no longer available from the originally specified supplier, which may result in manufacturing delays. If we do not maintain important manufacturing relationships, we may fail to find a replacement manufacturer or to develop our own manufacturing capabilities. If we cannot do so, it could delay or impair our ability to obtain regulatory approval for our products and substantially increase our costs or deplete any profit margins. If we do find replacement manufacturers, we may not be able to enter into agreements with them on terms and conditions favorable to us and, there could be a substantial delay before a new facility could be qualified and registered with the FDA and foreign regulatory authorities.

**OUR INTERNAL CONTROLS AND PROCEDURES HAVE BEEN MATERIALLY DEFICIENT, AND WE ARE BEGINNING THE PROCESS OF CORRECTING INTERNAL CONTROL DEFICIENCIES.**

In October 2004, we and our independent registered public accounting firm recognized that our internal controls had material weaknesses. These material weaknesses led in part to the delay in the production of our audited financial statements for fiscal 2004. We have restated our results of operations for the fiscal years ended July 31, 2003, and July 31, 2002, and for our quarterly results in fiscal years 2004, 2003 and 2002. Our independent registered public accounting firm advised us of material weaknesses noted during its audit of our 2004 financial statements.

If we cannot rectify these material weaknesses through remedial measures and improvements to our systems and procedures, management may encounter difficulties in timely assessing business performance and identifying incipient strategic and oversight issues. In December 2004, we hired a new Chief Financial Officer and in March 2005, we hired a Corporate Controller. We believe that these hirings have improved and will

continue to improve our internal controls, particularly with respect to our need to comply with Section 404 of the Sarbanes-Oxley Act of 2002.

We will apply resources at all relevant managerial levels toward the task of improving our internal control environment. We cannot provide assurances as to the timing of the completion of these efforts or estimates of the prospective costs of these efforts, either in dollar terms or in the form of management attention. We cannot be certain that the measures we take will ensure that we implement and maintain adequate internal controls in the future. Any failure to implement required new or improved controls, or difficulties encountered in their implementation, could harm our operating results or cause us to fail to meet our reporting obligations.

**FAILURE TO ACHIEVE AND MAINTAIN EFFECTIVE INTERNAL CONTROLS IN ACCORDANCE WITH SECTION 404 OF THE SARBANES-OXLEY ACT COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS AND OPERATING RESULTS. IN ADDITION, CURRENT AND POTENTIAL STOCKHOLDERS COULD LOSE CONFIDENCE IN OUR FINANCIAL REPORTING, WHICH COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR STOCK PRICE.**

Effective internal controls are necessary for us to provide reliable financial reports and effectively prevent fraud. If we cannot provide reliable financial reports or prevent fraud, our operating results could be harmed.

We will be required to document and test our internal control procedures in order to satisfy the requirements of Section 404 of the Sarbanes-Oxley Act, which requires annual management assessments of the effectiveness of our internal controls over financial reporting and a report by our independent registered public accounting firm addressing these assessments. During the course of our testing we may identify deficiencies which we may not be able to remediate in time to meet the deadline imposed by the Sarbanes-Oxley Act for compliance with the requirements of Section 404. In addition, if we fail to maintain the adequacy of our internal controls, as such standards are modified, supplemented or amended from time to time, we may not be able to ensure that we can conclude on an ongoing basis that we have effective internal controls over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act. Failure to achieve and maintain an effective internal control environment could also cause investors to lose confidence in our reported financial information, which could have a material adverse effect on the stock price of our common stock.

**COMPLIANCE WITH CHANGING REGULATION OF CORPORATE GOVERNANCE AND PUBLIC DISCLOSURE MAY RESULT IN ADDITIONAL EXPENSES.**

Changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002, new regulations promulgated by the Securities and Exchange Commission and American Stock Exchange ( AMEX ) rules, are creating uncertainty for companies such as ours. These new or changed laws, regulations and standards are subject to varying interpretations in many cases due to their lack of specificity, and as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies, which could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We are committed to maintaining high standards of corporate governance and public disclosure. As a result, our efforts to comply with evolving laws, regulations and standards have resulted in, and are likely to continue to result in, increased general and administrative expenses and a diversion of management time and attention from revenue-generating activities to compliance activities. In particular, our efforts to comply with Section 404 of the Sarbanes-Oxley Act of 2002 and the related regulations regarding our required assessment of our internal controls over financial reporting and our independent registered public accounting firm's audit of that assessment will require the commitment of significant financial and managerial resources. In addition, it has become more difficult and more expensive for us to obtain director and officer liability insurance. We expect these efforts to require the continued commitment of significant resources. Further, our board members, Chief Executive Officer and Chief Financial Officer could face an increased risk of personal liability in connection with the performance of their duties. As a result, we may have difficulty attracting and retaining qualified board members and executive officers, which could harm our business. If our efforts to comply with new or changed laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to practice, our reputation may be harmed.

**WE FACE INTENSE COMPETITION.**

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

Accordingly, our competitors may succeed in obtaining patent protection, receiving FDA or comparable foreign approval or commercializing products before us. If we commence commercial product sales, we will compete against companies with greater marketing and manufacturing capabilities who may successfully develop and commercialize products that are more effective or less expensive than ours. Our competitors may be more successful in receiving third party reimbursements from government agencies and others for their commercialized products which are



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similar to our products. If we cannot receive third party reimbursement for our products, we may not be able to commercialize our products. These are areas in which, as yet, we have limited or no experience. In addition, developments by our competitors may render our product candidates obsolete or noncompetitive.

We are aware of several companies that are selling or developing oral spray products. First Horizon Pharmaceutical Corporation, headquartered in Alpharetta, Georgia, currently markets Nitrolingual® Pumpspray, a nitroglycerin oral spray which is an air propelled dispensing system (our nitroglycerin lingual spray is a propellant based dispensing system). Generex Biotechnology Corporation, based in Toronto, Canada, is developing an insulin formulation that is delivered directly into the mouth via its RapidMist® device. They also state that they have begun research on four specific target molecules for their RapidMist® delivery system: morphine, fentanyl, heparin and flu vaccine. Generex is listed as the assignee on 15 United States patents. RapidMist® is a pending trademark of Generex Biotechnology Corporation. There are several other companies that we are aware of that market oral spray products containing vitamins and homeopathic ingredients. GW Pharmaceuticals plc, based in the United Kingdom, has developed a cannabinoid lingual spray called Sativex®. Sativex® was approved by Health Canada in April 2005 for the relief of neuropathic pain in Multiple Sclerosis (MS) and was launched in Canada in June 2005 by Bayer HealthCare, who will exclusively market Sativex® in Canada. Arakis Ltd., based in the United Kingdom, also claims to be developing an analgesic to be delivered suborally via a non-pressurized metered dose spray formulation.

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

#### **LIMITED PRODUCT LIABILITY INSURANCE COVERAGE MAY AFFECT OUR BUSINESS.**

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

#### **EXTENSIVE GOVERNMENT REGULATION MAY AFFECT OUR BUSINESS.**

The development, manufacture and commercialization of pharmaceutical products is generally subject to extensive regulation by various federal and state governmental entities. The FDA, which is the principal United States regulatory authority over pharmaceutical products, has the power to seize adulterated or misbranded products and unapproved new drugs, to request their recall from the market, to enjoin further manufacture or sale, to publicize certain facts concerning a product and to initiate criminal proceedings. As a result of federal statutes and FDA regulations pursuant to which new pharmaceuticals are required to undergo extensive and rigorous testing, obtaining pre-market regulatory approval requires extensive time and expenditures. Under the Federal Food, Drug, and Cosmetic Act (the "FFDCA"), as amended (21 U.S.C. 301 et. seq.), a new drug may not be commercialized or otherwise distributed in the United States without the prior approval of the FDA or pursuant to an applicable exemption from the FFDCA. 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 an NDA, which includes complete reports of pre-clinical, clinical and laboratory studies to prove such product's safety and efficacy. The NDA process generally requires, before the submission of the NDA, submission of an IND, pursuant to which permission is sought to begin preliminary clinical testing of the new drug. Such clinical trials are required to meet good clinical practices under the FFDCA. An NDA, based on published safety and efficacy studies conducted by others, may also be required to be submitted for a drug product with a previously approved active ingredient if the method of delivery, strength or dosage form is changed. Alternatively, a drug having the same active ingredients as a drug previously approved by the FDA may be eligible to be submitted under an ANDA, which is significantly less stringent than the NDA approval process. While the ANDA process requires a manufacturer to establish bioequivalence to the previously approved drug, it permits the manufacturer to rely on the safety and efficacy studies contained in the NDA for the previously approved drug. We believe that the products we develop in spray dosage form will require the submission of an NDA, which may be based upon published safety and efficacy studies conducted by others, which is referred to as a 505(b)(2) NDA. We estimate that the development of new formulations of pharmaceutical products, including formulation, testing and obtaining FDA approval, generally takes two to three years for the 505(b)(2) NDA process. Our determinations may prove to be inaccurate or pre-marketing approval relating to our proposed products may not be obtained on a timely basis, if at all. The failure by us to obtain necessary regulatory approvals, whether on a timely basis or at all, would have a material adverse effect on our business.

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

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

On June 1, 2005, we received an approvable letter from the FDA regarding its NDA for its nitroglycerin lingual aerosol, indicated for acute relief of an attack or acute prophylaxis of angina pectoris due to coronary artery disease. We believe that the FDA will give final approval once we complete our previously agreed to manufacturing process validation commitments. The FDA is not requiring any additional clinical studies for approval. We are currently planning to complete our process validation commitments in the second calendar quarter of 2006 and, if this timeline is met, we may obtain final approval from the FDA by the end of the second calendar quarter of 2006.

We had a pre-IND meeting with the FDA on August 10, 2005, and filed the IND in December 2005 for our sumatriptan oral spray product. Subsequent to the IND submission, we plan to execute the clinical protocol and administer clinical trials for the sumatriptan oral spray product. We are currently targeting a NDA submission in the third quarter of calendar 2007.

We had a pre-IND meeting with the FDA on August 31, 2005 and anticipate filing the IND during the third quarter of calendar year 2006 for our zolpidem oral spray product. In our 10-Q filed for the quarter ended October 31, 2005, we indicated that we anticipated filing the IND during the first quarter of calendar year 2006. However, the FDA has required that we complete certain studies prior to IND submission, and we have therefore delayed the filing of such IND pending completion of those studies. Subsequent to the IND submission, we plan to execute the clinical protocol and administer clinical trials for the zolpidem oral spray product. We are currently targeting a NDA submission for its zolpidem product candidate in the first quarter of calendar 2007, which target was not affected by the delay in the IND filing.

Our partner for the ondansetron oral spray product, Hana Biosciences, filed the IND in November 2005. Subsequent to the IND submission, Hana plans to execute the clinical protocol and administer clinical trials for the ondansetron oral spray product, Zensana, and is planning to submit its NDA in May 2006. While Hana has the rights to the ondansetron product candidate in the United States and Canada, NovaDel retains the rights in the rest of the world.

In the 10-Q filed for the quarter ended October 31, 2005, we indicated plans to request a pre-IND meeting with the FDA with an anticipated goal of filing the IND during the first half of calendar year 2006 for the alprazolam oral spray product. Following the IND meeting, we were planning to execute the clinical protocol and administer clinical trials for the alprazolam oral spray product. We have since determined that, in order to devote sufficient resources to other projects noted above, it is appropriate to defer further efforts on alprazolam. As a result, we are not currently scheduling a pre-IND meeting with the FDA, nor do we contemplate a specific timeframe for submitting an IND, pending further review.

We continue to support our partner, Manhattan Pharmaceuticals, who has filed an IND with the FDA for the propofol oral spray product. Manhattan Pharmaceuticals will oversee all clinical development and regulatory approval for this product.

Our veterinary initiatives are being carried out largely by our partner, Velcera Pharmaceuticals.

We plan to hire additional employees in the laboratory to support our research and development efforts going forward; however, we do not believe that a significant number of new employees will be required in the next 12 months.

