

NOVADEL PHARMA INC

Form S-3

January 18, 2007

As filed with the Securities and Exchange Commission on January 18, 2007

Registration Statement No. 333-

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

WASHINGTON, D.C. 20549

**FORM S-3**

REGISTRATION STATEMENT

UNDER THE SECURITIES ACT OF 1933

**NovaDel Pharma Inc.**

(Exact name of Registrant as Specified in Its Charter)

Delaware  
(State or other jurisdiction of incorporation or  
organization)  
25 Minneakoning Road

2834  
(Primary Standard Industrial  
Classification Code)

22-2407152  
(I.R.S. Employer Identification No.)

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 and Chief Executive Officer

NovaDel Pharma Inc.

25 Minneakoning Road

Flemington, NJ 08822

(908) 782-3431

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

**Copies to:**

Emilio Ragoza, Esq.

Morgan, Lewis & Bockius, LLP

502 Carnegie Center

Princeton, New Jersey 08540

(609) 919-6600

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

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

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

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

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

If 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.

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.

## CALCULATION OF REGISTRATION FEE

<b>Title of Shares To Be Registered</b>	<b>Amount To Be Registered</b>	<b>Proposed Maximum Aggregate Price Per Share</b>	<b>Proposed Maximum Aggregate Offering Price</b>	<b>Amount Of Registration Fee</b>
Common Stock, \$0.001 par value	14,207,935(1)	\$1.55 (2)	\$22,022,300	\$2,360

(1) Includes 4,383,952 shares of common stock that may be issued upon the exercise of warrants held by the selling security holders. Pursuant to Rule 416 of the Securities Act of 1933, as amended, this registration statement shall also cover any additional shares of common stock by reason of any stock dividend, stock split, recapitalization or other similar transaction or to cover such additional shares as may hereinafter be offered or issued to prevent dilution resulting from stock splits, stock dividends, recapitalizations or certain other capital adjustments, effected without the registrant's receipt of consideration, which results in an increase in the number of the outstanding shares of registrant's common stock.

(2) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(c). Such price is based upon the average of the high and low sales prices of the registrant's common stock as reported on the American Stock Exchange on January 16, 2007.

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

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The information in this prospectus is not complete and may be changed or amended. The selling security holders 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 January 18, 2007**

**Prospectus**

**14,207,935**

### **SHARES OF COMMON STOCK**

This prospectus covers resales by certain of our stockholders of up to 14,207,935 shares of our common stock, par value \$0.001 per share, for their own accounts. Of those shares, 4,383,952 are issuable upon the exercise of warrants held by the stockholders at an exercise price of \$1.70 per share. Such stockholders are referred to throughout this prospectus as selling security holders.

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

Our common stock is listed for trading on the American Stock Exchange, or AMEX, under the symbol NVD. On January 16, 2007, the closing sales price for our common stock on the AMEX was \$1.52 per share.

**INVESTING IN OUR COMMON STOCK INVOLVES A HIGH DEGREE OF RISK. YOU SHOULD READ THE RISK FACTORS SECTION BEGINNING ON PAGE 9 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 \_\_\_\_\_, 2007**

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**TABLE OF CONTENTS**

Prospectus Summary	3
The Offering	6
Risk Factors	7
Special Note Regarding Forward-Looking Statements	25
Use of Proceeds	25
Selling Security Holders	25
Plan of Distribution	31
Legal Matters	32
Experts	32
Where You Can Find Additional Information	32
Information Incorporated by Reference	33

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## PROSPECTUS SUMMARY

### *About This Prospectus*

This prospectus is a part of a registration statement on Form S-3 filed by us with the Securities and Exchange Commission, referred to herein as the SEC, to register 14,207,935 shares of our common stock. This prospectus does not contain all of the information set forth in the registration statement, certain parts of which are omitted in accordance with the rules and regulations of the SEC. Accordingly, you should refer to the registration statement and its exhibits for further information about us and our common stock. Copies of the registration statement and its exhibits are on file with the SEC. Statements contained in this prospectus concerning the documents we have filed with the SEC are not intended to be comprehensive, and in each instance we refer you to the copy of the actual document filed as an exhibit to the registration statement or otherwise filed with the SEC.

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

### *About NovaDel*

NovaDel Pharma Inc., a Delaware corporation, referred to herein as we, us and our, is a specialty pharmaceutical company engaged in the development of novel drug delivery systems for prescription and over-the-counter, or OTC, drugs. Our oral spray therapeutics are administered by a novel application drug delivery system for presently marketed prescription, OTC, and veterinary drugs. This patented and patent-pending delivery system is an oral spray potentially enabling drug absorption through the oral mucosa, potentially 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 proprietary novel drug delivery system are concentrated on making such system available for drugs that are already available and proven in the marketplace. We believe that our proprietary drug delivery system could offer the following significant advantages: (i) more rapid delivery of drugs to the bloodstream allowing for quicker onset of therapeutic effects compared to conventional oral dosage forms; (ii) increased bioavailability of a drug by avoiding metabolism by the liver; (iii) improved drug safety profile by reducing the required dosage, including possible reduction of side-effects; (iv) improved dosage reliability; (v) allowing medication to be taken without water; (vi) avoiding the need to swallow as is the case with many medications; and (vii) improved patient convenience and compliance. Currently, we have eight patents which have been issued in the U.S. and 53 patents which have been issued outside of the U.S. Additionally, we have over 80 patents pending around the world. We look for drug compounds that are off patent or are coming off patent in the near future, and we reformulate these compounds in conjunction with our proprietary drug delivery method. Once reformulated, we file for new patent applications on these reformulated compounds that comprise our product candidates. Our patent portfolio includes patents and patent applications with claims directed to the pharmaceutical formulations, methods of use and methods of manufacturing of a number of our product candidates.

Our goal is to become a leading specialty pharmaceutical company that develops and commercializes improved formulations of existing drugs using our patented oral spray technology. We believe that our technology has application to a broad number of therapeutic areas and product categories. Our strategy is to concentrate our product development activities primarily on pharmaceutical products which meet the following characteristics:

Significant prescription sales already exist;

Our proprietary novel drug delivery technology enhances the performance of the active ingredient of the target compound, potentially addressing unmet patient needs;

Increasing focus on products in targeted therapeutic areas, like, neurology, where the benefits of our technology may apply to multiple target compounds, and where we can achieve distribution with a small specialized sales and marketing group; and

Applicability of an efficient regulatory pathway to approval using the 505(b)(2) pathway.

In today's environment of escalating drug development costs and time to market, we believe that the ability to bring products with some degree of differentiation and competitive advantage to the marketplace in a timely and cost-effective manner is a viable strategy.

We currently have six product candidates in our pipeline. Two of these product candidates, NitroMist and Zensana, are currently licensed to marketing partners who will commercialize these product candidates, with us receiving milestone and royalty income from revenue upon product approval. For our zolpidem oral spray and sumatriptan oral spray, currently in development, we will most likely seek marketing partners to commercialize these product candidates, as their broad distribution will require significant resources. No current marketing partners exist for these product candidates. We expect to secure marketing partners for these product candidates after we have generated sufficient clinical data to demonstrate the effectiveness of these product candidates, and would anticipate that such marketing partners would provide us with milestone payments and royalties based on revenues.

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Our two remaining product candidates, tizanidine and ropinirole, are targeted for a specific therapeutic area: neurology. Among other alternatives, we will consider developing and commercializing these product candidates ourselves, as we believe that the neurology market has the potential to be served with a small, specialized marketing and sales group. If we determine that commercializing these product candidates ourselves is appropriate, we would begin building such sales and marketing infrastructure in conjunction with our clinical development process, such that we will be in a position to begin marketing these products as soon as possible after attaining approval from the Food & Drug Administration, or FDA. In addition to our existing product candidates, we intend to continue to identify and pursue additional product candidates for development.

As discussed above, certain of our product candidates are in early stages of clinical development and some are in preclinical testing. These product candidates are continuously evaluated and assessed and are often subject to changes in formulation and technology. As a result, these product candidates are subject to a more difficult, time-consuming and expensive regulatory path in order to commence and complete the preclinical and clinical testing of these product candidates as compared to other product candidates in later stages of development.

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. We are devoting 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, Inc., or Par, who has exclusive rights to market, sell and distribute NitroMist in the U.S. and Canada. On November 3, 2006, we announced that we received an approval letter from the FDA regarding our New Drug Application, or NDA, for NitroMist. We are currently in the process of working with Par to finalize the commercialization strategy for this product. 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. In October 2006, we announced positive study results of a pharmacokinetic study of our improved oral spray formulation of zolpidem, a study which demonstrated that zolpidem oral spray achieves a statistically significant faster rate of absorption than Ambien® tablets. 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, or GSK. In October 2006, we announced positive study results of a pharmacokinetic study of our improved oral spray formulation of sumatriptan, a study which demonstrated that sumatriptan oral spray achieves a statistically significant faster rate of absorption than Imitrex® tablets. 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; however, we will not be able to launch this product candidate until after the expiration of the relevant Imitrex® patents and extensions thereof in February 2009.

**Tizanidine Oral Spray**. Tizanidine is indicated for the treatment of spasticity, a symptom of several neurological disorders, including Multiple Sclerosis, spinal cord injury, stroke and cerebral palsy, and leads to involuntary tensing, stiffening and contracting of muscles. Tizanidine treats spasticity by blocking nerve impulses through pre-synaptic inhibition of motor neurons. This method of action results in decreased spasticity without a corresponding reduction in muscle strength. Because patients experiencing spasticity may have difficulty swallowing the tablet formulation of the drug, our tizanidine oral spray may provide patients suffering from spasticity with a very convenient solution to this serious treatment problem. We are currently targeting a NDA submission for our tizanidine product candidate in calendar 2008. If this timeline is met, we may obtain final approval from the FDA in calendar 2009.

