NOVADEL PHARMA INC
Form S-3
July 08, 2005

As filed with the Securities and Exchange Commission on July 8, 2005
Registration No. [_____]

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

25 Minneakoning Road
Flemington, NJ 08822
(908) 782-3431
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Gary A. Shangold, M.D.
President and Chief Executive Officer
NovaDel Pharma Inc.
25 Minneakoning Road
Flemington, NJ 08822
(908) 782-3431
(Name, address, including zip code, and telephone number including area code, of agents for service)

_____

Copies to:
Ira L. Kotel, Esq.
Dickstein Shapiro Morin & Oshinsky LLP
1177 Avenue of the Americas, 47th Floor
New York, New York 10036-2714
(212) 835-1400

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. |X|

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

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 delivery of the prospectus is expected to be made pursuant to Rule 434, please check the following box. |_|

CALCULATION OF REGISTRATION FEE

Title of Securities to be Registered	Amount to be Registered(1)	Proposed Maximum Offering Price Per Share(1)(2)	Proposed Maximum Aggregate Offering Price(2)	Amount of Registration Fee(1)(2)
Common Stock, $0.001 par value	9,426,234	$ 1.17	$ 11,028,693.78	$ 1,298.08

(1) Includes 6,733,024 shares of common stock and 2,693,210 shares of common stock issuable upon the exercise of certain warrants issued by the registrant.

(2) Pursuant to paragraphs (c) and (h) of Rule 457 of the Securities Act, the proposed per share maximum offering price of such shares of common stock is estimated solely for the purpose of determining the registration fee. The amount of the fee was calculated in accordance with Rule 457(c) based on the average of the high and low sales prices of our common stock as reported on the American Stock Exchange on July 7, 2005, solely for the purpose of calculating the amount of the registration fee.

Pursuant to Rule 416 under the Securities Act of 1933, as amended, there are also being registered such additional shares of common stock as may become issuable upon the exercise of the warrants to purchase 2,693,210 shares of common stock described in footnote 1 in connection with stock splits, stock dividends and anti-dilution provisions.

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

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

Subject to Completion
Preliminary Prospectus dated July 8, 2005

9,426,234

Shares of common stock

This prospectus relates to the public offering of up to 9,426,234 shares of our common stock, par value $0.001 per share, for sale by certain of our stockholders identified in this prospectus for their own accounts. Such stockholders are referred to throughout this prospectus as "selling security holders." These shares include 2,693,210 shares that are issuable upon exercise of certain warrants.

In this prospectus and any amendment or supplement hereto, unless otherwise indicated, the terms "NovaDel", the "Company", "we", "us", and "our" refer 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 for working capital and general corporate purposes. One should read this prospectus and any amendment or supplement hereto together with additional information described under the heading "Available Information".

Our common stock is listed for trading on the American Stock Exchange ("AMEX") under the symbol "NVD". On July 7, 2005, the closing sales price for the common stock on the AMEX was $1.18 per share.

OUR COMMON STOCK BEING OFFERED BY THIS PROSPECTUS INVOLVES A HIGH DEGREE OF RISK. YOU SHOULD READ THE "RISK FACTORS" SECTION BEGINNING ON PAGE 3 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 _____, 2005

TABLE OF CONTENTS

About this Prospectus	1
Summary Information and Risk Factors	1
Recent Events	2
Risk Factors	3
Forward-Looking Statements	22
Use of Proceeds	23
Selling Security Holders	23
Plan of Distribution	25
Experts	28
Legal Matters	28
Where you can find additional Information	28
Information Incorporated By Reference	29

Any prospective investor should not rely on any information not contained in this document. We have not authorized anyone to provide any other information to the contrary. This document may only be used where it is legal to sell these securities. The information in this document may only be accurate as of and on the date of this document.

