NOVADEL PHARMA INC
Form S-3/A
July 28, 2006
As filed with the Securities and Exchange Commission on July 28, 2006

Registration Statement No. 333-135902

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

AMENDMENT NO. 1

to

FORM S-3

REGISTRATION STATEMENT

UNDER THE SECURITIES ACT OF 1933

NovaDel Pharma Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**2834**	**22-2407152**
(State or other jurisdiction of incorporation or organization)	**(Primary Standard Industrial Classification Code)**	**(I.R.S. Employer Identification No.)**

25 Minneakoning Road

Flemington, NJ 08822

(908) 782-3431

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

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)

Copies to:

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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.

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

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, 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

EXPLANATORY NOTE

This Amendment No. 1 to the Registration Statement on Form S-3 (File No. 333-135902) is filed solely for the purpose of filing the exhibits attached hereto. Except as described above, there have been no other material changes to the Registration Statement on Form S-3 (File No. 333-135902).

The information in this prospectus is not complete and may be changed or amended. We 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 July 28, 2006

Prospectus

14,000,000

SHARES OF COMMON STOCK

We may offer and sell, from time to time, up to 14,000,000 shares of our common stock, $0.001 par value per share. Specific terms of these offerings will be provided in supplements to this prospectus. You should read this prospectus and any supplement carefully before you invest.

We may offer our common stock in one or more offerings in amounts, at prices, and on terms determined at the time of the offering. We may sell our common stock through agents we select or through underwriters and dealers we select. If we use agents, underwriters or dealers, we will name them and describe their compensation in a prospectus supplement. We will receive all proceeds from the sale of securities hereunder.

Our common stock is listed for trading on the American Stock Exchange, AMEX, under the symbol NVD. On July 26, 2006, the closing sales price for our common stock on the AMEX was $1.11 per share.

INVESTING IN OUR COMMON STOCK INVOLVES A HIGH DEGREE OF RISK. YOU SHOULD READ THE RISK FACTORS SECTION BEGINNING ON PAGE 8 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

The following is only a summary. We urge you to read the entire prospectus, including the more detailed financial statements (including the accompanying notes) and other information included herein or incorporated by reference from our other filings with the SEC. In this prospectus, the terms company, we, us, and our refer to NovaDel Pharma Inc.

This prospectus is part of a shelf registration statement that we filed with the Securities and Exchange Commission, the SEC. By using a shelf registration statement, we may sell our common stock, as described in this prospectus, from time to time in one or more offerings, up to a total of 14,000,000 shares of our common stock, $0.001 par value per share. Each time we sell our common stock, we will provide a supplement to this prospectus that contains specific information about the terms of such offering. The supplement may also add, update or change information contained in this prospectus if there is any inconsistency between the information in the prospectus and any prospectus supplement, you should rely upon the information in the prospectus supplement. Before purchasing any of our common stock, you should carefully read both this prospectus and any supplement, together with the additional information incorporated into this prospectus or described under the heading Where You Can Find More Information, beginning on page 26.

You should rely only on the information contained or incorporated by reference in this prospectus and any supplement. We have not authorized any other person to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. We will not make an offer to sell our common stock in any jurisdiction where the offer or sale is not permitted. You should assume that the information appearing in this prospectus, as well as information we previously filed with the SEC and have incorporated by reference, is accurate as of the date on the front cover of this prospectus only. Our business, financial condition, results of operations and prospects may have changed since that date.

We will not use this prospectus to offer and sell our common stock unless it is accompanied by a supplement that more fully describes the terms of the offering.

About NovaDel

NovaDel Pharma Inc. is an emerging specialty pharmaceutical company that is developing and commercializing oral spray therapeutics to fulfill unmet medical needs predominately focused on neurology. We are engaged in the development of novel application drug delivery systems for presently marketed prescription, over-the-counter, or OTC, and veterinary drugs. Our patented and patent-pending delivery system is an oral spray potentially enabling drug absorption through the oral mucosa, increasing the benefits of clinically proven compounds, including more rapid absorption into the bloodstream than presently available oral delivery systems. Our proprietary delivery system potentially enhances and accelerates the onset of the therapeutic benefits within minutes of administration. Our development efforts for our novel drug delivery system are concentrated on making it available for drugs that are already available and proven in the marketplace.