The approval process is lengthy, expensive and uncertain. It is also possible that the FDA or comparable foreign regulatory authorities could interrupt, delay or halt any one or more of our clinical trials. If we, or any regulatory authorities, believe that trial participants face unacceptable health risks, any one or more of our trials could be suspended or terminated. We also may fail to reach agreement with the FDA and/or comparable foreign agencies on the design of any one or more of the clinical studies necessary for approval. Conditions imposed by the FDA and comparable agencies in foreign countries on our clinical trials could significantly increase the time required for completion of such clinical trials and the costs of conducting the clinical trials. Data obtained from clinical trials are susceptible to varying interpretations which may delay, limit or prevent regulatory approval.

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



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

**WE EXPECT TO FACE UNCERTAINTY OVER REIMBURSEMENT AND HEALTHCARE REFORM.**

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

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

Our strategy for the completion of the required development and clinical testing of our proposed products and for the manufacturing, marketing and commercialization of such products depends upon entering into collaboration arrangements with pharmaceutical companies to market, commercialize and distribute the products. We have entered into a license agreement with Manhattan Pharmaceuticals for the worldwide, exclusive rights to our oral spray technology to deliver propofol for pre-procedural sedation; an exclusive worldwide license for our proprietary oral spray technology with Velcera Pharmaceuticals for the development of innovative veterinary medicines pursuant to which we are entitled to milestone payments for each product developed by Velcera and royalties on product sales and Velcera will fund all development and regulatory expenses; a license and supply agreement with Par Pharmaceutical pursuant to which Par Pharmaceutical has the exclusive rights to market, sell and distribute our nitroglycerin lingual spray in the United States and Canada; and a license agreement with Hana Biosciences for the marketing rights in the United States and Canada for our ondansetron oral spray. Our success depends upon obtaining additional collaboration partners and maintaining our relationships with our current partners. In addition, we may depend on our partners' expertise and dedication of sufficient resources to develop and commercialize our proposed products. We may, in the future, grant to collaboration partners, rights to license and commercialize pharmaceutical products developed under collaboration agreements. Under these arrangements, our collaboration partners may control key decisions relating to the development of the products. The rights of our collaboration partners could limit our flexibility in considering alternatives for the commercialization of the products. If we fail to successfully develop these relationships or if our collaboration partners fail to successfully develop or commercialize any of our products, it may delay or prevent us from developing or commercializing our proposed products in a competitive and timely manner and would have a material adverse effect on our business.

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

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

defend our patents and otherwise prevent others from infringing on our proprietary rights;

protect our trade secrets; and

operate without infringing upon the proprietary rights of others, both in the United States and in other countries.

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

We have received a request for information from a third party in response to the information we have set forth in the paragraph IV certification of the NDA we have filed for NitroMist. Such request no longer has any effect on PDUFA dates for such NDA. However, the request may be a precursor for a patent infringement claim by such third party. We do not believe that we have infringed on any intellectual property rights of such party and if such a claim is filed, we intend to vigorously defend our rights in response to such claim.



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

We, and the parties licensing technologies to us, have filed various United States and foreign patent applications with respect to the products and technologies under our development, and the United States Patent and Trademark Office and foreign patent offices have issued patents with respect to our products and technologies. These patent applications include international applications filed under the Patent Cooperation Treaty. We currently have seven patents issued in the United States and seven patents issued outside of the United States. In addition, we have approximately 120 patents pending worldwide. Our pending patent applications, those we may file in the future and those we may license from third parties may not result in the United States Patent and Trademark Office or any foreign patent office issuing patents. Also, if patent rights covering our products are not sufficiently broad, they may not provide us with sufficient proprietary protection or competitive advantages against competitors with similar products and technologies. Furthermore, if the United States Patent and Trademark Office or foreign patent offices issue patents to us or our licensors, others may challenge the patents or circumvent the patents, or the patent office or the courts may invalidate the patents. Thus, any patents we own or license from or to third parties may not provide any protection against competitors.

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

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

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

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

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

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

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

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

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

they will breach these agreements;

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

our competitors will independently discover our proprietary information and trade secrets.

**WE ARE DEPENDENT ON EXISTING MANAGEMENT.**

Our success is substantially dependent on the efforts and abilities of the principal members of our management team and our directors. Decisions concerning our business and our management are and will continue to be made or significantly influenced by these individuals. The loss or interruption of their continued services would have a materially adverse effect on our business operations and prospects. Although our employment agreements with members of management generally provide for severance payments that are contingent upon the applicable officer's refraining from competition with us, the loss of any of these persons' services would adversely affect our ability to develop and market our products and obtain necessary regulatory approvals, and the applicable noncompetition provisions can be difficult and costly to monitor and enforce. Further, we do not maintain key-man life insurance.

On September 6, 2005, our Board of Directors announced that they would not be renewing the employment contract of Dr. Shangold. Accordingly, Dr. Shangold ceased to be the President and Chief Executive Officer of the Company on December 22, 2005.

On September 28, 2005, the Board announced its appointment of Dr. Jan H. Egberts as our Chief Operating Officer, effective September 26, 2005, reporting to the Chairman of the Board. Dr. Egberts assumed the positions of President and Chief Executive Officer on December 23, 2005 and Chairman of the Board on January 17, 2006.

On October 19, 2005, our Board of Directors appointed Dr. William F. Hamilton as Chairman of the Corporate Governance and Nominating Committee. On January 17, 2006, we announced that Dr. Hamilton had been named to the newly-created position of Lead Independent Director.

On October 20, 2005, we announced that Dr. Henry Kwan will no longer serve as Head of Pharmaceutical Sciences.

On November 22, 2005, we announced that Board of Directors member, and non-executive Chairman of the Board, Mr. Robert G. Savage announced his intention not to stand for re-election to our board at the Company's 2006 annual meeting of stockholders. Mr. Savage served as a director of the Company since 2004 and as our non-executive Chairman of the Board since September 2, 2005.

On December 15, 2005, we announced that Board of Directors member, Dr. Mark Rachesky, announced his resignation from our Board. Dr. Rachesky served as a director of the Company since 2003.

In our annual proxy statement, we announced that Dr. Lawrence J. Kessel was not being nominated to stand for re-election to our Board at the Company's 2006 annual stockholders' meeting. Dr. Kessel served as a director since March 2003.

On December 15, 2006, we announced the election of Mr. J. Jay Lobell as a member of our Board of Directors effective December 14, 2005. Mr. Lobell was appointed as a result of Dr. Rosenwald's right to designate a director nominee for the Company's Board.

On January 17, 2006, we announced the election of Mr. Steven B. Ratoff as a member of our Board of Directors.

On April 28, 2006, we announced that Ms. Jean Frydman will no longer serve as Vice President, General Counsel and Corporate Secretary.



Our future success also will depend in part on the continued service of our key scientific and management personnel and our ability to identify, hire and retain additional personnel, including scientific, development and manufacturing staff.

**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) greater than 30% of the common stock on a fully-diluted basis. Specifically, Dr. Rosenwald has the ability to exert significant influence over the election of the Board and other matters submitted to our stockholders for approval. Dr. Rosenwald has the ability to designate an individual to serve on the Company's Board of Directors ( Board ) and has exercised such ability by designating Mr. J. Jay Lobell to serve on the Board. On December 14, 2005 based upon the recommendation of the Corporate Governance and Nominating Committee, the Board elected Mr. Lobell as a member of the Board. Pursuant to the listing standards of the AMEX, Mr. Lobell is not deemed to be an independent director. Such positions may discourage or prevent any proposed takeover of NovaDel, including transactions in which our stockholders might otherwise receive a premium for their shares over the then current market prices. Our directors, executive officers and principal stockholders may influence corporate actions, including influencing elections of directors and significant corporate events.

**THE MARKET PRICE OF OUR STOCK AND OUR EARNINGS MAY BE ADVERSELY AFFECTED BY MARKET VOLATILITY.**

The market price of the common stock, like that of many other development stage pharmaceutical or biotechnology companies, has been and is likely to continue to be volatile. In addition to general economic, political and market conditions, the price and trading volume of the common stock could fluctuate widely in response to many factors, including:

announcements of the results of clinical trials by us or our competitors;

adverse reactions to products;

governmental approvals, delays in expected governmental approvals or withdrawals of any prior governmental approvals or public or regulatory agency concerns regarding the safety or effectiveness of our products;

changes in the United States or foreign regulatory policy during the period of product development;

developments in patent or other proprietary rights, including any third party challenges of our intellectual property rights;

announcements of technological innovations by us or our competitors;

announcements of new products or new contracts by us or our competitors;

actual or anticipated variations in our operating results due to the level of development expenses and other factors;

changes in financial estimates by securities analysts and whether our earnings meet or exceed the estimates;

conditions and trends in the pharmaceutical and other industries;

new accounting standards; and

the occurrence of any of the risks set forth in these Risk Factors.

Our common stock has been listed for quotation on the AMEX since May 11, 2004. Prior to May 11, 2004, our common stock was traded on the OTC Bulletin Board® of the National Association of Securities Dealers, Inc. During the 12-month period ended January 31, 2006, the closing price of our common stock has ranged from \$1.09 to \$1.85. We expect the price of our common stock to remain volatile. The average daily trading volume in our common stock varies significantly. For the 12-month period ended January 31, 2006, the average daily trading volume in our common stock was approximately 44,863 shares. Our relatively low average volume and low average number of transactions per day may affect the ability of our stockholders to sell their shares in the public market at prevailing prices and a more active market may never develop.

In addition, we may not be able to continue to adhere to the strict listing criteria of the AMEX. If our common stock were no longer listed on the AMEX, investors might only be able to trade on the OTC Bulletin Board® or in the Pink Sheets® (a quotation medium operated by Pink Sheets LLC). This would impair the liquidity of our securities not only in the number of shares that could be bought and sold at a given price, which might be depressed by the relative illiquidity, but also through delays in the timing of transactions and reduction in media coverage.

In the past, following periods of volatility in the market price of the securities of companies in our industry, securities class action litigation has often been instituted against companies in our industry. If we face securities litigation in the future, even if without merit or unsuccessful, it would result in substantial costs and a diversion of management attention and resources, which would negatively impact our business.



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

The Commission has adopted regulations which generally define a penny stock to be any equity security that has a market price of less than \$5.00 per share or an exercise price of less than \$5.00 per share, subject to certain exceptions. As a result, 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 such rules, the broker dealer must make a special suitability determination for the purchase of such securities and have received the purchaser's written consent to the transaction prior to the purchase. Additionally, for any transaction involving a penny stock, unless exempt, the rules require the delivery, prior to the transaction, of a risk disclosure document mandated by the Commission relating to the penny stock market. The broker dealer must also disclose the commission payable to both the broker dealer and the registered representative, current quotations for the securities and, if the broker dealer is the sole market maker, the broker dealer must disclose this fact and the broker dealer's presumed control over the market. Finally, monthly statements must be sent disclosing recent price information for the penny stock held in the account and information on the limited market in penny stocks. Broker-dealers must wait two business days after providing buyers with disclosure materials regarding a security before effecting a transaction in such security. Consequently, the penny stock rules restrict the ability of broker dealers to sell our securities and affect the ability of investors to sell our securities in the secondary market and the price at which such purchasers can sell any such securities, thereby affecting the liquidity of the market for our common stock.

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

- control of the market for the security by one or more 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.

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

We are authorized to issue a total of 100,000,000 shares of common stock. As of May 1, 2006, there were 48,874,623 shares of common stock issued and outstanding. However, the total number of shares of our common stock issued and outstanding does not include shares reserved in anticipation of the exercise of options or warrants. As of May 1, 2006, we had outstanding stock options and warrants to purchase approximately 31.1 million shares of common stock, the exercise price of which range between \$0.46 per share to \$3.18 per share, and we have reserved shares of our common stock for issuance in connection with the potential exercise thereof.