**Ropinirole Oral Spray**. Ropinirole is indicated for the treatment of the signs and symptoms of idiopathic Parkinson's disease. Ropinirole oral spray is ideal for the geriatric population who may be suffering from dysphagia (difficulty swallowing); 85% of sufferers of Parkinson's are 65 years of age or older and it is estimated that approximately 45% of elderly people have some



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difficulty in swallowing. Our formulation of ropinirole oral spray may represent a more convenient way for the patient or healthcare provider to deliver ropinirole to patients suffering stiffness and/or tremors. We are currently targeting a NDA submission for our ropinirole product candidate in calendar 2008. If this timeline is met, we may obtain final approval from the FDA in calendar 2009.

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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 corporate 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 Zensana, Hana Biosciences, is overseeing all clinical development and regulatory approval activities for this product in the U.S. and Canada. In January 2006, Hana Biosciences announced positive study results of a pivotal clinical trial for Zensana. Hana Biosciences submitted its NDA on June 30, 2006. Such NDA was accepted for review by the FDA in August 2006. Hana Biosciences is currently targeting final approval from the FDA and commercial launch in calendar 2007. We will receive a milestone payment from Hana Biosciences upon 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®, an 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., or Velcera. Our partner has not provided guidance regarding the clinical and regulatory development plan for the potential veterinary product candidates.

From our inception, our principal sources of capital have been consulting revenues, private placements and public offerings of our securities, as well as loans and capital contributions from our principal stockholders. We have a history of recurring losses, giving rise to accumulated deficit as of July 31, 2006 of \$44,475,000. For the fiscal year ended July 31, 2006, we reported a net loss of \$10.1 million, or \$0.23 cents per share and cash, cash equivalents and short-term investments of \$10.1 million, as of July 31, 2006. For the quarter ended October 31, 2006, we reported a net loss of \$2.5 million, or \$0.05 cents per share and cash, cash equivalents and short-term investments of \$8.6 million for the quarter ended October 31, 2006.

At our inception in 1982, then known as Pharmaconsult, we 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 again changed our name to NovaDel Pharma Inc. We maintain a website at [www.novadel.com](http://www.novadel.com). We include our website address in this prospectus only as an inactive textural reference and do not intend it to be an active link to our website. The material on our website is not part of our prospectus. You may also obtain a free copy of these reports and amendments, as well as our Corporate Governance Guidelines, committee charters and Code of Conduct, by contacting our Chief Financial Officer and Corporate Secretary. Our principal business address is 25 Minneakoning Road, Flemington, New Jersey, 08822, and our telephone number is (908) 782-3431.

**THE OFFERING**

Number of shares of our common stock  
offered by the selling security holders..... 14,207,935<sup>(1)</sup> shares

Number of shares of our common stock  
outstanding after the offering..... 63,717,184<sup>(2)</sup> shares

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

American Stock Exchange symbol..... NVD

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- (1) Includes warrants to purchase 4,383,952 shares of common stock.
  - (2) Based upon 59,333,232 shares of common stock issued and outstanding as of January 11, 2007, after giving effect to the exercise of warrants to purchase up to an aggregate of 4,383,952 shares of common stock, and excluding shares of common stock to be issued upon the exercise of outstanding warrants.

## **RISK FACTORS**

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

### ***RISKS RELATED TO OUR BUSINESS***

#### **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 engaged in the development of novel drug delivery systems for prescription and over-the-counter drugs. 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 Food & Drug Administration, or FDA, approval and achieve market acceptance of our proposed products and respond to competition. The filing of a New Drug Application, or NDA, with the FDA is an important step in the approval process in the U.S. 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. On November 3, 2006, we announced that we received an approval letter from the FDA regarding our NDA for NitroMist<sup>®</sup>. We are currently in the process of working with Par Pharmaceutical, Inc., or Par, to finalize the commercialization strategy for this product. We cannot be certain as to when to anticipate commercializing and marketing any of our product candidates 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 October 31, 2006 of approximately \$47.0 million. We incurred losses in each of our last ten fiscal years, including net losses of approximately \$2.5 million for the three months ended October 31, 2006, \$10.1 million for the fiscal year ended July 31, 2006, \$9.5 million for the fiscal year ended July 31, 2005 and \$6.3 million for the fiscal year ended July 31, 2004. Additionally, we have reported negative cash flows from operations of approximately \$1.7 million for the three months ended October 31, 2006, \$8.9 million for the fiscal year ended July 31, 2006, \$6.3 million for the fiscal year ended July 31, 2005, and \$6.1 million for the fiscal year ended July 31, 2004. Because we increased our product development activities, we anticipate that we will incur substantial operating expenses in connection with continued research and development, clinical trials, testing and approval of our proposed products, and expect these expenses will result in continuing and, perhaps, significant operating losses until such time, if ever, that we are able to achieve adequate product sales levels. Our ability to generate revenue and achieve profitability depends upon our ability, alone or with others, to complete the development of our product candidates, obtain the required regulatory approvals and manufacture, market and sell our product candidates.

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

The research, development, testing and approval of our product candidates 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 and cash flow, 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 positive cash flows from operating activities, 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, license payments from existing, current and future partners, and royalty payments from sales of approved drugs by partners. We can give no assurances that any additional capital that we are able to obtain will be sufficient to meet our needs. On December 27, 2006, we completed an equity financing in which we received gross proceeds of \$14.2 million and approximate net proceeds of \$13.0 million. Given the current and desired pace of development of our product candidates, we estimate that we will have sufficient cash on hand to fund development of our product candidates through December 31, 2007. We may, however, choose to raise additional capital before December 31, 2007 to fund future development activities or to take advantage of other strategic opportunities. This could include the securing of funds through new strategic partnerships and/or the sale of our common stock or other securities. 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 existing 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 our 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 200,000,000 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 our Common Stock and Preferred Stock Available for Issuance May Adversely Affect the Market for a description of certain rights of Paramount BioCapital Inc., or 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 could potentially enhance speed of onset of therapeutic effect, could potentially 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. Our most recent new product candidates, tizanidine and ropinirole, are focused on the neurology segment, where we believe that the benefits of our proprietary drug delivery technology may apply to a number of different pharmaceutical products.

On November 3, 2006, we announced that the FDA has approved our NitroMist (nitroglycerin lingual aerosol) for acute relief of an attack or acute prophylaxis of angina pectoris due to coronary artery disease. NitroMist is NovaDel's first approval that utilizes its proprietary oral spray technology.

Our partner in North America, Hana Biosciences, Inc., or 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 on June 30, 2006. Such NDA was accepted for filing by the FDA in August 2006. Hana Biosciences expects final approval from the FDA and commercial launch in calendar 2007.

We completed pilot pharmacokinetic studies of certain of our product candidates during late calendar year 2004 and early calendar year 2005. These products are oral spray formulations of ondansetron, sumatriptan, propofol and zolpidem. In addition, in September and October 2006, we completed a pharmacokinetic study of our improved oral spray formulation of sumatriptan and zolpidem, respectively. 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 desired therapeutic 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.

We have also commenced formulation work on two new product candidates, tizanidine oral spray and ropinirole oral spray.

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.

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**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. As of January 11, 2007, Dr. Rosenwald beneficially owns approximately 14% 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. Although Mr. Lobell is a designee of Dr. Rosenwald's, he does not have any voting or dispositive control over the shares held directly or indirectly by Dr. Rosenwald. 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 has been deemed to be an independent director by our Board as of September 15, 2006. Dr. Rosenwald and Paramount may also be deemed to be affiliates of Manhattan Pharmaceuticals, Velcera and Hana Biosciences. In addition, Paramount has assisted us in the placement of shares in connection with private placements. Refer to Note 7 Related Party Transactions and License and Development Agreements of the Condensed Financial Statements included in our Quarterly Report on Form 10-Q for the quarterly period ended October 31, 2006 for additional information. 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 to successfully raise additional funds to complete the development of, obtain regulatory approvals for and license out or market our product candidates. 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 product candidates 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 Includes Entering Into Collaboration Agreements With Third Parties For Certain of our Product Candidates 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.

**SOME OF OUR PRODUCT CANDIDATES ARE IN EARLY STAGES OF CLINICAL DEVELOPMENT AND SOME ARE IN PRECLINICAL TESTING, WHICH MAY AFFECT OUR ABILITY OR THE TIME WE REQUIRE TO OBTAIN NECESSARY REGULATORY APPROVALS.**

Some of our product candidates are in early stages of clinical development and some are in preclinical testing. These product candidates are continuously evaluated and assessed and are often subject to changes in formulation and technology. The regulatory requirements governing these types of products may be less well defined or more rigorous than for conventional products. As a result, we may experience delays with our preclinical and clinical testing, and a longer and more expensive regulatory process in connection with obtaining regulatory approvals of these types of product candidates as compared to others in our pipeline at later stages of development. These delays may negatively affect our business and operations.