About this Prospectus

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

Summary Information and Risk Factors

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

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

We have identified six (6) tier-one priority products for development, namely nitroglycerin, sumatriptan, alprazolam, zolpidem, ondansetron and propofol. We have also identified a number of other development initiatives, which are currently less of a priority than our six (6) tier-one priority programs. These products include, among other products, clemastine, loratadine, and estradiol and progesterone lingual sprays. However, additional development work on such products has been put on hold due to changes in the marketplace which have significantly reduced the market potential for these compounds.

In light of the material expense and delays associated with independently developing and obtaining approval of pharmaceutical products, we continue to develop a number of such products through collaborative arrangements with major pharmaceutical and veterinary companies, such pharmaceutical companies providing the funding for the development of specified drug products. To date, other than license agreements with (i) Manhattan Pharmaceuticals, Inc., in connection with propofol, (ii) Velcera Pharmaceuticals, Inc., in connection with veterinary applications for currently marketed veterinary drugs, (iii) Par Pharmaceutical, Inc., for the marketing rights in the United States and Canada for our nitroglycerin lingual spray, and (iv) Hana Biosciences, Inc., for the marketing rights in the United States and Canada for our ondansetron lingual spray, we have not entered into any material development arrangements with any pharmaceutical companies. We believe that we will require additional financing and/or additional alliances with well-funded development partners to undertake and maintain our business plan.

On November 18, 2004, we entered into a manufacturing and supply agreement with INyX USA, Ltd., pursuant to which INyX agreed to manufacture and supply our nitroglycerin lingual spray, NitroMist™. Pursuant to the terms and conditions of the agreement, for a five-year period, INyX will be our exclusive provider of the nitroglycerin lingual spray, and is required to manufacture, package and supply the nitroglycerin lingual spray, for sales worldwide, excluding Poland, Byelorussia, the former Russian Republics of Ukraine, Latvia, Lithuania, Estonia and the United Arab Emirates. Thereafter, INyX will have a non-exclusive right to manufacture the nitroglycerin lingual spray for an additional five years. We had total fixed assets of $543,000 and inventories of $433,000 at the facilities of INyX as of April 30, 2005. Such assets are our property and cannot be used by INyX for any other business. In the event that our agreement with INyX is terminated for any reason, such assets are to be returned to us.

NitroMist™ is a pending trademark of Par Pharmaceutical Companies, Inc.

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

Recent Events

Approvable Letter

On June 2, 2005, we received an approvable letter from the U.S. Food and Drug Administration regarding our New Drug Application (NDA) for NitroMist, our nitroglycerin lingual spray (nitroglycerin lingual aerosol), indicated for acute relief of an attack or acute prophylaxis of angina pectoris due to coronary artery disease. We believe that the FDA will give final approval of NitroMist™ once we complete certain manufacturing process validation commitments which we had previously agreed to with the FDA, although we may not complete such commitments and the FDA may not grant such final approval. The FDA is not requiring us to complete any additional clinical studies for approval. We have partnered this product with Par Pharmaceutical, Inc., who has exclusive rights to market, sell and distribute NitroMist in the United States and Canada. We are entitled to a milestone payment from Par upon receiving final approval from the FDA, if at all, and are entitled to receive royalties on sales of NitroMist by Par, assuming that Par is successful in marketing, selling and distributing NitroMist. Manufacturing of the product will occur at the Manati, Puerto Rico facility of Inyx USA, Ltd.

Private Placement

On May 26, 2005, we completed a private placement of 6,733,024 shares of our common stock and Class D warrants to purchase a total of 2,356,559 shares of our common stock, with an initial exercise price equal to $1.30 per share, subject to adjustment. We received gross proceeds of approximately $7,069,675 and net proceeds of approximately $6,300,000, from the private placement. In connection with the private placement, we paid a cash commission equal to 7% of the gross proceeds from the private placement to Paramount BioCapital, Inc., who acted as our placement agent, and issued to Paramount BioCapital a warrant to purchase 336,651 shares of our common stock. The warrant issued to Paramount BioCapital is exercisable at an initial exercise price equal to $1.30 per share (subject to adjustment). Paramount BioCapital was also entitled to an expense allowance of up to $50,000 to reimburse it for its out of pocket expenses incurred in connection with the private placement. Paramount BioCapital and its affiliates are beneficial owners of a significant amount of shares of our common stock and securities exercisable for shares of our common stock and accordingly, Paramount BioCapital may be deemed to be our affiliate.