Since inception, substantially all of our revenues have been derived from consulting activities, primarily in connection with product development for various pharmaceutical companies. More recently, we have begun to derive revenues from license fees and milestone payments stemming from our partnership agreements. Our future growth and profitability will be principally dependent upon our ability to successfully develop our products and to market and distribute the final products either internally or with the assistance of a strategic partner.

Recent highlights include the following product development and business achievements:

- Completed two pre-Investigational New Drug Application, or IND, meetings with the Food and Drug Administration, FDA, including meetings for our sumatriptan (Imitrex®) and zolpidem (Ambien®) product candidates. In addition, NovaDel participated in a pre-IND meeting with its partner Hana Biosciences, Inc. (Hana Biosciences) for the ondansetron (Zofran®) (Zensana) product candidate.

- Filing of IND for ondansetron (Zensana) by our partner, Hana Biosciences.

- Announcement by our partner, Hana Biosciences, of positive study results of a pivotal clinical trial for Zensana Ondansetron Oral Spray, a study which definitively demonstrated Zensana 8mg dose is bioequivalent to the current commercially available 8mg tablet (Zofran®).

- Addition of Jan Egberts, M.D. who assumed the positions of President and Chief Executive Officer on December 23, 2005 and Chairman of the Board of Directors on January 17, 2006.

- Issuance of two patents by the U.S. Patent and Trademark Office and one additional patent in Canada that further strengthens our intellectual property position in the oral delivery of pharmaceuticals. The issued patents cover the use of multiple classes of drugs in oral sprays, including those for the treatment of pain, central nervous system disorders, and for anesthesia under our oral spray delivery system.

- Completion of a private placement of our common stock, raising gross proceeds of approximately $11.8 million.

- Receipt of notice from the FDA indicating acceptance of our New Drug Application, or NDA, submission for our nitroglycerin lingual spray (NitroMist) as a complete response and an indicated target of early November 2006 for action on the submission.

- Filing of NDA for ondansetron (Zensana) by our partner, Hana Biosciences.

Drug development in the United States and most countries throughout the world is a process that includes several steps defined by the FDA and similar regulatory authorities in foreign countries. The FDA approval processes relating to new drugs differ, depending on the nature of the particular drug for which approval is sought. With respect to any drug product with active ingredients not previously approved by the FDA, a prospective drug manufacturer is required to submit a New Drug Application, or 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 Investigational New Drug Application, or IND, pursuant to which permission is sought to begin preliminary clinical testing of the new drug. An NDA, based on published safety and efficacy studies conducted by others, may also be required to be submitted for a drug product with a previously approved active ingredient if the method of delivery, strength or dosage form is changed. We believe that our current product candidates will require the submission of an NDA, which will 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 our pharmaceutical product candidates, including formulation, testing and obtaining FDA approval, generally takes two to three years for the 505(b)(2) NDA process and requires approximately $3 million to $5 million of direct research and development expenditures. 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, and research and development expenditures may significantly exceed management s expectations.

It is not anticipated that we will generate any revenues from royalties or sales of our product candidates until regulatory approvals are obtained and marketing activities begin. Any one or more of our product candidates may not prove to be commercially viable, or if viable, may not reach the marketplace on a basis consistent with our desired timetables, if at all. 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.

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The successful development of our product candidates is highly uncertain. Estimates of the nature, timing and estimated expenses of the efforts necessary to complete the development of, and the period in which material net cash inflows are expected to commence from, any of our product candidates are subject to numerous risks and uncertainties, including:

- the scope, rate of progress and expense of our clinical trials and other research and development activities;
- results of future clinical trials;
- the expense of clinical trials for additional indications;
- the terms and timing of any collaborative, licensing and other arrangements that we may establish;
- the expense and timing of regulatory approvals;
- the expense of establishing clinical and commercial supplies of our product candidates and any products that we may develop;
- the effect of competing technologies and market developments; and
- the expense of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

We expect to continue to spend significant amounts on the development of our product candidates and we expect our costs to increase as we continue to develop and ultimately commercialize our product candidates. Over the next fiscal year, we expect to devote the majority of our 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., or Par, who has exclusive rights to market, sell and distribute NitroMist in the United States and Canada. On June 1, 2005, we received an approvable letter from the FDA regarding our NDA for NitroMist . The FDA is not requiring any additional clinical studies for approval, but has requested that we complete certain manufacturing process validation commitments. On April 30, 2006, we submitted the necessary documentation to the FDA for the process validation commitments. On May 26, 2006, we announced that the FDA has accepted our submission regarding our NDA as a complete response and that the FDA indicated a target of early November 2006 for action on the submission. We will receive a milestone payment from Par should final approval from the FDA be obtained. In addition, we will receive royalty payments based upon a percentage of net sales.