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

Our principal efforts are the development of, and obtaining regulatory approvals for, our product candidates. We anticipate that marketing activities for our product candidates, whether by us or one or more of our licensees, if any, will not begin until the first half of calendar 2007 at the earliest. On November 3, 2006, we announced that we received an approval letter from the FDA regarding our NDA for NitroMist. We are currently in the process of working with Par to finalize the commercialization strategy for this product. Accordingly, it is not anticipated that we will generate any revenues from royalties or sales of our product candidates until regulatory approvals are obtained, if ever, 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. The failure or the delay of any one or more of our proposed product candidates 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 product candidates 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 product candidates must be obtained before the product candidates will become available for commercial sale. We do not anticipate generating material revenue from product sales until perhaps the first half of calendar 2007 at the earliest. On November 3, 2006, we announced that we received an approval letter from the FDA regarding our NDA for NitroMist . We are currently in the process of working with Par to finalize the commercialization strategy for this product. 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 product candidates or develop such product candidates on a timely basis. Further, such product candidates 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 product candidates, particularly in instances in which we have made significant capital expenditures, could have a material adverse effect on our business and operations.

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

We have no experience in marketing or distribution at the consumer level of our product candidates. 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 Pharmaceuticals, Velcera and Hana Biosciences, we have not entered into any significant agreements or arrangements with respect to the marketing of our product candidates. 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 possibly 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 product candidates. 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 product candidates are presently available from numerous suppliers located in the U.S., 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 product candidates, 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., which 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

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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.

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**FAILURE TO ACHIEVE AND MAINTAIN EFFECTIVE INTERNAL CONTROLS IN ACCORDANCE WITH SECTION 404 OF THE SARBANES-OXLEY ACT OF 2002 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 of 2002, which requires annual management assessments of the effectiveness of our internal controls over financial reporting and reports by our independent registered public accounting firm addressing these assessments and our internal controls. 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 of 2002 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 of 2002. 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. As of the date of the filing of this Registration Statement, we will have to comply with Section 404 of the Sarbanes-Oxley Act of 2002 as of December 31, 2007.

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

Changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002, new regulations promulgated by the Securities and Exchange Commission, or SEC, and American Stock Exchange, or 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, larger and/or better capitalized pharmaceutical companies with currently marketed 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 product candidates. We expect that technological developments will occur at a rapid rate and that competition is likely to intensify as enhanced dosage from technologies gain greater acceptance. Additionally, the markets for formulated products which we have targeted for development are intensely competitive, involving numerous competitors and products. Most of our prospective competitors possess substantially greater financial, technical and other resources than we do. Moreover, many of these companies possess greater marketing capabilities than we do, including the resources necessary to enable them to implement extensive advertising campaigns. We may not be able to compete successfully with such competitors.

Accordingly, our competitors may succeed in obtaining patent protection, receiving FDA or comparable foreign approval or commercializing products before us. If we commence commercial product sales, we will compete against companies with greater marketing and manufacturing capabilities who may successfully develop and commercialize products that are more effective or less expensive than ours. Our competitors may be more successful in receiving third party reimbursements from government agencies and others for their commercialized products which are 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 U.S. 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 UK, 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 product candidates, 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 product candidates, 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 U.S. 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 FFDC, as amended (21 U.S.C. 301 et. seq.), a new drug may not be commercialized or otherwise distributed in the U.S. without the prior approval of the FDA or pursuant to an applicable exemption from the FFDC. 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. Prior to submission of the NDA, it is necessary to submit an Investigational New Drug, or IND, to obtain permission to begin clinical testing of the new drug. Such clinical trials are required to meet good clinical practices under the FFDC. Given that our current product candidates are based on a new technology for formulation and delivery of active pharmaceutical ingredients that have been previously approved and that have been shown to be safe and effective in previous clinical trials, we believe that we will be eligible to submit what is known as a 505(b)(2). We estimate that the development of new formulations of pharmaceutical products, including formulation, testing and NDA submission, generally takes two to three years under 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 U.S. 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 for an NDA 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. We are devoting the majority of our internal research and development resources to the following product candidates:

NitroMist (nitroglycerin lingual aerosol). This product candidate is 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 U.S. and Canada. On November 3, 2006, we announced that we received an approval letter from the FDA regarding our NDA for NitroMist. We are currently in the process of working with Par to finalize the commercialization strategy for this product. 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. In October 2006, we announced positive study results of a pharmacokinetic study of our improved oral spray formulation of zolpidem, a study which demonstrated that zolpidem oral spray achieves a statistically significant faster rate of absorption than Ambien® tablets. 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. In October 2006, we announced positive study results of a pharmacokinetic study of our improved oral spray formulation of sumatriptan, a study which demonstrated that sumatriptan oral spray achieves a statistically significant faster rate of absorption than Imitrex® tablets. We are currently targeting a NDA submission for our sumatriptan product candidate in the second

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half of calendar 2007. If this timeline is met, we may obtain final approval from the FDA in calendar 2008; however, we will not be able to launch this product candidate until after the expiration of the relevant Imitrex® patents and extensions thereof in February 2009.

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Tizanidine oral spray. Tizanidine is indicated for the treatment of spasticity, a symptom of several neurological disorders, including Multiple Sclerosis, spinal cord injury, stroke and cerebral palsy, and leads to involuntary tensing, stiffening and contracting of muscles. Tizanidine treats spasticity by blocking nerve impulses through pre-synaptic inhibition of motor neurons. This method of action results in decreased spasticity without a corresponding reduction in muscle strength. Because patients experiencing spasticity may have difficulty swallowing the tablet formulation of the drug, our tizanidine oral spray may provide patients suffering from spasticity with a very convenient solution to this serious treatment problem. We are currently targeting a NDA submission for our tizanidine product candidate in calendar 2008. If this timeline is met, we may obtain final approval from the FDA in calendar 2009.

Ropinirole oral spray. Ropinirole is indicated for the treatment of the signs and symptoms of idiopathic Parkinson's disease. Ropinirole oral spray is ideal for the geriatric population who may be suffering from dysphagia (difficulty swallowing); 85% of sufferers of Parkinson's are 65 years of age or older and it is estimated that approximately 45% of elderly people have some difficulty in swallowing. Our formulation of ropinirole oral spray may represent a more convenient way for the patient or healthcare provider to deliver ropinirole to patients suffering stiffness and/or tremors. We are currently targeting a NDA submission for our ropinirole product candidate in calendar 2008. If this timeline is met, we may obtain final approval from the FDA in calendar 2009.

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 Zensana, Hana Biosciences, is overseeing all clinical development and regulatory approval activities for this product in the U.S. and Canada. In January 2006, Hana Biosciences announced positive study results of a pivotal clinical trial for Zensana. Hana Biosciences submitted its NDA on June 30, 2006. Such NDA was accepted for review by the FDA in August 2006. Hana Biosciences is currently targeting final approval from the FDA and commercial launch in calendar 2007. We will receive a milestone payment from Hana Biosciences upon 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®, an 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 U.S., we also need to comply with foreign regulatory requirements governing human clinical trials and marketing approval for pharmaceutical products. Other than the approval of NitroMist, the FDA and foreign regulators have not yet approved any of our products under development for marketing in the U.S. 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 U.S. and other countries, sales of our products will depend in part upon the availability of reimbursement from third-party payers, which include government health administration authorities, managed care providers and private health insurers. Third-party payers are increasingly challenging the price and examining the cost effectiveness of medical products and services.

**OUR STRATEGY INCLUDES ENTERING INTO COLLABORATION AGREEMENTS WITH THIRD PARTIES FOR CERTAIN OF OUR PRODUCT CANDIDATES 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 certain of our product candidates and for the manufacturing, marketing and commercialization of such product candidates includes 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 U.S. and Canada; and a license agreement with Hana Biosciences for the marketing rights in the U.S. 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 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 such product candidates. If we fail to successfully develop these relationships or if our collaboration partners fail to successfully develop or commercialize such product candidates, 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 U.S. 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 U.S. Patent and Trademark Office has not adopted a consistent policy regarding the breadth of claims that the U.S. 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.

Section 505(b)(2) of the FDCA was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, otherwise known as the Hatch-Waxman Act. Section 505(b)(2) permits the submission of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. For example, the Hatch-Waxman Act permits an applicant to rely upon the FDA's findings of safety and effectiveness for an approved product. The FDA may also require companies to perform one or more additional studies or measurements to support the change from the approved product. The FDA may then approve the new formulation for all or some of the label indications for which the referenced product has been approved, or a new indication sought by the Section 505(b)(2) applicant.



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To the extent that the Section 505(b)(2) applicant is relying on the FDA's findings for an already-approved product, the applicant is required to certify to the FDA concerning any patents listed for the approved product in the FDA's Orange Book publication. Specifically, the applicant must certify that: (1) the required patent information has not been filed (paragraph I certification); (2) the listed patent has expired (paragraph II certification); (3) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration (paragraph III certification); or (4) the listed patent is invalid or will not be infringed by the manufacture, use or sale of the new product (paragraph IV certification). If the applicant does not challenge the listed patents, the Section 505(b)(2) application will not be approved until all the listed patents claiming the referenced product have expired, and once any pediatric exclusivity expires. The Section 505(b)(2) application may also not be approved until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the referenced product has expired.

If the applicant has provided a paragraph IV certification to the FDA, the applicant must also send notice of the paragraph IV certification to the NDA holder and patent owner once the NDA has been accepted for filing by the FDA. The NDA holder and patent owner may then initiate a legal challenge to the paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of their receipt of a paragraph IV certification automatically prevents the FDA from approving the Section 505(b)(2) NDA until the earliest of 30 months, expiration of the patent, settlement of the lawsuit or a decision in an infringement case that is favorable to the Section 505(b)(2) applicant. Thus, a Section 505(b)(2) applicant may invest a significant amount of time and expense in the development of its products only to be subject to significant delay and patent litigation before its products may be commercialized. Alternatively, if the NDA holder or patent owner does not file a patent infringement lawsuit within the required 45-day period, the applicant's NDA will not be subject to the 30-month stay.