The following table provides an overview of the Company's stock options and corresponding plans:

Plan	Shares Authorized	Options Outstanding at May 1, 2006	Remaining Shares Available for Issuance	Comments
1992 Stock Option Plan	500,000	80,000		Plan Closed
1997 Stock Option Plan	500,000	100,000		Plan Closed
1998 Stock Option Plan	3,400,000	2,727,000	378,000	
2006 Equity Incentive Plan	6,000,000	450,000	5,550,000	
Non-Plan	n/a	5,286,034		

To the extent such options or warrants are exercised, the holders of our common stock will experience further dilution. In addition, in the event that any future financing should be in the form of, be convertible into or exchangeable for, equity securities, and upon the exercise of options and warrants, investors may experience additional dilution.

See Risk Factors - Our Additional Financing Requirements Could Result In Dilution To Existing Stockholders included in the Company's Annual Report on Form 10-KSB for the fiscal year ended July 31, 2005. The exercise of the outstanding derivative securities will reduce the percentage of common stock held by our stockholders in relation to our aggregate outstanding capital stock. Further, the terms on which we could obtain additional capital during the life of the derivative securities may be adversely affected, and it should be expected that the holders of the derivative securities would exercise them at a time when we would be able to obtain equity capital on terms more favorable than those provided for by such derivative securities. As a result, any issuance of additional shares of our common stock may cause our current stockholders to suffer significant dilution which may adversely affect the market.

In addition to the above referenced shares of our common stock which may be issued without stockholder approval, we have 1,000,000 shares of authorized preferred stock, the terms of which may be fixed by our Board 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 stockholder approval, to create and issue one or more series of such preferred stock and to determine the voting, dividend and other rights of holders of such preferred stock. The issuance of any of such series of preferred stock may have an adverse effect on the holders of our common stock.

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

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

**LIMITATION ON DIRECTOR/OFFICER LIABILITY.**

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

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

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

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

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

**SALES OF LARGE QUANTITIES OF OUR COMMON STOCK, INCLUDING THOSE SHARES ISSUABLE IN CONNECTION WITH PRIVATE PLACEMENT TRANSACTIONS, COULD REDUCE THE PRICE OF OUR COMMON STOCK.**

In 2005, we sold securities in a private placement transaction resulting in the issuance of 6,733,024 shares of our Common Stock, and certain warrants to purchase 2,693,209 shares of our Common Stock. The sales of the shares of Common Stock and warrants resulted in gross proceeds to the Company of \$7.1 million, prior to offering expenses. The resale of our Common Stock and the exercise of the warrants described immediately above in this risk factor are subject to a currently effective registration statement filed by the Company on Form S-3. There can be no assurance as to the prices at which our Common Stock will trade in the future, although they may continue to fluctuate significantly. Prices for our Common Stock will be determined in the marketplace and may be influenced by many factors, including the following:

The depth and liquidity of the markets for our Common Stock

Investor perception of the Company and the industry in which we participate

General economic and market conditions

Any sales of large quantities of our Common Stock could reduce the price of our Common Stock. The holders of the shares may sell such shares at any price and at any time, as determined by such holders in their sole discretion without limitation. If any such holders sell such shares in large quantities, our Common Stock price may decrease and the public market for our Common Stock may otherwise be adversely affected because of the additional shares available in the market.

**THE UNCERTAINTY CREATED BY CURRENT ECONOMIC CONDITIONS AND POSSIBLE TERRORIST ATTACKS AND MILITARY RESPONSES THERETO COULD MATERIALLY ADVERSELY AFFECT OUR ABILITY TO SELL OUR PRODUCTS, AND PROCURE NEEDED FINANCING.**

Current conditions in the domestic and global economies continue to present challenges. We expect that the future direction of the overall domestic and global economies will have a significant impact on our overall performance. Fiscal, monetary and regulatory policies worldwide will continue to influence the business climate in which we operate. If these actions are not successful in spurring continued economic growth, we expect that our business will be negatively impacted, as customers will be less likely to buy our products, if and when we commercialize our products. The potential for future terrorist attacks or war as a result thereof has created worldwide uncertainties that make it very difficult to estimate how the world economy will perform going forward.

**OUR INABILITY TO MANAGE THE FUTURE GROWTH THAT WE ARE ATTEMPTING TO ACHIEVE COULD SEVERELY HARM OUR BUSINESS.**

We believe that, given the right business opportunities, we may expand our operations rapidly and significantly. If rapid growth were to occur, it could place a significant strain on our management, operational and financial resources. To manage any significant growth of our operations, we will be required to undertake the following successfully:

We will need to improve our operational and financial systems, procedures and controls to support our expected growth and any inability to do so will adversely impact our ability to grow our business. Our current and planned systems, procedures and controls may not be adequate to support our future operations and expected growth. Delays or problems associated with any improvement or expansion of our operational systems and controls could adversely impact our relationships with customers and harm our reputation and brand.

We will need to attract and retain qualified personnel, and any failure to do so may impair our ability to offer new products or grow our business. Our success will depend on our ability to attract, retain and motivate managerial, technical, marketing, and administrative personnel. Competition for such employees is intense, and we may be unable to successfully attract, integrate or retain sufficiently qualified personnel. If we are unable to hire, train, retain or manage the necessary personnel, we may be unable to successfully introduce new products or otherwise implement our business strategy.

If we are unable to manage growth effectively, our business, results of operations and financial condition could be materially adversely affected.

**WE MAY BE OBLIGATED, UNDER CERTAIN CIRCUMSTANCES, TO PAY LIQUIDATED DAMAGES TO HOLDERS OF OUR COMMON STOCK.**

We have entered into an agreement with the holders of our Common Stock that requires us to continuously maintain as effective, a registration statement covering the underlying shares of Common Stock. Such a registration statement was declared effective on July 28, 2005 and must continuously remain effective for a specified term. If we fail to continuously maintain such a registration statement as effective throughout the specified term, we may be subject to liability to pay liquidated damages.



**SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS**

This prospectus contains some forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995 and information relating to us that are based on the beliefs of our management, as well as assumptions made by and the information currently available to our management. When used in this prospectus, the words estimate, project, believe, anticipate, intend, expect and similar expressions are intended to identify forward-looking statements. These statements reflect our current views with respect to future events and are subject to risks and uncertainties that could cause actual results to differ materially from those contemplated in these forward-looking statements, including those risks discussed in this prospectus. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this prospectus. Except for special circumstances in which a duty to update arises when prior disclosure becomes materially misleading in light of subsequent circumstances, we do not intend to update any of these forward-looking statements to reflect events or circumstances after the date of this prospectus or to reflect the occurrence of unanticipated events.

**USE OF PROCEEDS**

We will not receive any of the proceeds from the sale of the shares owned by the selling security holders. However, we will receive proceeds from the exercise of outstanding warrants, if such warrants are exercised. However, the warrants contain provisions for cashless exercise, in which case, we will not receive any proceeds from the exercise of the warrants from the selling security holders. The warrants entitle the selling stockholders to purchase shares of our common stock at an exercise price of \$1.60 per share. Any such proceeds will be used primarily for increased or additional research and development and general working capital.

The selling security holders will pay any underwriting discounts and commissions and expenses incurred by the selling security holders in disposing of the shares. We will bear all other costs, fees and expenses incurred in effecting the issuance and registration of the shares covered by this prospectus, including, without limitation, all registration and filing fees, American Stock Exchange listing fees and fees and expenses of our counsel and our accountants.

**SELLING SECURITY HOLDERS**

The following is a summary of the transactions by which the selling security holders acquired the securities being registered by this registration statement.

On April 19, 2006, we completed a private placement of 8,092,796 shares of our common stock and warrants to purchase a total of 2,896,168 shares of our common stock, including warrants issued to the Placement Agents in connection with the private placement, with an exercise price equal to \$1.60 per share. We received gross proceeds of \$11,773,963 and net proceeds of approximately \$10,400,000, from the private placement.

The following table sets forth the aggregate number of shares of common stock beneficially owned by the selling security holders as of May 1, 2006, after giving effect to the private placement, and the percentage of all shares of common stock held by such selling security holders prior to and after giving effect to the offering based on 48,874,623 shares of common stock outstanding as of May 1, 2006. Except as described in this prospectus, the selling stockholders have not held any position or office or had any other material relationship with us or any of our predecessors or affiliates within the past three years. We considered the following factors and made the following assumptions regarding the table:

beneficial ownership is determined under Section 13(d) of the Securities Exchange Act of 1934 (Exchange Act) and generally includes voting or investment power with respect to securities and including any securities that grant the selling stockholder the right to acquire Common Stock within 60 days of May 1, 2006; and

the selling stockholders may sell all of the securities offered by this prospectus under certain circumstances.

Notwithstanding these assumptions, the selling stockholders may sell less than all of the shares listed on the table. In addition, the shares listed below may be sold pursuant to this prospectus or in privately negotiated transactions. Accordingly, we cannot estimate the number of shares of Common Stock that the selling stockholders will sell under this prospectus.

Except as indicated in the footnotes to this table, the persons named in the table have sole voting and investment control with respect to all shares of our Common Stock shown as beneficially owned by them.



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Name of Selling Stockholder(3)	Shares of Common Stock Beneficially Owned Prior to Offering (1)		Number of Shares of Common Stock Being Offered	Shares of Common Stock to be Beneficially Owned After Offering (1)(2)	
	Number	Percentage		Number	Percentage
Adam S. Leeds, Trustee of Trust A U/D/T dated 1/23/81	22,413 <sup>(4)</sup>	*	22,413		
Alfred Abraham	42,038 <sup>(5)</sup>	*	42,038		
Harewood Nominees Ltd. A/C 4689000	632,069 <sup>(6)</sup>	1.3%	302,138		
Atlas Master Fund, Ltd.	1,607,871 <sup>(7)</sup>	3.3%	70,350	890,632	1.8%
Visium Balanced Fund, L.P.	1,607,871 <sup>(8)</sup>	3.3%	170,088	890,632	1.8%
Visium Balanced Offshore Fund, Ltd.	1,607,871 <sup>(9)</sup>	3.3%	254,201	890,632	1.8%
Visium Long Bias Fund, Ltd.	1,607,871 <sup>(10)</sup>	3.3%	51,146	890,632	1.8%
Visium Long Bias Offshore Fund, Ltd.	1,607,871 <sup>(11)</sup>	3.3%	171,454	890,632	1.8%
Ben Heller	244,276 <sup>(12)</sup>	*	188,276	56,000	*
Caisse de Depot et Placement du Quebec	5,837,931 <sup>(13)</sup>	11.6%	3,137,931	2,700,000	5.4%
Capital Ventures International	448,276 <sup>(14)</sup>	*	448,276		
Clearwater Fund I, L.P.	2,949,808 <sup>(15)</sup>	6.0%	260,000	1,649,808	3.4%
Clearwater Offshore Fund, Ltd.	2,949,808 <sup>(16)</sup>	6.0%	260,000	1,649,808	3.4%
Hans F. Heye	2,949,808 <sup>(17)</sup>	6.0%	780,000	1,649,808	3.4%
Cranshire Capital L.P.	179,310 <sup>(18)</sup>	*	179,310		
Daniel Gallagher	11,207 <sup>(19)</sup>	*	11,207		
David Jaroslawicz	293,339 <sup>(20)</sup>	*	188,276	105,063	*
David Weisberg	44,828 <sup>(21)</sup>	*	44,828		
Dean Glasser	33,690 <sup>(22)</sup>	*	17,931	15,759	*
H. Martyn Group, Ltd. Profit Sharing Plan & Trust	20,172 <sup>(23)</sup>	*	20,172		
Hauck & Aufhauser Barquies Luxembourg S.A.	53,793 <sup>(24)</sup>	*	53,793		
Henderson North American Multi-Strategy Fund	632,069 <sup>(25)</sup>	1.3%	252,828		
Isaac R. Dweck	470,476 <sup>(26)</sup>	1.0%	208,989	261,487	*
J. Jay Lobell	273,149 <sup>(27)</sup>	*	41,140	232,009	*
Joseph J. Vale	454,063 <sup>(28)</sup>	*	130,000	324,063	*
Lewis Opportunity Fund	112,069 <sup>(29)</sup>	*	112,069		
Michael Chill	20,570 <sup>(30)</sup>	*	20,570		
MA Egberts Gunning	164,557 <sup>(31)</sup>	*	164,557		
Neil Herskowitz	122,759 <sup>(32)</sup>	*	62,759	60,000	*
Nicole Berg	395,431 <sup>(33)</sup>	*	277,931	117,500	*
Oppenheim Pramerica Asset Management S.a.r.l.. on behalf of FCP OP MEDICAL BioHe@lth-Trends	215,172 <sup>(34)</sup>	*	215,172		
ProQuest Investments II Advisors Fund L.P.	7,128,152 <sup>(35)</sup>	14.1%	4,356	6,231,590	12.3%
ProQuest Investments II, L.P.	7,128,152 <sup>(36)</sup>	14.1%	180,631	6,231,590	12.3%
ProQuest Investments III, L.P.	7,128,152 <sup>(37)</sup>	14.1%	711,575	6,231,590	12.3%
Riverside Contracting, LLC	128,202 <sup>(38)</sup>	*	62,759	65,443	*
Shea Diversified Investments, Inc.	231,712 <sup>(39)</sup>	*	170,344	61,368	*
South Ferry Building Company	1,411,248 <sup>(40)</sup>	2.8%	851,724	559,524	1.1%
Stephan P. Vermut & Barbara T. Vermut Trust dtd March 2002	185,397 <sup>(41)</sup>	*	134,482	50,915	*
Steven B. Ratoff	167,817 <sup>(42)</sup>	*	167,817		
	632,069 <sup>(43)</sup>	1.3%	77,103		