- Zolpidem oral spray. Zolpidem is the active ingredient in Ambien®, the leading hypnotic marketed by Sanofi-Aventis. We are currently targeting a NDA submission for our zolpidem product candidate in the first half of calendar 2007. If this timeline is met, we may obtain final approval from the FDA in calendar 2008.

Sumatriptan oral spray. Sumatriptan is the active ingredient in Imitrex® which is the largest selling migraine remedy marketed by GlaxoSmithKline (GSK). We are currently targeting a NDA submission for our sumatriptan product candidate in the second half of calendar 2007. If this timeline is met, we may obtain final approval from the FDA in calendar 2008.

Additional Product Candidates. We have identified a number of additional product candidates for which we have recently commenced preliminary development activities. At least two of those candidates are targeted to the neurology market.

We will also support our partners, as necessary, with the following product candidates and opportunities although we do not expect to devote 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. In January 2006, Hana Biosciences announced positive study results of a pivotal clinical trial for Zensana . Hana Biosciences submitted its NDA in the second quarter of calendar 2006. Hana Biosciences is currently targeting final approval from the FDA and commercial launch in calendar 2007. We will receive milestone payments from Hana Biosciences should the following regulatory events occur: (i) acceptance of the NDA for review by the FDA and (ii) final approval from the FDA. In addition, we will receive royalty payments based upon a percentage of net sales.

Propofol oral spray. Propofol is the active ingredient in Diprivan®, the world s leading intravenous anesthetic marketed by AstraZeneca. We continue to support our partner, Manhattan Pharmaceuticals, Inc., or Manhattan Pharmaceuticals, who will oversee all clinical development and regulatory approval for this product. Our partner has not provided guidance regarding the clinical and regulatory development plan for this product candidate.

Our veterinary initiatives are being carried out largely by our partner, Velcera Pharmaceuticals, Inc. (Velcera). Our partner has not provided guidance regarding the clinical and regulatory development plan for the potential veterinary product candidates.

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.

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. We maintain a website at www.novadel.com.

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 that is developing and commercializing oral spray therapeutics to fulfill unmet medical needs predominately focused on neurology. 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. The filing of an NDA with the FDA is an important step in the approval process in the United States. Acceptance for filing by the FDA does not mean that the NDA has been or will be approved, nor does it represent an evaluation of the adequacy of the data submitted.

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

We had an accumulated deficit as of April 30, 2006 of approximately $41.9 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 $7.5 million for the nine months ended April 30, 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 to us 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. On April 19, 2006, we completed an equity financing in which we received gross proceeds of $11.8 million and approximate net proceeds of $10.6 million. Such net proceeds reflect offering costs incurred through April 30, 2006. We will incur additional offering costs which will reduce the amount of net proceeds. Although we expect to have sufficient cash to fund our operations through July 31, 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 will 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 , on June 21, 2004, which was accepted for filing by the FDA on September 29, 2004. We received a Prescription Drug User Fee Act, or PDUFA, date of June 4, 2005, for NitroMist , and received an approvable letter from the FDA on June 1, 2005. In the June 1, 2005 letter, the FDA requested that we complete certain manufacturing process validation commitments. On April 30, 2006, we submitted the necessary documentation to the FDA for the process validation commitments. On May 26, 2006, we announced that the FDA has accepted our submission regarding our NDA as a complete response and that the FDA indicated a target of early November 2006 for action on the submission. NitroMist is a trademark of Par.

Our partner in North America, Hana Biosciences, for our ondansetron oral spray product candidate is overseeing all clinical development and regulatory approval activities. In January 2006, Hana Biosciences announced positive study results of a pivotal clinical trial for Zensana . Hana Biosciences submitted its NDA in the second quarter of calendar 2006. Hana Biosciences is currently targeting final approval from the FDA and commercial launch in calendar 2007.

We completed pharmacokinetic studies of our certain product candidates during late calendar year 2004 and early calendar year 2005. These products are oral spray formulations of ondansetron, sumatriptan, 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, an alprazolam 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 these product candidates has been put on hold.