Notwithstanding the approval of many products by the FDA pursuant to Section 505(b)(2), over the last few years, certain brand-name pharmaceutical companies and others have objected to the FDA's interpretation of Section 505(b)(2). If the FDA changes its interpretation of Section 505(b)(2), this could delay or even prevent the FDA from approving any Section 505(b)(2) NDA that we submit.

Our partner, Hana Biosciences, submitted a Section 505(b)(2) NDA for Zensana in the second quarter of 2006. The safety and efficacy of the drug will be based on a demonstration of the bioequivalence of Zensana to oral ondansetron, marketed under the tradename Zofran®. This Zofran® formulation is protected by two unexpired patents, one of which expired in June 2006, and that is subject to a period of pediatric exclusivity, which expired in December 2006. The second patent is scheduled to expire in September 2011, and is subject to a period of pediatric exclusivity expiring in March 2012. Hana Biosciences' Section 505(b)(2) NDA contained a paragraph III certification acknowledging that the first patent will expire in December 2006, and a paragraph IV certification to the second patent. Based on the paragraph IV certification, it is possible that the NDA holder or the patent owner will sue us and/or Hana Biosciences for patent infringement, and that the FDA will be prevented from approving our application until the earliest of 30 months, settlement of the lawsuit, or a decision in an infringement case that is favorable to us. Hana Biosciences has announced that it has not received any objections related to these patent certifications.

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 U.S. and foreign patent applications with respect to the products and technologies under our development, and the U.S. 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. Currently, we have eight patents which have been issued in the U.S. and 53 patents which have been issued outside of the U.S. Additionally, we have over 80 patents pending around the world. Our pending patent applications, those we may file in the future and those we may license from third parties, may not result in the U.S. 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 U.S. 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 product candidates and processes in the U.S. 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 U.S. Patent and Trademark Office keeps U.S. 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 AND BOARD MEMBERS.**

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 could 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 could adversely affect our ability to develop and market our products and obtain necessary regulatory approvals, and the applicable noncompetition provisions can be difficult and costly to monitor and enforce. Further, we do not maintain key-man life insurance.

On September 6, 2005, our Board of Directors, or 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, 2005, 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. Although Mr. Lobell is a designee of Dr. Rosenwald's, he does not have any voting or dispositive control over the shares held directly or indirectly by Dr. Rosenwald. As of September 15, 2006, Mr. Lobell has been deemed independent by our Board of Directors in accordance with the rules of AMEX.

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 24, 2006, Ms. Jean Frydman ceased to serve as Vice President, General Counsel and Corporate Secretary.

On September 15, 2006, our Board of Directors appointed Steven B. Ratoff as Chairman of the Board, with Dr. Egberts remaining a member of the Board of Directors.

On December 4, 2006, our Board of Directors appointed David H. Bergstrom, Ph.D. as Chief Operating Officer.

On January 4, 2007, Mr. Barry Cohen ceased to serve as Vice President, Business and New Product Development.

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.





**RISKS RELATED TO OUR COMMON STOCK**

**WE ARE INFLUENCED 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. As of January 11, 2007, management and our affiliates currently beneficially own, including shares they have the right to acquire, approximately 40% of the common stock on a fully-diluted basis. For this purpose, affiliates include each officer and director and each person known to the registrant who owned 5% or more of our common stock. This determination of affiliate status is not necessarily a conclusive determination for other purposes. 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. Although Mr. Lobell is a designee of Dr. Rosenwald's, he does not have any voting or dispositive control over the shares held directly or indirectly by Dr. Rosenwald. 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 has been deemed to be an independent director by our Board of Directors on September 15, 2006.

Such positions may discourage or prevent any proposed takeover of us, including transactions in which our stockholders might otherwise receive a premium for their shares over the then current market prices. Our directors, executive officers and principal stockholders may influence corporate actions, including influencing elections of directors and significant corporate events.

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

The market price of 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 U.S. 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 and other reports, including this Report and other filings filed with the Securities and Exchange Commission from time to time.

Our common stock has been listed for quotation on the AMEX since May 11, 2004 under the symbol **NVD**. 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 December 31, 2006, the closing price of our common stock has ranged from \$1.11 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 December 31, 2006, the average daily trading volume in our common stock was approximately 115,000 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.

**BECAUSE THE AVERAGE DAILY TRADING VOLUME OF OUR COMMON STOCK IS LOW, THE ABILITY TO SELL OUR SHARES IN THE SECONDARY TRADING MARKET MAY BE LIMITED.**

Because the average daily trading volume of our common stock on the AMEX is low, the liquidity of our common stock may be impaired. As a result, prices for shares of our common stock may be lower than might otherwise prevail if the average daily trading volume of our common stock was higher. The average daily trading volume of our common stock may be low relative to the stocks of exchange-listed companies, which could limit investors' ability to sell shares in the secondary trading market.

**WE LIKELY WILL ISSUE ADDITIONAL EQUITY SECURITIES, WHICH WILL DILUTE CURRENT STOCKHOLDERS' SHARE OWNERSHIP.**

We likely will issue additional equity securities to raise capital and through the exercise of options and warrants that are outstanding or may be outstanding. These additional issuances will dilute current stockholders' share ownership.

**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 200,000,000 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. As of January 11, 2007, there were 59,333,232 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 January 11, 2007, we had outstanding stock options and warrants to purchase approximately 35.5 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 January 11, 2007	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	2,624,000	471,000	
2006 Equity Incentive Plan	6,000,000	1,350,000	4,550,000	
Non-Plan	n/a	4,584,000		

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 of 1933, as amended, 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.**

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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.**

On July 20, 2006, we filed a shelf registration statement on Form S-3 registering for sale by us of up to 14,000,000 shares of our common stock. Such shelf registration statement was declared effective by the SEC on August 2, 2006. We may offer and sell such shares from time to time, in one or more offerings in amounts and at prices, and on terms determined at the time of the offering. Such offerings of our common stock may be made 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 at the time of the offering. As of the filing date of this Registration Statement, such shelf registration statement is no longer effective.

In December 2006, we sold securities in a private placement transaction resulting in the issuance of 9,823,983 shares of our common stock, and warrants to purchase 4,383,952 shares of our common stock. The sale of the shares of common stock and warrants resulted in gross proceeds to us of approximately \$14.2 million, prior to offering expenses.

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 2,896,168 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, prior to offering expenses.

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 2,693,210 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 offering of, and/or 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 Forms 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.



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As of January 11, 2006, we have 59,333,232 shares of common stock issued and outstanding and approximately 35.5 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 200,000,000 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 SECURITIES TO BE ISSUED IN OUR DECEMBER 2006 PRIVATE PLACEMENT ARE RESTRICTED SECURITIES.**

The offer and sale of the common stock (and the shares of common stock underlying the warrants) in our December 2006 private placement have not been registered under the Securities Act or the securities laws of any state. Accordingly, these securities may not be sold or otherwise transferred unless such sale or transfer is subsequently registered under the Securities Act and applicable state securities laws or unless exemptions from such registration are available. Notwithstanding our registration obligations regarding these securities, investors may be required to hold these securities for an indefinite period of time. All investors who purchase these securities are required to make representations that it will not sell, transfer, pledge or otherwise dispose of any of the securities in the absence of an effective registration statement covering such transaction under the Securities Act and applicable state securities laws, or the receipt by us of an opinion of counsel to the effect that registration is not required.

### **WE WILL HAVE BROAD DISCRETION AS TO THE USE OF THE PROCEEDS FROM THE DECEMBER 2006 PRIVATE PLACEMENT AND MAY USE THE PROCEEDS IN A MANNER WITH WHICH YOU DISAGREE.**

Our board of directors and management will have broad discretion over the use of the net proceeds of the December 2006 private placement. Stockholders may disagree with the judgment of the board of directors and management regarding the application of the proceeds of the December 2006 private placement. We cannot predict that investments of the proceeds will yield a favorable, or any, return.

### **WE MAY INCUR SIGNIFICANT COSTS FROM CLASS ACTION LITIGATION DUE TO OUR EXPECTED STOCK VOLATILITY.**

In the past, following periods of large price declines in the public market price of a company's stock, holders of that stock occasionally have instituted securities class action litigation against the company that issued the stock. If any of our stockholders were to bring this type of lawsuit against us, even if the lawsuit is without merit, we could incur substantial costs defending the lawsuit. The lawsuit also could divert the time and attention of our management, which would hurt our business. Any adverse determination in litigation could also subject us to significant liabilities.

### **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:



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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 not receive any of the proceeds from the sale of the shares owned by the selling security holders. However, we will receive proceeds from the exercise of outstanding warrants, if such warrants are exercised. However, the warrants contain provisions for cashless exercise in certain circumstances, in which case, we will not receive any proceeds from the exercise of the warrants from the selling security holders. The warrants entitle the selling security holders to purchase shares of our common stock at an exercise price of \$1.70 per share. Any such proceeds will be used primarily for increased or additional research and development and general working capital.

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

## **SELLING SECURITY HOLDERS**

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

On December 27, 2006, we completed a private placement of 9,823,983 shares of our common stock and warrants to purchase a total of 4,383,952 shares of our common stock, including warrants issued to the Placement Agents in connection with the private placement, with an exercise price equal to \$1.70 per share. We received gross proceeds of approximately \$14,245,000 and net proceeds of approximately \$13,000,000, from the private placement.