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Harewood Nominees Ltd-A/C  
4721300

Griffin Securities, Inc.	187,332 <sup>(44)</sup>	*	187,332		
Lindsay Rosenwald	12,391,924 <sup>(45)</sup>	22.0%	156,388	12,235,536	21.8%
Scott Katzmann	135,622 <sup>(46)</sup>	*	10,151	125,471	*
Michael Rosenman	61,224 <sup>(47)</sup>	*	9,001	52,223	*
Andrew Miles	379 <sup>(48)</sup>	*	379		
Timothy McInerney	696,050 <sup>(49)</sup>	1.4%	79,904	616,146	1.2%
Harris Lydon	14,239 <sup>(50)</sup>	*	10,072	4,167	*
Michael Weiser	1,163,271 <sup>(51)</sup>	2.3%	8,102	1,155,169	2.3%
John Knox	90,532 <sup>(52)</sup>	*	2,000	88,532	*
Stephen C. Rocamboli	195,285 <sup>(53)</sup>	*	2,000	193,285	*
Louis Smookler	4,000 <sup>(54)</sup>	*	2,000	2,000	*
Basil Christakos	21,883 <sup>(55)</sup>	*	1,000	20,883	*

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\*Less than 1%.

(1) Shares of common stock issuable under stock options and warrants that are exercisable within 60 days after May 1, 2006 are deemed outstanding for computing the percentage ownership of the selling stockholder holding the options or warrants, prior to and after giving effect to the offering, but are not deemed outstanding for computing the percentage ownership of any other selling stockholder.

(2) The selling security holders may offer and sell all or a part of the common stock pursuant to this prospectus, but no estimates can be made as to the amount of shares of common stock that will be held by the selling security holders after the completion of this offering.

(3) Based on the information received by the Company from each known holder of the securities, except as disclosed below, no selling stockholder is an affiliate of any registered broker-dealer.

(4) Includes 17,241 shares of common stock and warrants to purchase 5,172 shares of common stock. Adam S. Leeds, as Trustee, has voting and investment control over the shares of common stock and warrants held by the trust, but disclaims beneficial ownership of such shares and warrants, except to the extent of any pecuniary interest therein.

(5) Includes 32,337 shares of common stock and warrants to purchase 9,701 shares of common stock.

(6) Includes (i) 232,414 shares of common stock and warrants to purchase 69,724 shares of common stock, (ii) 59,310 shares of common stock and warrants to purchase 17,793 shares of common stock held in the name of Harewood Nominees Ltd. A/C 4721300, and (iii) 194,483 shares of common stock and warrants to purchase 58,345 shares of common stock held in the name of Henderson North American Multi-Strategy Fund. Harewood Nominees Ltd. A/C 4689000 and Harewood Nominees Ltd. A/C 4721300 are the nominees of AMP Enhanced Index International Share Fund and Witan Investment Trust, respectively. Harewood Nominees are the appointed custodian for Henderson Global Investors. Robert Villiers, Fund Manager of AMP Enhanced Index International Share Fund has voting and investment control over the shares of common stock and warrants held by Harewood Nominees LTD A/C 4689000, but disclaims beneficial ownership of such shares and warrants, except to the extent of any pecuniary interest therein.

(7) Includes (i) 702,294 shares of common stock and warrants to purchase 258,688 shares of common stock, (ii) 130,837 shares of common stock and warrants to purchase 39,251 of common stock held in the name of Visium Balanced Fund, LP, (iii) 195,539 shares of common stock and warrants to purchase 58,662 shares of common stock held in the name of Visium Balanced Offshore Fund, Ltd., (iv) 39,343 shares of common stock and warrants to purchase 11,803 shares of common stock held in the name of Visium Long Bias Fund, Ltd., and (v) 131,888 shares of common stock and warrants to purchase 39,566 shares of common stock held in the name of Visium Long Bias Offshore Fund, Ltd. Dimitri Balyasny is a Partner in Balyasny Asset Management, the Investment Manager to Atlas Master Fund, Ltd. and sub-advisor to Visium Balanced Fund L.P., Visium Balanced Offshore Fund, Ltd., Visium Long Bias Fund, Ltd. and Visium Long Bias Offshore Fund, Ltd. Mr. Balyasny has voting and investment control over the shares of common stock and warrants held by Atlas Master Fund, Ltd. Mr. Balyasny disclaims beneficial ownership of such shares and warrants, except to the extent of any pecuniary interest therein.

(8) Includes (i) 130,837 shares of common stock and warrants to purchase 39,251 shares of common stock, (ii) 195,539 shares of common stock and warrants to purchase 58,662 shares of common stock held in the name of Visium Balanced Offshore Fund, Ltd., (iii) 39,343 shares of common stock and warrants to purchase 11,803 shares of common stock held in the name of Visium Long Bias Fund, Ltd., (iv) 131,888 shares of common stock and warrants to purchase 39,566 shares of common stock held in the name of Visium Long Bias Offshore Fund, Ltd. and (v) 702,294 shares of common stock and warrants to purchase 258,688 shares of common stock held in the name of Atlas Master Fund Ltd. Dimitri Balyasny is a Partner in Balyasny Asset Management, the Investment Manager to Atlas Master Fund, Ltd. and sub-advisor to Visium Balanced Fund L.P., Visium Balanced Offshore Fund, Ltd., Visium Long Bias Fund, Ltd. and Visium Long Bias Offshore Fund, Ltd. Jacob Gottlieb is a Portfolio Manager in Balyasny Asset Management and a Managing Member of Visium Asset Management, LLC, Investment Advisor to Visium Balanced Fund, LP. Each of Mr. Balyasny and Mr. Gotleib have voting and investment control over the shares of common stock and warrants held by Visium Balanced Fund, LP and each disclaim beneficial ownership of such shares and warrants, except to the extent of any pecuniary interest therein.

(9) Includes (i) 195,539 shares of common stock and warrants to purchase 58,662 shares of common stock, (ii) 130,837 shares of common stock and warrants to purchase 39,251 of common stock held in the name of Visium Balanced Fund, L.P., (iii) 39,343 shares of common stock and warrants to purchase 11,803 shares of common stock held in the name of Visium Long Bias Fund, Ltd., (iv) 131,888 shares of common stock and warrants to purchase 39,566 shares of common stock held in the name of Visium Long Bias Offshore Fund, Ltd. and (v) 702,294 shares of common stock and warrants to purchase 258,688 shares of common stock held in the name of Atlas Master Fund Ltd. Dimitri Balyasny is a Partner in Balyasny Asset Management, the Investment Manager to Atlas Master Fund, Ltd. and sub-advisor to Visium Balanced Fund L.P., Visium Balanced Offshore Fund, Ltd., Visium Long Bias Fund, Ltd. and Visium Long Bias Offshore Fund, Ltd.. Jacob Gottlieb is a Portfolio Manager in Balyasny Asset Management and a Managing Member of Visium Asset Management, LLC, Investment Advisor to Visium Balanced Offshore Fund, Ltd. Each of Mr. Balyasny and Mr. Gotleib have voting and investment control over the shares of common stock and warrants held by Visium Balanced Offshore Fund, Ltd and each disclaim beneficial ownership of such shares and warrants, except to the extent of any pecuniary interest therein.



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(10) Includes (i) 39,343 shares of common stock and warrants to purchase 11,803 shares of common stock, (ii) 130,837 shares of common stock and warrants to purchase 39,251 of common stock held in the name of Visium Balanced Fund, L.P., (iii) 195,539 shares of common stock and warrants to purchase 58,662 shares of common stock held in the name of Visium Balanced Offshore Fund, Ltd., (iv) 131,888 shares of common stock and warrants to purchase 39,566 shares of common stock held in the name of Visium Long Bias Offshore Fund, Ltd. and (v) 702,294 shares of common stock and warrants to purchase 258,688 shares of common stock held in the name of Atlas Master Fund, Ltd. Dimitri Balyasny is a Partner in Balyasny Asset Management, the Investment Manager to Atlas Master Fund, Ltd. and sub-advisor to Visium Balanced Fund L.P., Visium Balanced Offshore Fund, Ltd., Visium Long Bias Fund, Ltd. and Visium Long Bias Offshore Fund, Ltd. Jacob Gottlieb is a Portfolio Manager in Balyasny Asset Management and a Managing Member of Visium Asset Management, LLC, Investment Advisor to Visium Long Bias Fund, Ltd. Each of Mr. Balyasny and Mr. Gotleib have voting and investment control over the shares of common stock and warrants held by Visium Long Bias Fund, Ltd., and each disclaim beneficial ownership of such shares and warrants, except to the extent of any pecuniary interest therein.

(11) Includes (i) 131,888 shares of common stock and warrants to purchase 39,566 shares of common stock, (ii) 130,837 shares of common stock and warrants to purchase 39,251 of common stock held in the name of Visium Balanced Fund, L.P., (iii) 195,539 shares of common stock and warrants to purchase 58,662 shares of common stock held in the name of Visium Balanced Offshore Fund, Ltd., (iv) 39,343 shares of common stock and warrants to purchase 11,803 shares of common stock held in the name of Visium Long Bias Fund, Ltd., and (v) 702,294 shares of common stock and warrants to purchase 258,688 shares of common stock held in the name of Atlas Master Fund, Ltd. Dimitri Balyasny is a Partner in Balyasny Asset Management, the Investment Manager to Atlas Master Fund, Ltd. and sub-advisor to Visium Balanced Fund, L.P., Visium Balanced Offshore Fund, Ltd., Visium Long Bias Fund, Ltd. and Visium Long Bias Offshore Fund, Ltd. Jacob Gottlieb is a Portfolio Manager in Balyasny Asset Management and a Managing Member of Visium Asset Management, LLC, Investment Advisor to Visium Long Bias Offshore Fund, Ltd. Each of Mr. Balyasny and Mr. Gotleib have voting and investment control over the shares of common stock and warrants held by Visium Long Bias Offshore Fund, Ltd., and each disclaim beneficial ownership of such shares and warrants, except to the extent of any pecuniary interest therein.

(12) Includes 200,828 shares of common stock and warrants to purchase 43,448 shares of common stock.