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. 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 16% 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, or the 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 American Stock Exchange, or 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 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 or 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 and 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 COMMERCIALLY AVAILABLE PRODUCTS.

Our principal efforts are the development of, and obtaining regulatory approvals for, our proposed products. We anticipate that marketing activities for our proprietary products, whether by us or one or more of our licensees, if any, will not begin until the second half of calendar 2006 or the first half of calendar 2007 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 the second half of calendar 2006 or the first half of calendar 2007 at the earliest. 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.

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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, Manhattan, Velcera 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, or 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.

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.

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 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 SEC and 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.

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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 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 Biotechnology Corporation 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. Sosei Co. Ltd. is 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, or 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 a 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 Abbreviated New Drug Application, or 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 filing of an NDA with the FDA is an important step in the approval process in the United States. Acceptance for filing by the FDA does not mean that the NDA has been or will be approved, nor does it represent an evaluation of the adequacy of the data submitted.

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.

We expect to continue to spend significant amounts on the development of our product candidates and we expect our costs to increase as we continue to develop and ultimately commercialize our product candidates. Over the next fiscal year, we expect to devote 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, who has exclusive rights to market, sell and distribute NitroMist in the United States and Canada. On June 1, 2005, we received an approvable letter from the FDA regarding our NDA for NitroMist . The FDA requested that we complete certain manufacturing process validation commitments. On April 30, 2006, we submitted the necessary documentation to the FDA for the process validation commitments. On May 26, 2006, we announced that the FDA has accepted our submission regarding our NDA as a complete response and that the FDA indicated a target of early November 2006 for action on the submission. We will receive a milestone payment from Par should final approval from the FDA be obtained. In addition, we will receive royalty payments based upon a percentage of net sales.

Zolpidem oral spray. Zolpidem is the active ingredient in Ambien®, the leading hypnotic marketed by Sanofi-Aventis. We are currently targeting a NDA submission for our zolpidem product candidate in the first half of calendar 2007. If this timeline is met, we may obtain final approval from the FDA in calendar 2008.

Sumatriptan oral spray. Sumatriptan is the active ingredient in Imitrex® which is the largest selling migraine remedy marketed by GSK. We are currently targeting a NDA submission for our sumatriptan product candidate in the second half of calendar 2007. If this timeline is met, we may obtain final approval from the FDA in calendar 2008.

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

We will also support our partners, as necessary, with the following product candidates and opportunities although we do not expect to devote 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. In January 2006, Hana Biosciences announced positive study results of a pivotal clinical trial for Zensana . Hana Biosciences submitted its NDA in the second quarter of calendar 2006. Hana Biosciences is currently targeting final approval from the FDA and commercial launch in calendar 2007. We will receive milestone payments from Hana Biosciences should the following regulatory events occur: (i) acceptance of the NDA for review by the FDA and (ii) final approval from the FDA. In addition, we will receive royalty payments based upon a percentage of net sales.

Propofol oral spray. Propofol is the active ingredient in Diprivan®, the world s leading intravenous anesthetic marketed by AstraZeneca. We continue to support our partner, Manhattan Pharmaceuticals, who will oversee all clinical development and regulatory approval for this product. Our partner has not provided guidance regarding the clinical and regulatory development plan for this product candidate.

Our veterinary initiatives are being carried out largely by our partner, Velcera. Our partner has not provided guidance regarding the clinical and regulatory development plan for the potential veterinary product candidates.

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.

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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 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 pursuant to which Par 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 eight 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 announced that they would not be renewing the employment contract of Dr. Gary A. 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 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 would no longer serve as Head of Pharmaceutical Sciences.

On November 22, 2005, we announced that Board 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 our 2006 annual meeting of stockholders. Mr. Savage served as a director since 2004 and as our non-executive Chairman of the Board since September 2, 2005.

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

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

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 our 2006 annual stockholders meeting. Dr. Kessel served as a director since March 2003.

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

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 our 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.