The following table sets forth the aggregate number of shares of common stock beneficially owned by the selling security holders as of January 11, 2007, after giving effect to the private placement, and the percentage of all shares of common stock held by such selling security holders prior to and after giving effect to the offering based on 59,333,232 shares of common stock outstanding as of January 11, 2007. Except as described in this prospectus, the selling security holders have not held any position or office or had any other material relationship with us or any of our predecessors or affiliates within the past three years. We considered the following factors and made the following assumptions regarding the table:

beneficial ownership is determined under Section 13(d) of the Securities Exchange Act of 1934 (Exchange Act) and generally includes voting or investment power with respect to securities and including any securities that grant the selling security holder the right to acquire Common Stock within 60 days of January 11, 2007; and

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

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

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



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Name of Selling Security holder <sup>(3)</sup>	Shares of Common Stock Beneficially Owned Prior to Offering <sup>(1)</sup>		Number of Shares of Common Stock Being Offered	Shares of Common Stock to be Beneficially Owned After Offering <sup>(1)(2)</sup>		
	Number	Percentage	Number	Number	Percentage	
Iroquois Master Fund Ltd	482,759	(4) *	482,759			
Capital Ventures International	2,034,482	(5) 3.4	% 1,931,034	103,448	*	
WHI Growth Fund Q.P., L.P.	3,862,068	(6) 6.4	% 3,862,068			
Crestview Capital Master, LLC	1,448,276	(7) 2.4	% 1,448,276			
ProMed Offshore Fund II, Ltd.	1,448,276	(8) 2.4	% 1,448,276			
Panacea Fund, LLC	3,862,068	(9) 6.4	% 3,862,068			
WHI Select Fund, L.P.	3,862,068	(10) 6.4	% 3,862,068			
Highbridge International LLC	751,372	(11) 1.3	% 482,759	268,613	*	
ProMed Partners, L.P.	1,448,276	(12) 2.4	% 1,448,276			
David Weisberg	82,759	(13) *	72,414	10,345	*	
ProMed Offshore Fund, Ltd.	1,448,276	(14) 2.4	% 1,448,276			
ProMed Partners II, L.P.	1,448,276	(15) 2.4	% 1,448,276			
Grand Cathay Venture Capital Co. Ltd.	1,544,828	(16) 2.6	% 1,544,828			
Grand Cathay Venture Capital III Co. Ltd.	1,544,828	(17) 2.6	% 1,544,828			
Prudence Venture Investment Corp.	1,544,828	(18) 2.6	% 1,544,828			
Springvest Corporation	407,280	(19) *	241,380	165,900	*	
Springbridge Capital Corporation	241,380	(20) *	241,380			
Harewood Nominees A/C 4689000	1,913,033	(21) 3.2	% 627,585	1,285,448	2.2	%
Henderson North American Multi-Strategy Equity Fund	1,913,033	(22) 3.2	% 627,585	1,285,448	2.2	%
Michael J. Chill	39,884	(23) *	24,137	15,747	*	
Henderson Global Multi-Strategy Equity Fund	1,913,033	(24) 3.2	% 627,585	1,285,448	2.2	%
ProQuest Investments II Advisor Fund L. P.	8,474,832	(25) 13.8	% 1,346,680	7,128,152	11.7	%
ProQuest Investments II, L.P.	8,474,832	(26) 13.8	% 1,346,680	7,128,152	11.7	%
ProQuest Investments III, L.P.	8,474,832	(27) 13.8	% 1,346,680	7,128,152	11.7	%
Oppenheimer & Co. Inc.	417,519	(28) *	417,519			
Adrian Stecyk	224,172	(29) *	36,840	187,332	*	

\*Less than 1%.

(1) Shares of common stock issuable under stock options and warrants that are exercisable within 60 days after January 11, 2007 are deemed outstanding for computing the percentage ownership of the selling security holder holding the options or warrants, prior to and after giving effect to the offering, but are not deemed outstanding for computing the percentage ownership of any other selling security holder.

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

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

(4) Includes 344,428 shares of common stock and warrants to purchase 137,931 shares of common stock. Joshua Silverman, Fund Manager of Iroquois Master Fund Ltd, has voting and investment control over the shares of common stock and warrants held by Iroquois Master Fund Ltd, but disclaims beneficial ownership of such shares and warrants, except to the extent of any pecuniary interest therein.

(5) Includes 1,379,310 shares of common stock and warrants to purchase 655,172 shares of common stock. Heights Capital Management, Inc., the authorized agent of Capital Ventures International ("CVI"), has discretionary authority to vote and dispose of the shares held by CVI and may be deemed to be the beneficial owner of these shares. Martin Kobinger, Investment Manager of Heights Capital Management, Inc. may also be deemed to have investment discretion and voting power over the shares held by CVI. Mr. Kobinger disclaims any beneficial ownership of such shares and warrants, except to the extent of any pecuniary interest therein. CVI is affiliated with one or more registered broker-dealers, and as a result, CVI may be deemed to be an affiliate of a broker-dealer. Accordingly, the selling security holder may be deemed to be an

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underwriter if it (i) did not acquire the shares of common stock in the ordinary course of business or (ii) had any agreement or understanding, directly or indirectly, with any person to distribute the shares of common stock. CVI has confirmed to the Company that it acquired the shares of common stock being registered hereunder in the ordinary course of business and at the time of purchase, had no agreements or understandings, directly or indirectly, with any other person to distribute such shares of common stock. Please see [Plan of Distribution](#) for further disclosure regarding these selling security holders.

26

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(6) Includes (i) 1,379,310 shares of common stock and warrants to purchase 551,724 shares of common stock, (ii) 689,655 shares of common stock and warrants to purchase 275,862 shares of common stock held in the name of Panacea Fund, LLC, and (iii) 689,655 shares of common stock and warrants to purchase 275,862 shares of common stock held in the name of WHI Select Fund, L.P. William Harris Investors, Inc. is the General Partner of WHI Growth Fund Q.P., L.P. Michael S. Resnick, an executive vice-president of William Harris Investors, Inc., and Charles Polsky, a vice-president of William Harris Investors, Inc. have voting and investment control over the shares of common stock and warrants held by WHI Growth Fund Q.P., L.P., but disclaim beneficial ownership of such shares and warrants, except to the extent of any pecuniary interest therein.

(7) Includes 1,034,483 shares of common stock and warrants to purchase 413,793 shares of common stock. Crestview Capital Master, LLC ( Crestview ) is a limited liability company whose sole manager is Crestview Capital Partners, LLC. Mr. Stewart R. Flink, Mr. Robert Hoyt and Mr. Daniel Warsh, as managers of Crestview Capital Partners, have voting and/or investment control over the shares of common stock and warrants held by Crestview Capital Master, LLC. Messrs. Flink, Hoyt and Warsh disclaim beneficial ownership of such shares and warrants except to the extent of any pecuniary interest therein. Stewart Flink is the controlling shareholder of Dillon Capital, Inc., a registered broker-dealer. As a result, Crestview may be deemed to be an affiliate of a broker-dealer. Accordingly, Crestview may be deemed to be an underwriter if it (i) did not acquire the shares of common stock in the ordinary course of business or (ii) had any agreement or understanding, directly or indirectly, with any person to distribute the shares of common stock. Crestview has confirmed to the Company that it acquired the shares of common stock being registered hereunder in the ordinary course of business and at the time of purchase, had no agreements or understandings, directly or indirectly, with any other person to distribute such shares of common stock. Please see Plan of Distribution for further disclosure regarding this selling security holder.

(8) Includes (i) 762,162 shares of common stock and warrants to purchase 304,865 shares of common stock, (ii) 227,620 shares of common stock and warrants to purchase 91,048 shares of common stock held in the name of ProMed Partners, L.P., (iii) 33,818 shares of common stock and warrants to purchase 13,527 shares of common stock held in the name of ProMed Offshore Fund, Ltd., and (iv) 10,883 shares of common stock and warrants to purchase 4,353 shares of common stock held in the name of ProMed Partners II, L.P. ProMed Offshore Fund II Ltd. is affiliated with one or more registered broker-dealers, and as a result, may be deemed to be an affiliate of a broker-dealer. Accordingly, ProMed Offshore Fund II Ltd. may be deemed to be an underwriter if it (i) did not acquire the shares of common stock in the ordinary course of business or (ii) had any agreement or understanding, directly or indirectly, with any person to distribute the shares of common stock. ProMed Offshore Fund II Ltd. has confirmed to the Company that it acquired the shares of common stock being registered hereunder in the ordinary course of business and at the time of purchase, had no agreements or understandings, directly or indirectly, with any other person to distribute such shares of common stock. Please see Plan of Distribution for further disclosure regarding this selling security holder. Barry Kurokawa and David B. Musket, Directors of ProMed Offshore Fund II, Ltd. have dispositive and voting power over the shares of common stock and warrants held by ProMed Offshore Fund II Ltd., but disclaim beneficial ownership of such shares and warrants, except to the extent of any pecuniary interest therein.

(9) Includes (i) 689,655 shares of common stock and warrants to purchase 275,862 shares of common stock, (ii) 1,379,310 shares of common stock and warrants to purchase 551,724 shares of common stock held in the name of WHI Growth Fund Q.P., L.P., and (iii) 689,655 shares of common stock and warrants to purchase 275,862 shares of common stock held in the name of WHI Select Fund, L.P. William Harris Investors, Inc. is the Manager of Panacea Fund, LLC. Michael S. Resnick, an executive vice-president of William Harris Investors, Inc., Charles Polsky and Fred Houbow, co-Fund Managers of Panacea Fund, LLC, have voting and investment control over the shares of common stock and warrants held by Panacea Fund, LLC but disclaim beneficial ownership of such shares and warrants, except to the extent of any pecuniary interest therein.