(13) Includes 4,413,793 shares of common stock and warrants to purchase 1,424,138 shares of common stock. Two groups of persons, collectively comprised of Normand Provost, Pierre Pharad, Diane Favreau, Pierre Fortier, Paul-Henri Couture, Michel Lefebvre, Ghislain Gauthier, Sylvain Gareau, Luc Houle, Gilles Godbout, James McMullan, Louise Lalonde, Jean-Pierre Jetté, Julie Prémont, Bruno Guilmette, Francois Maheu, Cyrille Viltecoq, Alain Tremblay, Marcel Gagnon, Pierre Piché, Eric Lachance, Mackey Tall, Stephane René, Frederick Godbout, Eric Cantin, Monique Laliberté, Dave Brochet, Eric Legault, Marc-Andre Aubé, Maxine Durivage, Francois Boundreault, Steve Lachaine, Pierre Lépine and Pierre Lambert, has voting and investment control over the shares of common stock and warrants held by Caisse de dépôt et placement du Québec, and each disclaim beneficial ownership of such shares, except to the extent of any pecuniary interest therein. Normand Provost, Pierre Pharad, Diane Favreau, Peirre Fortier, Paul-Henri Courture, Michel Lefebvre, Ghislain Gauthier, Sylvain Gareau, Luc Houle and Gilles Godbout make up Group A. James McMullan, Louise Lalonde, Jean-Pierre Jetté, Julie Prémont, Bruno Guilmette, Francois Maheu, Cyrille Viltecoq, Alain Tremblay, Marcel Gagnon, Pierre Piché, Eric Lachance, Mackey Tall, Stephane René, Frederick Godbout, Eric Cantin, Monique Laliberté, Dave Brochet, Eric Legault, Marc-Andre Aubé, Maxine Durivage, Francois Boundreault, Steve Lachaine, Pierre Lépine and Pierre Lambert make up Group B. Any person in Group A in conjunction with any person in Group B has voting and investment control.

(14) Includes 344,828 shares of common stock and warrants to purchase 103,448 of shares common stock. Heights Capital Management, Inc., the authorized agent of Capital Ventures International ( CVI ), has discretionary authority to vote and dispose of the shares held by CVI and may be deemed to be the beneficial owner of these shares. CVI is affiliated with one or more registered broker-dealers, and as a result CVI may be deemed to be an affiliate of a broker-dealer. Accordingly, the selling security holder may be deemed to be an underwriter if it (i) did not acquire the shares of common stock in the ordinary course of business or (ii) had any agreement or understanding, directly or indirectly, with any person to distribute the shares of common stock. CVI has confirmed to the Company that it acquired the shares of common stock being registered hereunder in the ordinary course of business and at the time of purchase, had no agreements or understandings, directly or indirectly, with any other person to distribute such shares of common stock. Please see [Plan of Distribution](#) for further disclosure regarding these selling security holders.

(15) Includes (i) 604,090 shares of common stock and warrants to purchase 181,227 shares of common stock, (ii) 604,090 shares of common stock and warrants to purchase 181,227 shares of common stock held in the name of Clearwater Offshore Fund, Ltd., and (iii) 1,077,947 shares of common stock and warrants to purchase 301,227 shares of common stock held in the name of Hans. F. Heye. Mr. Heye, the Managing Member of Clearwater Capital Group LLC, the General Partner of Clearwater Fund I, L.P., has voting and investment control over the shares of common stock and warrants held by Clearwater Fund I, L.P., but disclaims beneficial ownership of such shares of common stock and warrants, except to the extent of any pecuniary interest therein.

(16) Includes (i) 604,090 shares of common stock and warrants to purchase 181,227 shares of common stock, (ii) 604,090 shares of common stock and warrants to purchase 181,227 shares of common stock held in the name of Clearwater Fund I, L.P., and (iii) 1,077,947 shares of common stock and warrants to purchase 301,227 shares of common stock held in the name of Hans F. Heye. Mr. Heye, the President of Clearwater Funds, Inc., the Trading Manager of Clearwater Offshore Fund, Ltd., has voting and investment control over the shares of common

stock and warrants held by Clearwater Offshore Fund, Ltd., but disclaims beneficial ownership of such shares of common stock and warrants, except to the extent of any pecuniary interest therein.

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(17) Includes (i) 1,077,947 shares of common stock and warrants to purchase 301,227 shares of common stock, (ii) 604,090 shares of common stock and warrants to purchase 181,227 shares of common stock held in the name of Clearwater Fund I, L.P., and (iii) 604,090 shares of common stock and warrants to purchase 181,227 shares of common stock held in the name of Clearwater Offshore Fund. Mr. Heye, the President of Clearwater Funds, Inc., the Trading Manager of Clearwater Fund I, L.P. and Clearwater Offshore Fund, Ltd., has voting and investment control over the shares of common stock and warrants held by Clearwater Fund I, L.P. and Clearwater Offshore Fund, Ltd., but disclaims beneficial ownership of such shares and warrants, except to the extent of any pecuniary interest therein.

(18) Includes 137,931 shares of common stock and warrants to purchase 41,379 shares of common stock. Mitchell P. Kopin, President of Downsview Capital, Inc., the General Partner of Cranshire Capital L.P., has sole voting and investment control over the shares of common stock and warrants held by Cranshire Capital, LP but Mr. Koplun disclaims all beneficial ownership of such shares and warrants, except to the extent of any pecuniary interest therein.

(19) Includes 8,621 shares of common stock and warrants to purchase 2,586 shares of common stock.

(20) Includes 225,646 shares of common stock and warrants to purchase 67,693 shares of common stock.

(21) Includes 34,483 shares of common stock and warrants to purchase 10,345 shares of common stock.

(22) Includes 25,916 shares of common stock and warrants to purchase 7,774 shares of common stock.

(23) Includes 15,517 shares of common stock and warrants to purchase 4,655 shares of common stock. Harry Martyn and Anne Martyn, Co-Trustees of the Trust, have voting and investment control over the shares of common stock and warrants held by H. Martyn Group, Ltd. Profit Sharing Plan & Trust, but disclaim beneficial ownership of such shares of common stock and warrants, except to the extent of any pecuniary interest therein. Harry Martyn is an employee of a registered broker-dealer, and as a result, H. Martyn Group, Ltd. Profit Sharing Plan & Trust may be deemed an affiliate of a registered broker-dealer. Accordingly, the selling security holder may be deemed to be an underwriter if it (i) did not acquire the shares of common stock in the ordinary course of business or (ii) had any agreement or understanding, directly or indirectly, with any person to distribute the shares of common stock. H. Martyn Group, Ltd. Profit Sharing Plan & Trust has confirmed to the Company that it acquired the shares of common stock being registered hereunder in the ordinary course of business and does not have any agreement or understanding, directly or indirectly, with any person to distribute such shares of common stock. Please see Plan of Distribution for further disclosure regarding these selling security holders.

(24) Includes 41,379 shares of common stock and warrants to purchase 12,414 shares of common stock. Two groups of persons, collectively comprised of Tim Klefer, Siegfried Klink, Kirsten Meibner-Lange, Stephen Schmitz, Rolf Glasner, Ruth Hartman, Christian Henkgen, Sonia Hermann-Repplinger, Esther Hoffman, Fredy Jungbluth, Wolfram Prenzel, Jörg Schmidt, Charles Simon, Friedhelm Berg, Claud Buchler, Rita Bures, Bettina Chasse, Thomas Dahm, Mireille Doemer, Heinz Heksch has voting and investment control over the shares of common stock and warrants held by Hauck & Aufhauser Banquiers Luxemborg S.A., and each disclaim beneficial ownership of such shares, except to the extent of pecuniary interest therein. Tim Klefer, Siegfried Klink, Kirsten Meibner-Lange, Stephen Schmitz, Rolf Glasner, Ruth Hartman and Christian Henkgen are in Group A and Sonja Hermann-Repplinger, Ester Hoffmann, Fredy Jungbluth, Wolfram Prenzel, Jörg Schmidt, Charles Simon, Friedwilm Berg, Claude Buchler, Rita Bures, Bettina Chasse, Thomas Dahm, Mireille Doemer, and Heinz Heksch make up Group B. Any two persons in Group A have voting and investment control, and any person in Group B, in conjunction with any person in Group A has voting and investment control.

(25) Includes (i) 194,483 shares of common stock and warrants to purchase 58,345 shares of common stock, (ii) 232,414 shares of common stock and warrants to purchase 69,724 shares of common stock held in the name of Harewood Nominees Ltd. A/C 468900, and (iii) 59,310 shares of common stock and warrants to purchase 17,793 shares of common stock held in the name of Harewood Nominees Ltd. A/C 4721300. Harewood Nominees Ltd. A/C 4689000 and Harewood Nominees Ltd. A/C 4721300 are the nominees of AMP Enhanced Index International Share Fund and Witan Investment Trust, respectively. Harewood Nominees are the appointed custodian for Henderson Global Investors. Robert Villiers, Fund Manager of Henderson North American Multi-Strategy Fund, has voting and investment control over the shares of common stock and warrants, but disclaims beneficial ownership of such shares and warrants, except to the extent of any pecuniary interest therein.

(26) Includes 353,318 shares of common stock and warrants to purchase 117,158 shares of common stock.

(27) Includes 177,464 shares of common stock and warrants to purchase 95,685 shares of common stock. Mr. Lobell, a director of the Company, is an employee of Paramount BioCapital, Inc., a registered broker-dealer, and as a result, Mr. Lobell may be deemed an affiliate of a registered broker-dealer. Accordingly, the selling security holder may be deemed to be an underwriter if he (i) did not acquire the shares of common stock in the ordinary course of business or (ii) had any agreement or understanding, directly or indirectly, with any person to distribute the shares of common stock. Mr. Lobell has confirmed to the Company that he acquired the shares of common stock being registered hereunder in the ordinary course of business and he does not have any agreement or understanding, directly or indirectly, with any person to distribute such shares of common stock. Please see Plan of Distribution for further disclosure regarding these selling security holders.





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(28) Includes 399,818 shares of common stock and warrants to purchase 54,245 shares of common stock.

(29) Includes 86,207 shares of common stock and warrants to purchase 25,862 shares of common stock. W. Lewis Austin IV, General Partner of Lewis Opportunity Fund, L.P., has voting and investment control over the shares of common stock and warrants to purchase common stock held by Lewis Opportunity Fund, L.P., but disclaims beneficial ownership of such shares and warrants, except to the extent of any pecuniary interest therein. Lewis Opportunity Fund, L.P. is under common control of one or more registered broker-dealers, none of whom are participating in this offering in any manner, and as a result, Lewis Opportunity Fund, L.P. may be deemed to be an affiliate of a registered broker-dealer.

Accordingly, the selling security holder may be deemed an underwriter if it (i) did not acquire the shares of common stock in the ordinary course of business or (ii) had any agreement or understanding, directly or indirectly, with any person to distribute such shares of common stock. Lewis Opportunity Fund, L.P. has confirmed to the Company that it acquired the shares of common stock being registered hereunder in the ordinary course of business and it does not have any agreement or understanding, directly or indirectly, with any person to distribute the shares of common stock. Please see [Plan of Distribution](#) for further disclosure regarding these selling security holders.

(30) Includes 15,823 shares of common stock and warrants to purchase 4,747 shares of common stock. Mr. Chill is an employee of Paramount BioCapital, Inc., a broker-dealer, and as a result, Mr. Chill may be deemed an affiliate of a registered broker-dealer. Accordingly, the selling security holder may be deemed an underwriter if he (i) did not acquire the shares of common stock in the ordinary course of business or (ii) had any agreement or understanding, directly or indirectly, with any person to distribute the shares of common stock. Mr. Chill has confirmed to the Company that he acquired the shares of common stock being registered hereunder in the ordinary course of business and he does not have any agreement or understanding, directly or indirectly, with any person to distribute such shares of common stock. Please see [Plan of Distribution](#) for further disclosure regarding these selling security holders.