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

The market price of our 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 our 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 June 30, 2006, the closing price of our common stock has ranged from $1.09 to $1.90. 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 June 30, 2006, the average daily trading volume in our common stock was approximately 72,211 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 SEC 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 SEC 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 SEC, 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 July 1, 2006, there were 49,025,869 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 July 1, 2006, we had outstanding stock options and warrants to purchase approximately 30.6 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 our stock options and corresponding plans:

Plan	Shares Authorized	Options Outstanding at July 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	2,595,000	510,000	
2006 Equity Incentive Plan	6,000,000	450,000	5,550,000	
Non-Plan	n/a	4,976,000		

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 herein. 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. We presently have no issued and outstanding shares of preferred stock and while we have no present plans to issue any shares of preferred stock, our Board has the authority, without stockholder approval, to create and issue one or more series of such preferred stock and to determine the voting, dividend and other rights of holders of such preferred stock. The issuance of any of such series of preferred stock may have an adverse effect on the holders of 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 April 2006, we sold securities in a private placement transaction resulting in the issuance of 8,092,796 shares of our common stock, and warrants to purchase 2,896,167 shares of our common stock. The sale of the shares of common stock and warrants resulted in gross proceeds to us of approximately $11.8 million. In May 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 us 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 currently effective registration statements filed by us 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 us and the industry in which we participate; and

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.

As of July 1, 2006, we have 49,025,869 shares of common stock issued and outstanding and 30,590,737 million shares of common stock issuable upon the exercise of outstanding stock options and warrants. In the event we wish to offer and sell shares of our common stock in excess of the 100,000,000 shares of common stock currently authorized by our certificate of incorporation, we will first need to receive stockholder approval. Such stockholder approval has the potential to adversely affect the timing of any potential transactions.

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 agreements 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 registration statements were declared effective on July 28, 2005 and May 30, 2006 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 receive all of the net proceeds from the sale of our securities registered under the registration statement of which this prospectus is a part. We will retain broad discretion over the use of the net proceeds from the sale of our common stock offered hereby. Except as described in any prospectus supplement, we currently intend to use the net proceeds from the sale of our common stock under this prospectus for clinical trials, research and development, sales and marketing and general and administrative expenses. We may also use a portion of the net proceeds to acquire or invest in businesses, products and technologies that are complementary to our own. We have not determined the amount of net proceeds to be used for each of the specific purposes indicated. The amounts and timing of expenditures may vary significantly depending upon our numerous factors, including progress of our research and development efforts or the competitive environment for our products. Accordingly, we will have broad discretion to use the proceeds as we see fit.

DESCRIPTION OF SECURITIES TO BE REGISTERED

General

Our certificate of incorporation, as amended and restated to date, authorized the issuance of up to 100,000,000 shares of common stock, par value $0.001 per share, and 1,000,000 shares of blank check preferred stock, par value $0.001 per share. As of July 1, 2006, there were 49,025,869 shares of our common stock and no shares of preferred stock issued and outstanding.

Common Stock

Voting. The holders of our common stock are entitled to one vote for each outstanding share of common stock owned by that stockholder on every matter properly submitted to the stockholders for their vote. Stockholders are not entitled to vote cumulatively for the election of directors.

Dividend Rights. Subject to the dividend rights of the holders of any outstanding series of preferred stock, holders of our common stock are entitled to receive ratably such dividends and other distributions of cash or any other right or property as may be declared by our Board out of our assets or funds legally available for such dividends or distributions. 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.

Liquidation Rights. In the event of any voluntary or involuntary liquidation, dissolution or winding up of our affairs, holders of our common stock would be entitled to share ratably in our assets that are legally available for distribution to stockholders after payment of liabilities. If we have any preferred stock outstanding at such time, holders of the preferred stock may be entitled to distribution and/or liquidation preferences. In either such case, we must pay the applicable distribution to the holders of our preferred stock (if any) before we may pay distributions to the holders of common stock.

Conversion, Redemption and Preemptive Rights. Holders of our common stock have no conversion, redemption, preemptive, subscription or similar rights.

Preferred Stock

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

The purpose of authorizing our Board to issue preferred stock and determine its rights and preferences is to eliminate delays associated with a stockholder vote on specific issuances. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions, future financings and other corporate purposes, could have the effect of making it more difficult for a third party to acquire, or could discourage a third party from seeking to acquire, a majority of our outstanding voting stock. There are no shares of preferred stock outstanding and we have no present plans to issue any shares of preferred stock.

Warrants

As of July 1, 2006, we had warrants to purchase approximately 22.4 million shares of our common stock outstanding as follows:

Class B Warrants. We have 1,050,118 outstanding Class B Warrants with a weighted average exercise price equal to $1.92 per share. The Class B Warrants expire in April and May of 2008, and contain certain demand and piggyback registration rights. The Class B Warrants are exercisable in whole or in part, subject to any applicable law, rule or regulation. The exercise price of the Class B Warrants and the number of shares issuable upon exercise of the Class B Warrants are subject to adjustment for certain dilution events.