(10) Includes (i) 689,655 shares of common stock and warrants to purchase 275,862 shares of common stock, (ii) 1,379,310 shares of common stock and warrants to purchase 551,724 shares of common stock held in the name of WHI Growth Fund Q.P., L.P., and (iii) 689,655 shares of common stock and warrants to purchase 275,862 shares of common stock held in the name of Panacea Fund, LLC. William Harris Investors, Inc. is the General Partner of WHI Select Fund L.P. Michael S. Resnick, an executive vice-president of William Harris Investors, Inc., and Charles Polsky, a vice-president of William Harris Investors, Inc. have voting and investment control over the shares of common stock and warrants held by WHI Select Fund L.P., but disclaim beneficial ownership of such shares and warrants, except to the extent of any pecuniary interest therein.

(11) Includes 527,828 shares of common stock and warrants to purchase 223,544 shares of common stock. Highbridge Capital Management, LLC is the Trading Manager of Highbridge International LLC and has voting and investment control over the shares of common stock and warrants to purchase common stock held by Highbridge International LLC. Glenn Dubin and Henry Swieca control Highbridge Capital

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Management, LLC and have voting and investment control over the shares of common stock and warrants to purchase common stock held by Highbridge International LLC. Glenn Dubin and Henry Swieca disclaim beneficial ownership of such shares and warrants held by Highbridge International LLC, except to the extent of any pecuniary interest therein.

27

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(12) Includes (i) 227,620 shares of common stock and warrants to purchase 91,048 shares of common stock, (ii) 762,162 shares of common stock and warrants to purchase 304,865 shares of common stock held in the name of ProMed Offshore Fund II, Ltd., (iii) 33,818 shares of common stock and warrants to purchase 13,527 shares of common stock held in the name of ProMed Offshore Fund, Ltd., and (iv) 10,883 shares of common stock and warrants to purchase 4,353 shares of common stock held in the name of ProMed Partners II, L.P. ProMed Partners, L.P. is affiliated with one or more registered broker-dealers, and as a result, may be deemed to be an affiliate of a broker-dealer. Accordingly, ProMed Partners, L.P. may be deemed to be an underwriter if it (i) did not acquire the shares of common stock in the ordinary course of business or (ii) had any agreement or understanding, directly or indirectly, with any person to distribute the shares of common stock. ProMed Partners, L.P. has confirmed to the Company that it acquired the shares of common stock being registered hereunder in the ordinary course of business and at the time of purchase, had no agreements or understandings, directly or indirectly, with any other person to distribute such shares of common stock. Please see Plan of Distribution for further disclosure regarding these selling security holders. Barry Kurokawa and David B. Musket, members of the general partner of ProMed Partners, L.P. have dispositive and voting power over the shares of common stock and warrants held by ProMed Partners, L.P., but disclaim beneficial ownership of such shares and warrants, except to the extent of any pecuniary interest therein.

(13) Includes 51,724 shares of common stock and warrants to purchase 31,035 shares of common stock.

(14) Includes (i) 33,818 shares of common stock and warrants to purchase 13,527 shares of common stock, (ii) 762,162 shares of common stock and warrants to purchase 304,865 shares of common stock held in the name of ProMed Offshore Fund II, Ltd., (iii) 227,620 shares of common stock and warrants to purchase 91,048 shares of common stock held in the name of ProMed Partners, L.P., and (iv) 10,883 shares of common stock and warrants to purchase 4,353 shares of common stock held in the name of ProMed Partners II, L.P. ProMed Offshore Fund, Ltd. is affiliated with one or more registered broker-dealers, and as a result, may be deemed to be an affiliate of a broker-dealer. Accordingly, ProMed Offshore Fund, Ltd. may be deemed to be an underwriter if it (i) did not acquire the shares of common stock in the ordinary course of business or (ii) had any agreement or understanding, directly or indirectly, with any person to distribute the shares of common stock. ProMed Offshore Fund, Ltd. has confirmed to the Company that it acquired the shares of common stock being registered hereunder in the ordinary course of business and at the time of purchase, had no agreements or understandings, directly or indirectly, with any other person to distribute such shares of common stock. Please see Plan of Distribution for further disclosure regarding these selling security holders. Barry Kurokawa and David B. Musket, Directors of ProMed Offshore Fund, Ltd. have dispositive and voting power over the shares of common stock and warrants held by ProMed Offshore Fund, Ltd., but disclaim beneficial ownership of such shares and warrants, except to the extent of any pecuniary interest therein.

(15) Includes (i) 10,883 shares of common stock and warrants to purchase 4,353 shares of common stock, (ii) 762,162 shares of common stock and warrants to purchase 304,865 shares of common stock held in the name of ProMed Offshore Fund II, Ltd., (iii) 227,620 shares of common stock and warrants to purchase 91,048 shares of common stock held in the name of ProMed Partners, L.P., and (iv) 33,818 shares of common stock and warrants to purchase 13,527 shares of common stock held in the name of ProMed Offshore Fund, Ltd. ProMed Partners II, L.P. is affiliated with one or more registered broker-dealers, and as a result, may be deemed to be an affiliate of a broker-dealer. Accordingly, ProMed Partners II, L.P. may be deemed to be an underwriter if it (i) did not acquire the shares of common stock in the ordinary course of business or (ii) had any agreement or understanding, directly or indirectly, with any person to distribute the shares of common stock. ProMed Partners II, L.P. has confirmed to the Company that it acquired the shares of common stock being registered hereunder in the ordinary course of business and at the time of purchase, had no agreements or understandings, directly or indirectly, with any other person to distribute such shares of common stock. Please see Plan of Distribution for further disclosure regarding these selling security holders. Barry Kurokawa and David B. Musket, members of the general partner of ProMed Partners II, L.P. have dispositive and voting power over the shares of common stock and warrants held by ProMed Partners II, L.P., but disclaim beneficial ownership of such shares and warrants, except to the extent of any pecuniary interest therein.

(16) Includes (i) 448,276 shares of common stock and warrants to purchase 179,310 shares of common stock (ii) 448,276 shares of common stock and warrants to purchase 179,310 shares of common stock held in the name of Grand Cathay Venture Capital III Co., Ltd., and 206,897 shares of common stock and warrants to purchase 82,759 shares of common stock held in the name of Prudence Venture Investment Corp. Global Investment Holdings is the limited partner of Grand Cathay Venture Capital III Co., Ltd., Grand Cathay Venture Capital Co., Ltd., Prudence Venture Investment Corp. and China Investment Development Co. ( CIDC ). CIDC is the management company and limited partner of Grand Cathay Venture Capital III Co., Ltd. and Grand Cathay Venture Capital Co., Ltd. Dr. Edward Chang, President of Grand Cathay Venture Capital III Co., Ltd., Grand Cathay Venture Capital Co., Ltd., and CDIC has voting, dispositive and investment power over the shares of common stock and warrants held by Grand Cathay Venture Capital Co. Ltd. Dr. Chang disclaims beneficial ownership of such securities, shares and warrants, except to the extent of any pecuniary interest therein.



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(17) Includes (i) 448,276 shares of common stock and warrants to purchase 179,310 shares of common stock, (ii) 448,276 shares of common stock and warrants to purchase 179,310 shares of common stock held in the name of Grand Cathay Venture Capital Co., Ltd., and (iii) 206,897 shares of common stock and warrants to purchase 82,759 shares of common stock held in the name of Prudence Venture Investment Corp. Global Investment Holdings is the limited partner of Grand Cathay Venture Capital III Co., Ltd., Grand Cathay Venture Capital Co., Ltd., Prudence Venture Investment Corp., and China Investment Development Co. ( CIDC ). CIDC is the management company and limited partner of Grand Cathay Venture Capital III Co., Ltd. and Grand Cathay Venture Capital Co., Ltd. Dr. Edward Chang, President of Grand Cathay Venture Capital III Co., Ltd., Grand Cathay Venture Capital Co., Ltd., and CDIC has voting, dispositive and investment power over the shares of common stock and warrants held by Grand Cathay Venture Capital III Co. Ltd. Dr. Chang disclaims beneficial ownership of such shares and warrants, except to the extent of any pecuniary interest therein.

(18) Includes (i) 206,897 shares of common stock and warrants to purchase 82,759 shares of common stock, (ii) 448,276 shares of common stock and warrants to purchase 179,310 shares of common stock held in the name of Grand Cathay Venture Capital III Co., Ltd., and (iii) 448,276 shares of common stock and warrants to purchase 179,310 shares of common stock held in the name of Grand Cathay Venture Capital Co., Ltd. Global Investment Holdings is the limited partner of Grand Cathay Venture Capital III Co., Ltd., Grand Cathay Venture Capital Co., Ltd., Prudence Venture Investment Corp., and China Investment Development Co. Ms. Jessica Wu, President of Prudence Venture Investment Corp., has voting, dispositive and investment power over the shares of common stock and warrants held by Prudence Venture Investment Corp. Ms. Wu disclaims beneficial ownership of such shares and warrants, except to the extent of any pecuniary interest therein.

(19) Includes (i) 338,314 shares of common stock and warrants to purchase 68,966 shares of common stock . Bruce Hsiang, Director of Springvest Corporation has voting and investment control over the shares of common stock and warrants held by Springvest Corporation but disclaims beneficial ownership of such shares and warrants, except to the extent of any pecuniary interest therein.