(31) Includes 126,582 shares of common stock and warrants to purchase 37,975 shares of common stock. Mrs. MA Egberts Gunning is related to the Company's President and Chief Executive Officer.

(32) Includes 108,276 shares of common stock and warrants to purchase 14,483 shares of common stock.

(33) Includes (i) 213,793 shares of common stock and warrants to purchase 64,138 shares of common stock and (ii) warrants to purchase 117,500 shares of common stock held in the name of Mark Berg, Ms. Berg's husband. Ms. Berg is married to an affiliate of a registered broker-dealer, and as a result, Ms. Berg may be deemed to be an affiliate of a registered broker-dealer. Accordingly, the selling security holder may be deemed an underwriter if she (i) did not acquire the shares of common stock in the ordinary course of business or (ii) had any agreement or understanding, directly or indirectly, with any person to distribute the shares of common stock. Ms. Berg has confirmed to the Company that she acquired the shares of common stock being registered hereunder in the ordinary course of business and she does not have any agreement or understanding, directly or indirectly, with any person to distribute such shares of common stock. Please see [Plan of Distribution](#) for further disclosure regarding these selling security holders.

(34) Includes 165,517 shares of common stock and warrants to purchase 49,655 shares of common stock. Oppenheim Pramerica Asset Management S.a.r.l., is the Manager of FCP OP MEDICAL BioHe@lth-Trends. Dr. Detlef Bierbaum, Dr. Bernd Borgmeir, Dr. Rupert Hengster, Mr. Gabriel Irwin, Mr. Ferdinand-Alexander Leisten., Mr. Stephen Pelletier, Ms. Susan M. Scheader, Mr. John P. Smalling, Mr. Andreas Jockel, Mr. Harry Rosenbaum, Ms. Ute Becker, Mr. Alexander Schulligen, Mr. Max von Frantzius, Mr. Peter Balle, Mr. Thomas Becker, Ms. Julia Brauckmann, Mr. Otmar Gorges, Mr. Detlef Vallender, Mr. Johann Will, Mr. Andreas Becker, Ms. Katja Kirchen, Mr. Ralf Klein, and Ms. Ulrike Sauer of Oppenheim Pramerica Asset Management S.a.r.l have voting and investment control over the shares of common stock and warrants held by FCP OP MEDICAL Bio He@lth-Trends. Oppenheim Pramerica Asset Management S.a.r.l. can be bound by any two signatures of the aforementioned individuals, provided one such signature is from Mr. Bierbaum, Dr. Borgmeir, Dr. Hengster or Mr. Irwin. Oppenheim Pramerica Asset Management S.a.r.l., is an affiliate of a broker-dealer, and as a result, FCP OP MEDICAL Biohe@lth-Trends may be deemed to be an affiliate of a broker-dealer. Accordingly, the selling security holder may be deemed an underwriter if it (i) did not acquire the shares of common stock in the ordinary course of business or (ii) had any agreement or understanding, directly or indirectly, with any person to distribute the shares of common stock. Oppenheim Pramerica Asset Management S.a.r.l. on behalf of FCP OP MEDICAL BioHea@lth-Trends has confirmed to the Company that it acquired the shares of common stock being registered hereunder in the ordinary course of business and it does not have any agreements or understandings, directly or indirectly, with any other person to distribute such shares of common stock. Please see [Plan of Distribution](#) for further disclosure regarding these selling security holders.

(35) Includes (i) 25,732 shares of common stock and warrants to purchase 8,838 shares of common stock, (ii) 1,068,947 shares of common stock and warrants to purchase 367,184 shares of common stock held in the name of ProQuest Investments II, L.P., and (iii) 4,210,977 shares of common stock and warrants to purchase 1,446,474 shares of common stock held in the name of ProQuest Investments III, L.P. ProQuest Associates III LLC ( Associates III ) is the General Partner of ProQuest Investments III, L.P. ProQuest Associates II LLC ( Associates II ) is the general partner of ProQuest Investments II, L.P. and of ProQuest Investments II Advisors Fund, L.P. Jay Moorin and Alain Schreiber, Managing Members of Associates III and Associates II, have voting, dispositive and investment power with respect to the securities being offered hereunder. Each of Mr. Moorin and Mr. Schreiber disclaim beneficial ownership of such securities except to the extent of each such person's respective pecuniary interest in such securities.

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(36) Includes (i) 1,068,947 shares of common stock and warrants to purchase 367,184 shares of common stock, (ii) 25,732 shares of common stock and warrants to purchase 8,838 shares of common stock held in the name of ProQuest Investments II Advisors Fund L.P., and (iii) 4,210,977 shares of common stock and warrants to purchase 1,446,474 shares of common stock held in the name of ProQuest

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Investments III, L.P. ProQuest Associates III LLC ( Associates III ) is the general partner of ProQuest Investments III, L.P. ProQuest Associates II LLC ( Associates II ) is the general partner of ProQuest Investments II, L.P. and of ProQuest Investments II Advisors Fund, L.P. Jay Moorin and Alain Schreiber, Managing Members of Associates III and Associates II, have voting, dispositive and investment power with respect to the securities being offered hereunder. Each of Mr. Moorin and Mr. Schreiber disclaim beneficial ownership of such securities except to the extent of each such person's respective pecuniary interest in such securities.

(37) Includes (i) 4,210,977 shares of common stock and warrants to purchase 1,446,474 shares of common stock, (ii) 1,068,947 shares of common stock and warrants to purchase 367,184 shares of common stock held in the name of ProQuest Investments II, L.P., and (iii) 25,732 shares of common stock and warrants to purchase 8,838 shares of common stock held in the name of ProQuest Investments II Advisors Fund L.P., ProQuest Associates III LLC ( Associates III ) is the general partner of ProQuest Investments III, L.P. ProQuest Associates II LLC ( Associates II ) is the general partner of ProQuest Investments II, L.P. and of ProQuest Investments II Advisors Fund, L.P. Jay Moorin and Alain Schreiber, Managing Members of Associates III and Associates II, have voting, dispositive and investment power with respect to the securities being offered hereunder. Each of Mr. Moorin and Mr. Schreiber disclaim beneficial ownership of such securities except to the extent of each such person's respective pecuniary interest in such securities.

(38) Includes 105,385 shares of common stock and warrants to purchase 22,817 shares of common stock. Neil Herskowitz and Elliott Herskowitz, joint owners of Riverside Contracting LLC, each have voting and investment control over the shares of common stock and warrants, but each disclaim beneficial ownership of such shares and warrants, except to the extent of any pecuniary interest therein.

(39) Includes (i) 131,034 shares of common stock, (ii) warrants to purchase 36,368 shares of common stock held in the name of Edmund H. Shea, Jr., and (iii) warrants to purchase 25,000 shares of common stock held in the names of Edmund H. Shea, Jr. and Mary Shea. John F. Shea, Peter O. Shea, John Morrissey, Edmund H. Shea, Jr., and Ronald L. Lakey who hold the position of President, Vice-President, Vice-President, Secretary, and Assistant Secretary, respectively, each have voting and investment control over the shares of common stock and warrants held by Shea Diversified Investments, Inc, but disclaim beneficial ownership of such shares and warrants, except to the extent of any pecuniary interest therein.

(40) Includes (i) 655,172 shares of common stock and warrants to purchase 196,552 shares of common stock and (ii) 476,190 shares of common stock and warrants to purchase 83,334 shares of common stock held in the name of South Ferry #2, LP. Morris Wolfson, Portfolio Manager of South Ferry Building Company and South Ferry #2, LP, has voting and investment control over the shares of common stock and warrants held by South Ferry Building Company and South Ferry #2, LP, but disclaims beneficial ownership of such shares and warrants, except to the extent of any pecuniary interest therein.

(41) Includes (i) 103,448 shares of common stock and warrants to purchase 31,034 shares of common stock and (ii) warrants to purchase 50,915 shares of common stock held in the name of Stephen Vermut. Mr. Verumut and Barbara Verumut are the Co-Trustees of the Stephen P. Vermut & Barbara T. Vermut Trust dtd March 2002. Mr. Vermut is an employee of a registered broker-dealer, and as a result, the Stephen P. Vermut & Barbara T. Vermut Trust dtd March 2002 may be deemed an affiliate of a broker-dealer. Accordingly, the selling security holder may be deemed an underwriter if (i) it did not acquire the shares of common stock in the ordinary course of business or (ii) had any agreement or understanding, directly or indirectly, with any person to distribute the shares of common stock. The Stephen P. Vermut & Barbara T. Vermut Trust dtd March 2002 has confirmed to the Company that it acquired the shares of common stock being registered hereunder in the ordinary course of business and it does not have any agreements or understandings, directly or indirectly, with any other person to distribute such shares of common stock. Please see Plan of Distribution for further disclosure regarding these selling security holders.

(42) Includes 129,090 shares of common stock and warrants to purchase 38,727 shares of common stock. Mr. Ratoff is a director of the Company.

(43) Includes (i) 59,310 shares of common stock and warrants to purchase 17,793 shares of common stock; (ii) 194,483 shares of common stock and warrants to purchase 58,345 shares of common stock held in the name of Henderson North American Multi-Strategy Fund; and (iii) 232,414 shares of common stock and warrants to purchase 69,724 shares of common stock held in the name of Harewood Nominees Ltd. A/C 468900. Harewood Nominees Ltd. A/C 4689000 and Harewood Nominees Ltd. A/C 4721300 are the nominees of AMP Enhanced Index International Share Fund and Witan Investment Trust, respectively. Harewood Nominees are the appointed custodian for Henderson Global Investors. Robert Villiers, Fund Manager of Witan Investment Trust, has voting and investment control over the shares of common stock and warrants, but disclaims beneficial ownership of such shares and warrants, except to the extent of any pecuniary interest therein.

(44) Includes warrants to purchase 187,332 shares of common stock. Griffin Securities, Inc. is a registered broker-dealer and is deemed to be an underwriter within the meaning of the Securities Act, in connection with the sale of the foregoing securities. Please see Plan of Distribution for further disclosure regarding these selling security holders.

(45) Includes 5,055,660 shares of common stock and warrants to purchase 7,336,264 shares of common stock. Lindsay A. Rosenwald, M.D. is the Chairman and sole shareholder of Paramount BioCapital. Dr. Rosenwald beneficially owns shares of common stock, and securities exercisable for shares of common stock, equal to approximately 22.0% of the outstanding shares of common stock after giving effect to the

issuance of common stock upon exercise of warrants, options and other convertible securities. Does not include warrants which are convertible into 1,331,424 shares of common stock (the Trust Shares ) and are owned by certain trusts for the benefit of Dr. Rosenwald's children. Dr. Rosenwald is not a trustee of these trusts and disclaims beneficial ownership of the Trust Shares, except to any pecuniary interest therein. Dr. Rosenwald is the Chairman and sole shareholder of Paramount BioCapital, Inc., a registered broker-dealer, and as a result, the selling stockholder may be deemed an underwriter if he (i) did not acquire the shares of common stock in the ordinary course of business or (ii) had any agreement or understanding, directly or indirectly, with any person to distribute the shares of common stock. Dr. Rosenwald has confirmed to the Company that he acquired the shares of common stock in the ordinary course of business and does not have any agreement or understanding, directly or indirectly, with any person to distribute the shares of common stock. Please see Plan of Distribution for further disclosure regarding these selling security holders.

(46) Includes warrants to purchase 135,622 shares of common stock. Scott Katzmann is an employee of Paramount BioCapital, Inc., a registered broker-dealer, and as a result, Mr. Katzman may be deemed an affiliate of a broker-dealer. Accordingly, the selling security holder may be deemed to be an underwriter if he (i) did not acquire the shares of common stock in the ordinary course of business or (ii) had any agreement or understanding, directly or indirectly, with any person to distribute the shares of common stock. Mr. Katzman has confirmed to the Company that he acquired the shares of common stock in the ordinary course of business and does not have any agreement or understanding, directly or indirectly, with any person to distribute the shares of common stock. Please see Plan of Distribution for further disclosure regarding these selling stockholders.