Class C Warrants. We have 3,671,256 outstanding Class C Warrants with an exercise price equal to $1.40 per share. Further, Paramount and/or its designees, hold unit purchase options exercisable for 1,307,040 shares of our common stock and 399,082 Class C Warrants. The aggregate purchase price per unit is approximately $1.16. The Class C Warrants expire in December 2008 and January 2009, and contain certain demand and piggyback registration rights. The Class C Warrants will be exercisable in whole or in part subject to any applicable law, rule or regulation. The exercise price of the Class C Warrants and the number of shares issuable upon exercise of the Class C Warrants are subject to adjustment for certain dilution events.

Class D Warrants. We have 2,693,209 outstanding Class D Warrants with an exercise price equal to $1.30 per share. The Class D Warrants expire in November of 2010. The Class D Warrants are exercisable in whole or in part and may be exercised on a cashless basis, subject to any applicable law, rule or regulation. The exercise price of the Class D Warrants and the number of shares issuable upon exercise of the Class D Warrants are subject to adjustment in the event of stock dividends or splits, or similar transactions, and pro rata distributions by us to all holders of our common stock.

Class E Warrants. We have 2,896,167 outstanding Class E Warrants with an exercise price equal to $1.60 per share. The Class E Warrants expire in October of 2011. The Class E Warrants are exercisable in whole or in part and may be exercised on a cashless basis, subject to any applicable law, rule or regulation. The exercise price of the Class E Warrants and the number of shares issuable upon exercise of the Class E Warrants are subject to adjustment in the event of stock dividends or splits, or similar transactions, and pro rata distributions by us to all holders of our common stock.

Other Warrants. We have 10,373,158 outstanding other warrants with a weighted average exercise price equal to $0.52 per share. Such other warrants are exercisable in whole or in part and may be exercised on a cashless basis, subject to any applicable law, rule or regulation. As of July 1, 2006, such other warrants had a weighted average remaining contractual term of 2.6 years.

Options

As of July 1, 2006, options to purchase 8,200,701 shares of our common stock were outstanding at a weighted average exercise price of $1.64 per share, of which options to purchase 4,759,278 shares were exercisable. As of that date, an additional 510,000 shares of our common stock were available for issuance under our 1998 Stock Option Plan and 5,550,000 shares were available for issuance under our 2006 Equity Incentive Plan.

Registration Rights

Holders of approximately 41.2 million shares of our common stock, and warrants to purchase our common stock, listed as selling stockholders in our currently effective registration statements on Form SB-2 (SEC File Nos. 333-86262, 333-107122 and 333-112852), are entitled to cause us to register for resale all of the shares of our common stock owned by or issuable to these selling stockholders in the event that such registration statements are unavailable to sell all of the registrable shares of our common stock.

Delaware Takeover Statute

In general, Section 203 of the Delaware General Corporation Law prohibits a Delaware corporation that is a public company from engaging in any business combination (as defined below) with any interested stockholder (as defined below) for a period of three years following the date that such stockholder became an interested stockholder, unless: (1) prior to such date, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder; (2) on consummation of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the number of shares of voting stock outstanding (but not the outstanding voting stock owned by the interested stockholder) those shares owned (x) by persons who are directors and also officers and (y) by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or (3) on or subsequent to such date, the business combination is approved by the board of directors and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at lease 66 2/3% of the outstanding voting stock that is not owned by the interested stockholder.

Section 203 of the Delaware General Corporation Law defines a business combination to include, among other things, a merger or consolidation involving us, and the interested stockholder and the sale of more than 10% of our assets. In general, an interested stockholder is any entity or person beneficially owning 15% or more of our outstanding voting stock and any entity or person affiliated with or controlling or controlled by such entity or person.

Transfer Agent And Registrar

The transfer agent and registrar for our common stock is American Stock Transfer & Trust Company.

American Stock Exchange

Our common stock is listed on the American Stock Exchange under the symbol NVD.

PLAN OF DISTRIBUTION

We may sell the common stock covered by this prospectus:

- to or through one or more underwriters or dealers;
- directly to purchasers, or to purchasers through agents; or
- through a combination of any of these methods of sale.