(20) Includes (i) 172,414 shares of common stock and warrants to purchase 68,966 shares of common stock. Min Fu Change, Director of Springbridge Capital Corporation has voting and investment control over the shares of common stock and warrants held by Springbridge Capital Corporation but disclaims beneficial ownership of such shares and warrants, except to the extent of any pecuniary interest therein.

(21) Includes (i) 331,723 shares of common stock and warrants to purchase 109,448 shares of common stock, (ii) 264,091 shares of common stock and warrants to purchase 87,034 shares of common stock held in the name of Henderson North American Multi-Strategy Equity Fund, and (iii) 1,009,841 shares of common stock and warrants to purchase 110,896 shares of common stock held in the name of Henderson Global Multi-Strategy Equity Fund. Harewood Nominees Ltd. A/C 4689000 are the nominees of AMP Enhanced Index International Share Fund. Harewood Nominees are the appointed custodian for Henderson Global Investors. Robert Villiers, Fund Manager of AMP Enhanced Index International Share Fund has voting and investment control over the shares of common stock and warrants held by Harewood Nominees LTD A/C 4689000, but disclaims beneficial ownership of such shares and warrants, except to the extent of any pecuniary interest therein.

(22) Includes (i) 264,091 shares of common stock and warrants to purchase 87,034 shares of common stock, (ii) 331,723 shares of common stock and warrants to purchase 109,448 shares of common stock held in the name of Harewood Nominees Ltd. A/C 468900, and (iii) 1,009,841 shares of common stock and warrants to purchase 110,896 shares of common stock held in the name of Henderson Global Multi-strategy Equity Fund. Harewood Nominees Ltd. A/C 4689000 are the nominees of AMP Enhanced Index International Share Fund. Harewood Nominees are the appointed custodian for Henderson Global Investors. Robert Villiers, Fund Manager of Henderson North American Multi-Strategy Fund, has voting and investment control over the shares of common stock and warrants, but disclaims beneficial ownership of such shares and warrants, except to the extent of any pecuniary interest therein.

(23) Includes 28,241 shares of common stock and warrants to purchase 11,643 shares of common stock. Mr. Chill is an employee of a broker-dealer, and as a result, Mr. Chill may be deemed an affiliate of a registered broker-dealer. Accordingly, the selling security holder may be deemed an underwriter if he (i) did not acquire the shares of common stock in the ordinary course of business or (ii) had any agreement or understanding, directly or indirectly, with any person to distribute the shares of common stock. Mr. Chill has confirmed to the Company that he acquired the shares of common stock being registered hereunder in the ordinary course of business and he does not have any agreement or

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understanding, directly or indirectly, with any person to distribute such shares of common stock. Please see [Plan of Distribution](#) for further disclosure regarding this selling security holder.

(24) Includes (i) 1,009,841 shares of common stock and warrants to purchase 110,896 shares of common stock, (ii) 331,723 shares of common stock and warrants to purchase 109,448 shares of common stock held in the name of Harewood Nominees Ltd. A/C 468900, and (iii) 264,091 shares of common stock and warrants to purchase 87,034 shares of common stock held in the name of Henderson North American Multi-strategy Equity Fund. Harewood Nominees are the appointed custodian for Henderson Global Investors. Robert Villiers, Fund Manager of Henderson Global Multi-Strategy Fund, has voting and investment control over the shares of common stock and warrants, but disclaims beneficial ownership of such shares and warrants, except to the extent of any pecuniary interest therein.

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(25) Includes (i) 30,397 shares of common stock and warrants to purchase 10,704 shares of common stock, (ii) 1,262,747 shares of common stock and warrants to purchase 444,704 shares of common stock held in the name of ProQuest Investments II, L.P., and (iii) 4,974,426 shares of common stock and warrants to purchase 1,751,854 shares of common stock held in the name of ProQuest Investments III, L.P. ProQuest Associates III LLC ( Associates III ) is the general partner of ProQuest Investments III, L.P. ProQuest Associates II LLC ( Associates II ) is the General Partner of ProQuest Investments II, L.P. and of ProQuest Investments II Advisors Fund, L.P. Jay Moorin and Alain Schreiber, Managing Members of Associates III and Associates II, have voting, dispositive and investment power with respect to the securities being offered hereunder. Each of Mr. Moorin and Mr. Schreiber disclaim beneficial ownership of such securities except to the extent of each such person's respective pecuniary interest in such securities.

(26) Includes (i) 1,262,747 shares of common stock and warrants to purchase 444,704 shares of common stock, (ii) 30,397 shares of common stock and warrants to purchase 10,704 shares of common stock held in the name of ProQuest Investments II Advisors Fund L.P., and (iii) 4,974,426 shares of common stock and warrants to purchase 1,751,854 shares of common stock held in the name of ProQuest Investments III, L.P. ProQuest Associates III LLC ( Associates III ) is the general partner of ProQuest Investments III, L.P. ProQuest Associates II LLC ( Associates II ) is the general partner of ProQuest Investments II, L.P. and of ProQuest Investments II Advisors Fund, L.P. Jay Moorin and Alain Schreiber, Managing Members of Associates III and Associates II, have voting, dispositive and investment power with respect to the securities being offered hereunder. Each of Mr. Moorin and Mr. Schreiber disclaim beneficial ownership of such securities except to the extent of each such person's respective pecuniary interest in such securities.

(27) Includes (i) 4,974,426 shares of common stock and warrants to purchase 1,751,854 shares of common stock, (ii) 1,262,747 shares of common stock and warrants to purchase 444,704 shares of common stock held in the name of ProQuest Investments II, L.P., and (iii) 30,397 shares of common stock and warrants to purchase 10,704 shares of common stock held in the name of ProQuest Investments II Advisors Fund L.P. ProQuest Associates III LLC ( Associates III ) is the general partner of ProQuest Investments III, L.P. ProQuest Associates II LLC ( Associates II ) is the general partner of ProQuest Investments II, L.P. and of ProQuest Investments II Advisors Fund, L.P. Jay Moorin and Alain Schreiber, Managing Members of Associates III and Associates II, have voting, dispositive and investment power with respect to the securities being offered hereunder. Each of Mr. Moorin and Mr. Schreiber disclaim beneficial ownership of such securities except to the extent of each such person's respective pecuniary interest in such securities.

(28) Includes warrants to purchase 417,519 shares of common stock. Oppenheimer & Co., Inc. is a registered broker-dealer and is deemed to be an underwriter within the meaning of the Securities Act, in connection with the sale of the foregoing securities. Please see Plan of Distribution for further disclosure regarding these selling security holders.

(29) Includes (i) warrants to purchase 36,840 shares of common stock and (ii) warrants to purchase 187,332 shares of common stock held in the name of Griffin Securities, Inc. Mr. Stecyk is the President and CEO of Griffin Securities, Inc., a registered broker-dealer, and as a result, Mr. Stecyk may be deemed an affiliate of a registered broker-dealer. Accordingly, the selling security holder may be deemed an underwriter if he (i) did not acquire the shares of common stock in the ordinary course of business or (ii) had any agreement or understanding, directly or indirectly, with any person to distribute the shares of common stock. Mr. Stecyk has confirmed to the Company that he acquired the shares of common stock being registered hereunder in the ordinary course of business and he does not have any agreement or understanding, directly or indirectly, with any person to distribute such shares of common stock. Please see Plan of Distribution for further disclosure regarding these selling security holders.

## PLAN OF DISTRIBUTION

We are registering the shares offered by this prospectus on behalf of the selling security holders. The selling security holders, which as used herein includes donees, pledgees, transferees or other successors-in-interest selling shares of common stock or interests in shares of common stock received after the date of this prospectus from a selling security holder as a gift, pledge, partnership distribution or other transfer, may, from time to time, sell, transfer or otherwise dispose of any or all of their shares of common stock or interests in shares of common stock on any stock exchange, market or trading facility on which the shares are traded or in private transactions. These dispositions may be at fixed prices, at prevailing market prices at the time of sale, at prices related to the prevailing market price, at varying prices determined at the time of sale, or at negotiated prices. To the extent any of the selling security holders gift, pledge or otherwise transfer the shares offered hereby, such transferees may offer and sell the shares from time to time under this prospectus, provided that this prospectus has been supplemented under Rule 424(b)(3) or other applicable provision of the Securities Act to include the name of such transferee in the list of selling security holders under this prospectus. Within one business day of receipt by us of all requisite information from the transferee relating to any gift, pledge, or transfer of shares offered hereby, we shall supplement this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act to include the name of such transferee in the list of selling security holders.

The selling security holders may use any one or more of the following methods when disposing of shares or interests therein:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the shares as agent, but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions; short sales; through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;
- broker-dealers may agree with the selling security holders to sell a specified number of such shares at a stipulated price per share;
- a combination of any such methods of sale; and
- any other method permitted pursuant to applicable law.

The selling security holders may, from time to time, pledge or grant a security interest in some or all of the shares of common stock owned by them and, if they default in the performance of their secured obligations, the pledgees or secured parties may offer and sell the shares of common stock, from time to time, under this prospectus, or under an amendment to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act amending the list of selling security holders to include the pledgee, transferee or other successors in interest as selling security holders under this prospectus.