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(47) Includes warrants to purchase 61,224 shares of common stock. Michael Rosenman is an employee of Paramount BioCapital, Inc., a registered broker-dealer, and as a result, Mr. Rosenman may be deemed an affiliate of a broker-dealer. Accordingly, the selling security holder may be deemed an underwriter if he (i) did not acquire the shares of common stock in the ordinary course of business or (ii) had any agreement or understanding, directly or indirectly, with any person to distribute the shares of common stock. Mr. Rosenman has confirmed to the Company that he acquired the shares of common stock being registered hereunder in the ordinary course of business and he does not have any agreements or understandings, directly or indirectly, with any other person to distribute such shares of common stock. Please see [Plan of Distribution](#) for further disclosure regarding these selling security holders.

(48) Includes warrants to purchase 379 shares of common stock. Andrew Miles is an employee of Paramount BioCapital, Inc., a registered broker-dealer, and as a result, Mr. Miles may be deemed an affiliate of a broker-dealer. Accordingly, the selling security holder may be deemed an underwriter if he (i) did not acquire the shares of common stock in the ordinary course of business or (ii) had any agreement or understanding, directly or indirectly, with any person to distribute the shares of common stock. Mr. Miles has confirmed to the Company that he acquired the shares of common stock in the ordinary course of business and he does not have any agreement or understanding, directly or indirectly, with any person to distribute such shares of common stock. Please see [Plan of Distribution](#) for further disclosure regarding these selling security holders.

(49) Includes 64,844 shares of common stock and warrants to purchase 631,206 shares of common stock. Timothy McInerney is an employee of Paramount BioCapital, Inc., a registered broker-dealer, and as a result, Mr. McInerney may be deemed an affiliate of a broker-dealer. Accordingly, the selling security holder may be deemed an underwriter if he (i) did not acquire the shares of common stock in the ordinary course of business or (ii) had any agreement or understanding, directly or indirectly, with any person to distribute the shares of common stock. Mr. McInerney has confirmed to the Company that he acquired the shares of common stock in the ordinary course of business and he does not have any agreement or understanding, directly or indirectly, with any person to distribute such shares of common stock. Please see [Plan of Distribution](#) for further disclosure regarding these selling security holders.

(50) Includes warrants to purchase 14,239 shares of common stock. Harris Lydon is an employee of Paramount BioCapital, Inc., a registered broker-dealer, and as a result, Mr. Lydon may be deemed an affiliate of a broker-dealer. Accordingly, the selling security holder may be deemed an underwriter if he (i) did not acquire the shares of common stock in the ordinary course of business or (ii) had any agreement or understanding, directly or indirectly, with any person to distribute the shares of common stock. Mr. Lydon has confirmed to the Company that he acquired the shares being registered hereunder in the ordinary course of business and at the time of purchase, had no agreements or understandings, directly or indirectly, with any other person to distribute such shares of common stock. Please see [Plan of Distribution](#) for further disclosure regarding these selling security holders.

(51) Includes 472,040 shares of common stock and warrants to purchase 691,231 shares of common stock. Michael Weiser is an employee of Paramount BioCapital, Inc., a registered broker-dealer, and as a result, Mr. Weiser may be deemed an affiliate of a broker-dealer. Accordingly, the selling security holder may be deemed an underwriter if he (i) did not acquire the shares of common stock in the ordinary course of business or (ii) had any agreement or understanding, directly or indirectly, with any person to distribute the shares of common stock. Mr. Weiser has confirmed to the Company that he acquired the shares of common stock in the ordinary course of business and does not have any agreement or understanding, directly or indirectly, with any person to distribute such shares of common stock. Please see [Plan of Distribution](#) for further disclosure regarding these selling security holders.

(52) Includes 32,421 shares of common stock and warrants to purchase 58,111 shares of common stock. John Knox is an employee of Paramount BioCapital, Inc., a broker-dealer, and as a result, Mr. Knox may be deemed an affiliate of a broker-dealer. Accordingly, the selling security holder may be deemed an underwriter if he (i) did not acquire the shares of common stock in the ordinary course of business or (ii) had any agreement or understanding, directly or indirectly, with any person to distribute the shares of common stock. Mr. Knox has confirmed to the Company that he acquired the shares of common stock being registered hereunder in the ordinary course of business and he does not have any agreements or understandings, directly or indirectly, with any other person to distribute such shares of common stock. Please see [Plan of Distribution](#) for further disclosure regarding these selling security holders.

(53) Includes (i) warrants to purchase 2,000 shares of common stock and (ii) warrants to purchase 193,825 shares of common stock held in the name of the Stephen C. Rocamboli April 2005 Irrevocable Trust. Stephen C. Rocamboli is the Trustee of such Trust. Mr. Rocamboli is an employee of Paramount BioCapital, Inc., a registered broker-dealer, and as a result, Mr. Rocamboli may be deemed an affiliate of a registered broker-dealer. Accordingly, the selling security holder may be deemed an underwriter if he (i) did not acquire the shares of common stock in the ordinary course of business or (ii) had any agreement or understanding, directly or indirectly, with any person to distribute the shares of common stock. Mr. Rocamboli has confirmed to the Company that he acquired the shares of common stock in the ordinary course of business and does not have any agreement or understanding, directly or indirectly, with any person to distribute such shares of common stock. Please see [Plan of Distribution](#) for further disclosure regarding these selling security holders.

(54) Includes warrants to purchase 4,000 shares of common stock. Louis Smookler is an employee of Paramount BioCapital, Inc., a registered broker-dealer, and as a result, Mr. Smookler may be deemed an affiliate of a broker-dealer. Accordingly, the selling security holder may be deemed an underwriter if he (i) did not acquire the shares of common stock in the ordinary course of business or (ii) had any agreement or understanding, directly or indirectly, with any person to distribute the shares of common stock. Mr. Smookler has confirmed to the Company that he acquired the shares of common stock in the ordinary course of business and does not have any agreement or understanding, directly or

indirectly, with any person to distribute the shares of common stock. Please see [Plan of Distribution](#) for further disclosure regarding these selling security holders.

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(55) Includes warrants to purchase 21,883 shares of common stock. Basil Christakos is an employee of Paramount BioCapital, Inc., a registered broker-dealer, and as a result, Mr. Christakos may be deemed an affiliate of a broker-dealer. Accordingly, the selling security holder may be deemed an underwriter if he (i) did not acquire the shares of common stock in the ordinary course of business or (ii) had any agreement or understanding, directly or indirectly, with any person to distribute the shares of common stock. Mr. Christakos has confirmed to the Company that he acquired the shares of common stock in the ordinary course of business and does not have any agreement or understanding, directly or indirectly, with any person to distribute such shares of common stock. Please see [Plan of Distribution](#) for further disclosure regarding these selling security holders.

**PLAN OF DISTRIBUTION**

Each selling security holder set forth above and any of their pledgees, assignees and successors-in-interest may, from time to time, sell any or all of its or their shares of common stock on the AMEX (or any of the other following markets or exchanges on which the common stock is listed or quoted for trading on the date in question: the Nasdaq SmallCap Market, the New York Stock Exchange or the Nasdaq National Market) or any other stock exchange, market or trading facility on which the shares are traded or in private transactions. These sales may be at fixed or negotiated prices. Each selling security holder may use any one or more of the following methods when selling shares of common stock:

ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;

block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;

purchases by a broker-dealer as principal and resale by the broker-dealer for its account;

an exchange distribution in accordance with the rules of the applicable exchange;

privately negotiated transactions;

settlement of short sales entered into after the date of this prospectus;

broker-dealers may agree with any one or more selling security holders to sell a specified number of such shares at a stipulated price per share;

a combination of any such methods of sale;

through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise; or

any other method permitted pursuant to applicable law.

The selling security holders may also sell shares of our common stock under Rule 144 promulgated under the Securities Act, if available, rather than under this prospectus.

Broker-dealers engaged by the selling security holders may arrange for other brokers-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the selling security holders (or, if any broker-dealer acts as agent for the purchaser of shares, from the purchaser) in amounts to be negotiated, but, except as set forth in a supplement to this Prospectus, in the case of an agency transaction not in excess of a customary brokerage commission in compliance with NASDR Rule 2440; and in the case of a principal transaction a markup or markdown in compliance with NASDR IM-2440. In connection with the sale of shares of common stock or interests therein, the selling security holders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of shares of common stock in the course of hedging the positions they assume. The selling security holders may also sell shares of the common stock short and deliver these securities to close out their short positions, or loan or pledge the common stock to broker-dealers that in turn may sell such securities. The selling security holders may also enter into option or other transactions with broker-dealers or other financial institutions or the creation of one or more derivative securities which require the delivery to such broker-dealer or other financial institution of shares offered by this prospectus, which shares such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction).

The selling security holders and any broker-dealers or agents that are involved in selling the shares may be deemed to be underwriters within the meaning of the Securities Act in connection with such sales. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the shares purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. Each selling security holders has informed us that it does not have any written or oral agreement or understanding, directly or indirectly, with any person to distribute the shares of common stock. In no event shall any broker-dealer receive fees, commissions and markups which, in the aggregate, would exceed eight percent (8%). At the time a particular offering of the shares of common stock is made, a prospectus supplement, if required, will be distributed which will set forth the aggregate amount of shares of common stock being offered and the terms of the offering, including the name or names of any broker-dealers or agents, any discounts, commissions and other terms constituting compensation from the selling security holders and any discounts, commissions or concessions allowed or reallocated or paid to broker-dealers.

We are required to pay certain fees and expenses incurred by us incident to the registration of the shares registered by this prospectus. We have agreed to indemnify the selling security holders against certain losses, claims, damages and liabilities, including liabilities under the Securities Act.





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Because selling security holders may be deemed to be underwriters within the meaning of the Securities Act, they will be subject to the prospectus delivery requirements of the Securities Act. In addition, any securities covered by this prospectus which qualify for sale pursuant to Rule 144 under the Securities Act may be sold under Rule 144 rather than under this prospectus. Each selling security holder has advised us that it has not entered into any written or oral agreement, understanding or arrangement with any underwriter or broker-dealer regarding the sale of the resale shares. There is no underwriter or coordinating broker acting in connection with the proposed sale of the resale shares by the selling security holders. In addition, under the securities laws of some states, the shares of common stock may be sold in such states only through registered or licensed brokers or dealers. In some states the shares of common stock may not be sold unless such shares have been registered or qualified for sale in such state or an exemption from registration or qualification is available and is complied with.

We have agreed to keep this prospectus effective until the earlier of (i) the date on which the shares may be resold by the selling security holders without registration and without regard to any volume limitations pursuant to Rule 144(k) under the Securities Act or any other rule of similar effect or (ii) all of the shares have been sold pursuant to the prospectus or Rule 144 under the Securities Act or any other rule of similar effect but in any event for no more than two years from the date on which all of the shares of common stock issuable upon exercise of the Warrants and Placement Warrants have been issued. The resale shares will be sold only through registered or licensed brokers or dealers if required under applicable state securities laws. In addition, in certain states, the resale shares may not be sold unless they have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and is complied with.

Under applicable rules and regulations under the Exchange Act, any person engaged in the distribution of the resale shares may not simultaneously engage in market making activities with respect to the shares of common stock for a period of two business days prior to the commencement of the distribution. In addition, the selling security holders will be subject to applicable provisions of the Exchange Act and the rules and regulations thereunder, including Regulation M, which may limit the timing of purchases and sales of shares of the common stock by the selling security holders or any other person. We will make copies of this prospectus available to the selling security holders and have informed them of the need to deliver a copy of this prospectus to each purchaser at or prior to the time of the sale.

There can be no assurance that the selling security holders will sell any or all of the shares of common stock registered pursuant to the Registration Statement, of which this prospectus forms a part.