We may distribute the common stock offered hereby;

- from time to time in one or more transactions at a fixed price or prices, which may be changed from time to time;
- at market prices prevailing at the times of sale;
- at prices related to such prevailing market prices; or
- at negotiated prices.

We will describe the method of distribution of the securities in the applicable prospectus supplement.

We may determine the price or other terms of the common stock offered under this prospectus by use of an electronic auction. We will describe how any auction will determine the price or any other terms, how potential investors may participate in the auction and the nature of the obligations of the underwriter, dealer or agent in the applicable prospectus supplement.

Underwriters, dealers or agents may receive compensation in the form of discounts, concessions or commissions from us or our purchasers (as their agents in connection with the sale of the common stock). In addition, underwriters may sell common stock to or through dealers, and those dealers may receive compensation in the form of discounts, concessions or commissions from the underwriters and/or commissions from the purchasers for whom they act as agent. These underwriters, dealers or agents may be considered to be underwriters under the Securities Act. As a result, discounts, commissions, or profits on resale received by the underwriters, dealers or agents may be treated as underwriting discounts and commissions. Each applicable prospectus supplement will identify any such underwriter, dealer or agent, and describe any compensation received by them from us. Any initial public offering price and any discounts or concessions allowed or reallowed or paid to dealers may be changed from time to time.

We may enter into agreements that provide for indemnification against certain civil liabilities, including liabilities under the Securities Act, or for contribution with respect to payments made by the underwriters, dealers or agents and to reimburse these persons for certain expenses.

We may grant underwriters who participate in the distribution of the common stock an option to purchase additional shares of common stock to cover over-allotments, if any, in connection with the distribution. Underwriters or agents and their associates may be customers of, engage in transactions with, or perform services for us in the ordinary course of business.

In connection with the offering of the common stock, certain underwriters and selling group members and their respective affiliates, may engage in transactions that stabilize, maintain or otherwise affect the market price of the common stock. These transactions may include stabilization transactions effected in accordance with Rule 104 of Regulation M promulgated by the SEC pursuant to which these persons may bid for or purchase common stock for the purpose of stabilizing its market price.

The underwriters in an offering of the common stock may also create a short position for their account by selling more common stock in connection with the offering than they are committed to purchase from us. In that case, the underwriters could cover all or a portion of the short position by either purchasing common stock in the open market or by exercising any over-allotment option granted to them by us. In addition, any managing underwriter may impose penalty bids under contractual arrangements with other underwriters, which means that they can reclaim from an underwriter (or any selling group member participating in the offering) for the account of the other underwriters, the selling concession for the common stock that are distributed in the offering but subsequently purchased for the account of the underwriters in the open market. Any of the transactions described in this paragraph or comparable transactions that are described in any accompanying prospectus supplement may result in the maintenance of the price of the common stock at a level above that which might otherwise prevail in the open market. None of the transactions described in this paragraph or in an accompanying prospectus supplement are required to be taken by any underwriters and, if they are undertaken, may be discontinued at any time.

LEGAL MATTERS

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

EXPERTS

The financial statements of NovaDel Pharma Inc. 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, and have been incorporated by reference in the Prospectus and elsewhere in the registration statement in reliance upon the authority of said firm as experts in accounting and auditing.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We file annual, quarterly and special reports, proxy statements and other information with the SEC. You may read and copy any document we file at the SEC s public reference room at 100 F Street, N.E., Room 1580, Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the public reference rooms. Many of the filings we make with the SEC are also available to the public from the SEC 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 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 SEC a Registration Statement (which contains this prospectus) on Form S-3 under the Securities Act with respect to the securities offered by this prospectus. This prospectus does not contain all of the information set forth in the Registration Statement and the exhibits and schedules to the Registration Statement. Please refer to the Registration Statement and its exhibits and schedules for further information with respect to us and the common stock. Statements contained in this prospectus as to the contents of any contract or other document are not necessarily complete and, in each instance, we refer you to the copy of that contract or document filed as an exhibit to the Registration Statement. You may read and obtain a copy of the Registration Statement and its exhibits and schedules from the SEC, as described in the preceding paragraph.