In connection with the sale of our common stock or interests therein, the selling security holders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the common stock in the course of hedging the positions they assume. The selling security holders may also sell shares of our common stock short and deliver these securities to close out their short positions, or loan or pledge the common stock to broker-dealers that in turn may sell these securities. The selling security holders may also enter into option or other transactions with broker-dealers or other financial institutions or the creation of one or more derivative securities which require the delivery to such broker-dealer or other financial institution of shares offered by this prospectus, which shares such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction).

The aggregate proceeds to the selling security holders from the sale of the common stock offered by them will be the purchase price of the common stock less discounts or commissions, if any. Each of the selling security holders reserves the right to accept and, together with their agents from time to time, to reject, in whole or in part, any proposed purchase of common stock to be made directly or through agents. We will

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not receive any of the proceeds from this offering. Upon any exercise of the warrants by payment of cash, however, we will receive the exercise price of the warrants.

The selling security holders also may resell all or a portion of the shares in open market transactions in reliance upon Rule 144 under the Securities Act of 1933, provided that they meet the criteria and conform to the requirements of that rule.

31

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The selling security holders who are registered broker-dealers are deemed to be underwriters within the meaning of the Securities Act. In addition, selling security holders who are affiliates of registered broker-dealers may be deemed to be underwriters within the meaning of the Securities Act if such selling security holder (i) did not acquire the shares of common stock in the ordinary course of business or (ii) had any agreement or understanding, directly or indirectly, with any person to distribute the shares of common stock. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the shares purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act, and such selling security holders may be subject to certain additional regulations and statutory liabilities under the Securities Act and Exchange Act. Except for the warrant to purchase 417,519 shares of our common stock issued to Oppenheimer & Co. Inc. and as otherwise described in the footnotes to the Selling Security Holders table, to our knowledge and based upon information we received from the selling security holders, (i) each selling security holder that is a registered broker-dealer or affiliated with a registered broker-dealer acquired the shares of common stock in the ordinary course of business, (ii) such selling security holder did not have any agreement or understanding, directly or indirectly, with any person to distribute the shares of common stock, and (iii) no such selling security holder received any securities as underwriting compensation. We are also not aware of any underwriting plan or agreement, underwriters or dealers compensation, or passive market making or stabilizing transactions involving the purchase or distribution of these securities.

To the extent required, the shares of our common stock to be sold, the names of the selling security holders, the respective purchase prices and public offering prices, the names of any agents, dealer or underwriter, any applicable commissions or discounts with respect to a particular offer will be set forth in an accompanying prospectus supplement or, if appropriate, a post-effective amendment to the registration statement that includes this prospectus.

In order to comply with the securities laws of some states, if applicable, the common stock may be sold in these jurisdictions only through registered or licensed brokers or dealers. In addition, in some states the common stock may not be sold unless it has been registered or qualified for sale or an exemption from registration or qualification requirements is available and is complied with.

We have advised the selling security holders that the anti-manipulation rules of Regulation M under the Exchange Act may apply to sales of shares in the market and to the activities of the selling security holders and their affiliates. In addition, we will make copies of this prospectus (as it may be supplemented or amended from time to time) available to the selling security holders for the purpose of satisfying the prospectus delivery requirements of the Securities Act. The selling security holders may indemnify any broker-dealer that participates in transactions involving the sale of the shares against certain liabilities, including liabilities arising under the Securities Act.

We have agreed to indemnify the selling security holders against liabilities, including liabilities under the Securities Act and state securities laws, relating to the registration of the shares offered by this prospectus. The selling security holders have agreed to indemnify us in certain circumstances against certain liabilities, including liabilities under the Securities Act.

We have agreed with the selling security holders to keep the registration statement that includes this prospectus effective until the earlier of (1) such time as all of the shares covered by this prospectus have been disposed of pursuant to and in accordance with the registration statement or (2) the date on which the shares may be sold pursuant to Rule 144(k) of the Securities Act. We have agreed to pay all expenses in connection with this offering, but not including underwriting discounts, concessions, commissions or fees of the selling security holders or any fees and expenses of counsel or other advisors to the selling security holders.

### **LEGAL MATTERS**

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

### **EXPERTS**



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The financial statements as of July 31, 2006 and 2005 and for the years ended July 31, 2006, 2005 and 2004 incorporated by reference in this prospectus and elsewhere in the registration statement have been audited by J.H. Cohn LLP, independent registered public accounting firm, as indicated in their report with respect thereto, and are incorporated by reference herein 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 Commission. You may read and copy any document we file at the Commission's public reference room at 100 F Street, N.E., Room 1580, Washington, D.C. 20549. Please call the Commission at 1-800-SEC-0330 for further information on the public reference rooms. Many of the filings we make with the Commission are also available to the public from the Securities and Exchange Commission's Website at <http://www.sec.gov>. We make available free of charge our annual, quarterly and current reports, proxy statements and other information upon request. To request such materials, please send an e-mail to [mspicer@novadel.com](mailto:mspicer@novadel.com) or contact Michael Spicer, our Chief Financial Officer at our address as set forth above.

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

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

### INFORMATION INCORPORATED BY REFERENCE

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

1. Our Annual Report on Form 10-K for the fiscal year ended July 31, 2006, filed on October 27, 2006;
2. Our Proxy Statement for our annual meeting of stockholders, filed on November 28, 2006;
3. Our Quarterly Report (unaudited) on Form 10-Q for the quarterly period ended October 31, 2006, filed on December 14, 2006;
4. Our Current Reports on Form 8-K and 8K/A filed with the Commission on August 9, 2006, August 22, 2006, August 31, 2006, September 18, 2006, September 21, 2006, September 29, 2006, October 18, 2006 (only with respect to Item 8.01), November 1, 2006 (only with respect to Item 8.01), November 6, 2006, December 8, 2006, December 15, 2006, December 21, 2006 (only with respect to Item 8.01), January 4, 2007 and January 10, 2007;
5. The description of our capital stock contained in our Registration Statements on Form 8-A filed with the Commission on November 19, 1997, and May 10, 2004; and
6. All documents we have filed with the Commission pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934 after the date of the initial registration statement and prior to the effectiveness of the registration statement, as well as subsequent to the date of this prospectus and prior to the termination of this offering, shall be deemed to be incorporated by reference into this prospectus and to be a part of this prospectus from the date of the filing of the documents.

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

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

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

**14,207,935**

**Shares of**

**Common Stock**

\_\_\_\_\_  
**PROSPECTUS**  
\_\_\_\_\_

\_\_\_\_\_, 2007



**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	\$ 2,360.00
AMEX Additional Listing Fee	\$ 15,000.00
Accounting fees and expenses	\$ 7,500.00
Attorneys fees and expenses	\$ 20,000.00
Miscellaneous	\$ 10,000.00
Total	\$ 54,860.00

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

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

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

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

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

**Item 16. Exhibits.**

**Exhibit**

<b>No.</b>	<b>Description</b>
4.1	Form of Warrant issued to certain accredited investors and placement agents (Incorporated by reference to Exhibit 4.1 of the Company's Form 8-K, as filed with the SEC on January 4, 2007).
5.1*	Opinion of Morgan, Lewis & Bockius LLP.
10.1	Form of Securities Purchase Agreement by and between the Company and certain accredited investors, with attached schedule of parties and terms thereto (Incorporated by reference to Exhibit 10.1 of the Company's Form 8-K, as filed with the SEC on January 4, 2007).
10.2	Placement Agent Agreement, dated as of November 21, 2006, by and between the Company and Oppenheimer & Co, Inc. (Incorporated by reference to Exhibit 10.2 of the Company's Form 8-K, as filed with the SEC on January 4, 2007).
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).

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\* Filed herewith.

**Item 17. Undertakings.**

(a) The undersigned registrant hereby undertakes:

- (1) To file, during any period in which it offers or sells securities, a post-effective amendment to this registration statement:
  - (i) to include any prospectus required by section 10(a)(3) of Securities Act of 1933;
  - (ii) to reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or together, represent a fundamental change in the information in the registration statement. Notwithstanding the foregoing, any increase or decrease in the volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the 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 registration statement to be signed on its behalf by the undersigned, thereunto duly authorized in the City of Flemington, State of New Jersey, on January 18, 2007.

**NOVADEL PHARMA INC.**

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

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

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

Name	Title	Date
<u>/s/ Jan H. Egberts</u>	President, Chief Executive Officer	January 18, 2007
Jan H. Egberts, M.D.	<i>(Principal Executive Officer)</i> and Director	
<u>/s/ Michael E. Spicer</u>	Chief Financial Officer	January 18, 2007
Michael E. Spicer	<i>(Principal Financial Officer and Principal Accounting Officer)</i>	
<u>/s/ Thomas E. Bonney</u>	Director	January 18, 2007
Thomas E. Bonney		
<u>/s/ William F. Hamilton</u>	Director	January 18, 2007
William F. Hamilton, Ph.D.		
<u>/s/ J. Jay Lobell</u>	Director	January 18, 2007
J. Jay Lobell		
<u>/s/ Charles Nemeroff</u>	Director	January 18, 2007
Charles Nemeroff, M.D., Ph.D.		

/s/ Steven B. Ratoff

Director and Chairman of the Board of Directors

January 18, 2007

Steven B. Ratoff

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**EXHIBIT INDEX**

**Exhibit**

<b>No.</b>	<b>Description</b>
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5.1*	Opinion of Morgan, Lewis & Bockius LLP.
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10.2	Placement Agent Agreement, dated as of March 15, 2006, by and between the Company and Oppenheimer & Co, Inc. (Incorporated by reference to Exhibit 10.2 of the Company's Form 8-K, as filed with the SEC on January 4, 2007).
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).

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