We shall pay all expenses of the registration of the shares of common stock pursuant to the Registration Rights Agreement; provided, however, that the selling security holders will pay all underwriting discounts or broker or similar commissions, if any. We will indemnify the selling security holders against liabilities, including some liabilities under the Securities Act, in accordance with the registration rights agreements, or the selling security holders will be entitled to contribution. We may be indemnified by the selling security holders against civil liabilities, including liabilities under the Securities Act, that may arise from any written information furnished to us by the selling security holders specifically for use in this prospectus, in accordance with the related registration rights agreement, or we may be entitled to contribution.

Once sold under the Registration Statement, of which this prospectus forms a part, the shares of common stock will be freely tradable in the hands of persons other than our affiliates.

The selling security holders are not restricted as to the price or prices at which they may sell their shares. Sales of the shares may have an adverse effect on the market price of the common stock. Moreover, the selling security holders are not restricted as to the number of shares that may be sold at any time, and it is possible that a significant number of shares could be sold at the same time, which may have an adverse effect on the market price of the common stock.

### LEGAL MATTERS

The validity of the common stock offered hereby will be passed upon for us by Morgan, Lewis & Bockius, LLP, Princeton, New Jersey.

### EXPERTS

The financial statements as of and for the years ended July 31, 2005 and 2004 incorporated by reference in this prospectus and elsewhere in the registration statement have been audited by J.H. Cohn LLP, independent registered public accounting firm, as indicated in their report with respect thereto, and are incorporated by reference in reliance upon the authority of said firm as experts in accounting and auditing.

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### WHERE YOU CAN FIND ADDITIONAL INFORMATION

We file annual, quarterly and special reports, proxy statements and other information with the Commission. You may read and copy any document we file at the Commission's public reference room at 100 F Street, N.E., Room 1580, Washington, D.C. 20549. Please call the Commission at 1-800-SEC-0330 for further information on the public reference rooms. Many of the filings we make with the Commission are also available to the public from the Securities and Exchange Commission's Website at <http://www.sec.gov>. We make available free of charge our annual, quarterly and current reports, proxy statements and other information upon request. To request such materials, please send an e-mail to [mspicer@novadel.com](mailto:mspicer@novadel.com) or contact Michael Spicer, our Chief Financial Officer at our address as set forth above.

We maintain a Website at <http://www.novadel.com> (this is not a hyperlink, you must visit this website through an Internet browser). Our Website and the information contained therein or connected thereto are not incorporated into this Registration Statement.

We have filed with the Commission a Registration Statement (which contains this prospectus) on Form S-3 under the Securities Act. The registration statement relates to the common stock offered by the selling security holders. This prospectus does not contain all of the information set forth in the registration statement and the exhibits and schedules to the registration statement. Please refer to the registration statement and its exhibits and schedules for further information with respect to us and the common stock. Statements contained in this prospectus as to the contents of any contract or other document are not necessarily complete and, in each instance, we refer you to the copy of that contract or document filed as an exhibit to the Registration Statement. You may read and obtain a copy of the registration statement and its exhibits and schedules from the Commission, as described in the preceding paragraph.

### INFORMATION INCORPORATED BY REFERENCE

The Commission allows us to incorporate by reference the information we file with them, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is considered to be part of this prospectus, and information that we file later with the Commission will automatically update and supersede this information. We incorporate by reference the documents filed with Commission listed below:

1. Our Annual Report on Form 10-KSB for the fiscal year ended July 31, 2005, filed on October 31, 2005;
2. Our Proxy Statement for our annual meeting of stockholders, filed on December 27, 2005;
3. Our Quarterly Reports (unaudited) on Form 10-Q for the quarterly periods ended October 31, 2005, filed on December 15, 2005, and January 31, 2006, filed on March 15, 2006;
4. Our Current Reports on Form 8-K and 8K/A filed with the Commission on August 2, 2005, August 12, 2005, September 9, 2005 (only with respect to items 1.01, 1.02, 5.02 and 5.03), September 16, 2005 (only with respect to item 8.01), September 28, 2005 (only with respect to items 1.01, 3.02 and 5.02), October 21, 2005 (only with respect to items 1.02 and 5.02), October 25, 2005 (only with respect to item 8.01), November 8, 2005 (only with respect to item 8.01), November 23, 2005 (only with respect to items 5.02 and 8.01), December 2, 2005, December 15, 2005 (only with respect items 1.01 and 5.02), December 20, 2005, January 13, 2006 (only with respect to item 8.01), January 23, 2006 (only with respect to items 1.01 and 8.01), March 13, 2006 (only with respect to item 8.01), March 22, 2006 (only with respect to item 8.01), April 11, 2006, April 17, 2006, April 20, 2006 and April 28, 2006;
5. The description of our capital stock contained in our Registration Statements on Form 8-A filed with the Commission on November 19, 1997, and May 10, 2004; and
6. All documents we have filed with the Commission pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934 after the date of the initial registration statement and prior to the effectiveness of the registration statement, as well as subsequent to the date of this prospectus and prior to the termination of this offering, shall be deemed to be incorporated by reference into this prospectus and to be a part of this prospectus from the date of the filing of the documents.

You may request a copy of these filings, at no cost, by sending an e-mail to [mspicer@novadel.com](mailto:mspicer@novadel.com) and requesting any one or more of such filings or by contacting Michael Spicer, our Chief Financial Officer at the following address or telephone number: NovaDel Pharma Inc., 25 Minneakoning Road, Flemington, New Jersey 08822, Attention: Chief Financial Officer; (908) 782-3431. Exhibits to the documents will not be sent, unless those exhibits have specifically been incorporated by reference in this prospectus.

This prospectus is part of a registration statement we filed with the Commission. You should rely only on the information contained in this prospectus. We have authorized no one to provide you with different information. We are not making an offer of these securities in any state where the offer is not permitted. You should not assume that the information in this prospectus is accurate as of any date other than the date on the front of the document.



WE HAVE NOT AUTHORIZED ANY DEALER, SALES PERSON OR OTHER PERSON TO GIVE ANY INFORMATION OR TO MAKE ANY REPRESENTATIONS OTHER THAN THOSE CONTAINED IN THIS PROSPECTUS OR ANY PROSPECTUS SUPPLEMENT. THIS PROSPECTUS IS NOT AN OFFER OF THESE SECURITIES IN ANY STATE WHERE AN OFFER IS NOT PERMITTED. THE INFORMATION IN THIS PROSPECTUS IS CURRENT AS OF ITS DATE, REGARDLESS OF THE TIME OF DELIVERY OF THIS PROSPECTUS OR OF ANY SALE OF THE SHARES. YOU SHOULD NOT ASSUME THAT THIS PROSPECTUS IS ACCURATE AS OF ANY OTHER DATE.

**10,988,964**  
**Shares of**  
**Common Stock**

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**PROSPECTUS**

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\_\_\_\_\_, 2006

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## PART II

## INFORMATION NOT REQUIRED IN PROSPECTUS

**Item 14. Other Expenses of Issuance and Distribution.**

The following table sets forth an estimate of the fees and expenses payable by us in connection with the registration of the common stock offered hereby. We shall bear all expenses in connection with the issuance and distribution of the securities being offered hereby, provided that normal commission expenses and brokerage fees are payable individually by the selling security holders. All amounts are estimated except the Commission registration fee.

Commission registration fee	\$	1,930.00
Amex Additional Listing Fee	\$	45,000.00
Accounting fees and expenses	\$	7,500.00
Attorneys fees and expenses	\$	20,000.00
Miscellaneous	\$	10,000.00
Total	\$	84,430.00

**Item 15. Indemnification of Directors and Officers.**

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

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

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

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

**Item 16. Exhibits.**

Exhibit No.	Description
4.1	Form of Warrant issued to certain accredited investors and placement agents (Incorporated by reference to Exhibit 4.1 of our Current Report on Form 8-K, filed April 17, 2006).
5.1 *	Opinion of Morgan, Lewis & Bockius LLP.
10.1	Form of Securities Purchase Agreement by and between the Company and certain accredited investors, with attached schedule of parties and terms thereto (Incorporated by reference to Exhibit 10.1 of our Current Report on Form 8-K, filed April 17, 2006).
10.2	Form of Registration Rights Agreement by and between the Company and certain accredited investors, with attached schedule of parties and terms thereto (Incorporated by reference to Exhibit 10.2 of our Current Report on Form 8-K, filed April 17, 2006).
10.3	Placement Agent Agreement, dated as of March 15, 2006, by and between the Company, Griffin Securities, Inc. and Paramount BioCapital, Inc. (Incorporated by reference to Exhibit 10.1 of our Current Report on Form 8-K, filed April 20, 2006).
23.1 *	Consent of J.H. Cohn LLP
23.2 *	Consent of Morgan, Lewis & Bockius LLP (included in Exhibit 5.1).
24.1	Power of Attorney (included on signature page).

\* Filed herewith.

**Item 17. Undertakings.**

(a) The undersigned registrant hereby undertakes:

- (1) To file, during any period in which it offers or sells securities, a post-effective amendment to this registration statement:
  - (i) to include any prospectus required by section 10(a)(3) of Securities Act of 1933;
  - (ii) to reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or together, represent a fundamental change in the information in the registration statement. Notwithstanding the foregoing, any increase or decrease in the volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the SEC pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than twenty percent change in the maximum aggregate offering price set forth in the Calculation of Registration Fee table in the effective registration statement; and
  - (iii) to include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement; provided, however, that paragraphs (1)(i) and (1)(ii) do not apply if the registration statement is on Form S-3, Form S-8 or Form F-3, and the information required to be included in a post-effective amendment by those paragraphs is contained in periodic reports filed with or furnished to the Commission by the registrant pursuant to Sections 13 or 15(d) of the Exchange Act of 1934 that are incorporated by reference in the registration statement.
- (2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.
- (3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.





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

(c) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the provisions described under Item 15 above, or otherwise, the registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act of 1933 and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act of 1933 and will be governed by the final adjudication of such issue.

**SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements of filing on Form S-3 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized in the City of Flemington, State of New Jersey, on May 11, 2006.

**NOVADEL PHARMA INC.**

By: /s/ Jan H. Egberts

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Jan H. Egberts, M.D.  
President and Chief Executive Officer

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KNOW ALL MEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Jan H. Egberts, M.D., and Michael E. Spicer jointly and severally, his or her true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, for such person in his name, place and stead, in any and all capacities, in connection with the Company's Registration Statement on Form S-3 under the Securities Act of 1933, as amended, including, without limiting the generality of the foregoing, to sign the Registration Statement in the name and on behalf of the Company or on behalf of the undersigned as a director or officer of the Company, and any and all amendments or supplements to the Registration Statement, including any and all stickers and post-effective amendments to the Registration Statement, and to sign any and all additional registration statements relating to the same offering of securities as the Registration Statement that are filed pursuant to Rule 462(b) under the Securities Act of 1933, as amended, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission and any applicable securities exchange or securities self-regulatory body, granting unto said attorneys-in-fact and agents, each acting alone, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or their substitutes or substitute, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, this registration statement has been signed by the following persons in the capacities and on the dates indicated.

Name	Title	Date
<u>/s/ Jan H. Egberts</u> Jan H. Egberts, M.D.	President, Chief Executive Officer <i>(Principal Executive Officer)</i> and Director	May 11, 2006
<u>/s/ Michael E. Spicer</u> Michael E. Spicer	Chief Financial Officer <i>(Principal Financial Officer and Principal Accounting Officer)</i>	May 11, 2006
<u>/s/ Thomas E. Bonney</u> Thomas E. Bonney	Director	May 11, 2006
<u>/s/ William F. Hamilton</u> William F. Hamilton, Ph.D.	Director	May 11, 2006
<u>/s/ J. Jay Lobell</u> J. Jay Lobell	Director	May 11, 2006
<u>/s/ Charles Nemeroff</u> Charles Nemeroff, M.D., Ph.D.	Director	May 11, 2006
<u>/s/ Steven B. Ratoff</u> Steven B. Ratoff	Director	May 11, 2006

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## EXHIBIT INDEX

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