INFORMATION INCORPORATED BY REFERENCE

The SEC 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 SEC will automatically update and supersede this information. We incorporate by reference the documents filed with the SEC 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; January 31, 2006, filed on March 15, 2006, and April 30, 2006, filed on June 14, 2006;
4. Our Current Reports on Form 8-K and 8K/A filed with the SEC 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, April 28, 2006, May 15, 2006 (only with respect to item 8.01), May 26, 2006, June 7, 2006 and July 5, 2006;
5. The description of our capital stock contained in our Registration Statements on Form 8-A filed with the SEC on November 19, 1997, and May 10, 2004; and
6. All documents we have filed with the SEC 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 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 SEC. 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.

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 SEC, 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.

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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	$ 1,770
Amex Additional Listing Fee	$ 15,000
Accounting fees and expenses	$ 7,500
Attorneys fees and expenses	$ 20,000
Miscellaneous	$ 10,000
Total	$ 54,270

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 SEC, 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
1.1	+	Form of Underwriting Agreement or other Equity Purchase Agreement.
5.1	*++	Opinion of Morgan, Lewis & Bockius LLP.
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.
\+ To be filed by Post Effective Amendment or by Current Report on Form 8-K, or such other report.
++ The opinion of Morgan, Lewis & Bockius LLP filed herewith supercedes the previously filed opinion of Morgan, Lewis & Bockius.

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 Securities and Exchange Commission, or the Commission, pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 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
    (A) paragraphs (1)(i) and (1)(ii) do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the Commission by the registrant pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934, as amended, that are incorporated by reference in this registration statement; and
    (B) paragraphs (1)(i), (1)(ii) and (1)(iii) do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the Commission by the registrant pursuant to Section 13 or Section 15(d) of the Exchange Act of 1934, as amended, that are incorporated by reference in this registration statement, or is contained in a form of prospectus filed pursuant to Rule 424(b) that is a part of this 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.

(4) That, for the purpose of determining liability under the Securities Act to any purchaser:

(i) If the registrant is relying on Rule 430B:

(A) Each prospectus filed by the registrant pursuant to Rule 424(b)(3) shall be deemed to be part of this registration statement as of the date the filed prospectus was deemed part of and included in this registration statement; and

(B) Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5) or (b)(7) as part of this registration statement or in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii), or (x) for the purpose of providing the information required by Section 10(a) of the Securities Act shall be deemed to be part of and included in this registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of this registration statement relating to the securities in this registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof. Provided, however, that no statement made in this registration statement or prospectus that is part of this registration statement or made in a document incorporated or deemed incorporated by reference into this registration statement or prospectus that is part of this registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in this registration statement or prospectus that was part of this registration statement or made in any such document immediately prior to such effective date; or

(ii) If the registrant is subject to Rule 430C, each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in this registration statement as of the date it is first used after effectiveness. Provided, however, that no statement made in this registration statement or prospectus that is part of this registration statement or made in a document incorporated or deemed incorporated by reference into this registration statement or prospectus that is part of this registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in this registration statement or prospectus that was part of this registration statement or made in any such document immediately prior to such date of first use.

(5) That, for the purpose of determining liability of the registrant under the Securities Act to any purchaser in the initial distribution of the securities:

The undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

(i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;

(ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;

(iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and

(iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

(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) The undersigned registrant hereby undertakes that:

(i) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective; and

(ii) For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus 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.

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

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements of filing on Form S-3 and has duly caused this Amendment No. 1 to the registration statement to be signed on its behalf by the undersigned, thereunto duly authorized in the City of Flemington, State of New Jersey, on July 28, 2006.

NOVADEL PHARMA INC.

By: /s/ Jan H. Egberts
Jan H. Egberts, M.D.
President and Chief Executive Officer

Pursuant to the requirements of the Securities Act of 1933, this Amendment No. 1 to the registration statement has been signed by the following persons in the capacities and on the dates indicated.

Name	**Title**	**Date**
/s/ Jan H. Egberts Jan H. Egberts, M.D.	President, Chief Executive Officer and Director *(Principal Executive Officer)*	July 28, 2006
/s/ Michael E. Spicer Michael E. Spicer	Chief Financial Officer *(Principal Financial Officer and Principal Accounting Officer)*	July 28 , 2006
* Thomas E. Bonney	Director	July 28, 2006
* William F. Hamilton, Ph.D.	Director	July 28, 2006
* J. Jay Lobell	Director	July 28, 2006
* Charles Nemeroff, M.D., Ph.D.	Director	July 28, 2006
* Steven B. Ratoff	Director	July 28, 2006

*By: /s/ Michael E. Spicer

Michael E. Spicer
Attorney-In-Fact

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