Risk Factors

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

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

We are a pre-commercialization biopharmaceutical company. Therefore, you must evaluate us in light of the uncertainties and complexities present in such companies. We have not generated any revenue from the commercial sale of our proposed products and do not expect to receive such revenue in the near future. We have no material licensing or royalty revenue or products ready for use or licensing in the marketplace. This limited history may not be adequate to enable one to fully assess our ability to develop our technologies and proposed products, obtain FDA approval and achieve market acceptance of our proposed products and respond to competition. We cannot be certain as to when to anticipate commercializing and marketing any of our proposed products in development, if at all, and do not expect to generate sufficient revenues from proposed product sales to cover our expenses or achieve profitability in the near future.

We had an accumulated deficit as of April 30, 2005 of approximately $32.4 million. We incurred losses in each of our last eight fiscal years, including a net loss of approximately $6.3 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 proposed products, obtain the required regulatory approvals and manufacture, market and sell our proposed products.

WE WILL REQUIRE SIGNIFICANT CAPITAL FOR PRODUCT DEVELOPMENT AND COMMERCIALIZATION.

The research, development, testing and approval of our proposed products involve significant expenditures and accordingly we require significant capital to fund such expenditures. We anticipate, based on our current proposed plans and assumptions relating to our operations (including the timetable of, and costs associated with, new product development), our existing capital resources should be sufficient to satisfy our contemplated cash requirements into the fiscal quarter ended April 30, 2006. 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. We will require significant additional financing and/or a strategic alliance with a well-funded development partner to aggressively pursue our business plan. We have no current arrangements with respect to, or sources of, additional financing, and additional financing may not be available to us on acceptable terms, if at all. Unless we raise additional financing, we may not have sufficient funds and we may not be able to complete development and commercialization of our proposed products or continue operating.

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

The additional financings we require may be obtained through one or more transactions which effectively dilute the ownership interests of our stockholders. Further, we may not be able to secure such additional financing on terms acceptable to us, if at all. We have the authority to issue additional shares of common stock, as well as additional classes or series of ownership interests or debt obligations which may be convertible into any one or more classes or series of ownership interests. We are authorized to issue a total of 100,000,000 shares of common stock and 1,000,000 shares of preferred stock. Such securities may be issued without the approval or other consent of our stockholders. See “Risk Factors - Additional authorized shares of common stock and preferred stock available for issuance may adversely affect the market”.

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

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

We filed an NDA for our nitroglycerin lingual spray, NitroMist™, on June 21, 2004, which was accepted for filing by the FDA on September 29, 2004. We received a Prescription Drug User Fee Act ("PDUFA") date of June 4, 2005, for NitroMist, and received an approvable letter from the FDA on June 2, 2005. We believe that the FDA will give final approval of NitroMist once we complete certain manufacturing process validation commitments which we had previously agreed to with the FDA. The FDA is not requiring us to complete any additional clinical studies for approval. Although we currently intend to complete the manufacturing process validation commitments, the FDA may not grant us final marketing approval for NitroMist if do not timely complete the manufacturing process validation Commitments or for other reasons.

We have initiated and completed pharmacokinetic studies of Tier I priority products during late calendar year 2004 and early calendar year 2005. These products are lingual spray formulations of ondansetron, sumatriptan, alprazolam, propofol and zolpidem. The goal of these pilot pharmacokinetic studies is to determine whether or not a specific lingual spray can achieve therapeutic blood levels of an active ingredient via administration through the oral mucosa. If blood levels are not achieved, it could result in the need to reformulate the lingual 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 lingual sprays (loratadine and clemastine), an estradiol lingual spray and a progesterone lingual spray. In addition, we completed phase 2 clinical trials for the clemastine lingual spray. However, additional development work on loratadine, clemastine, estradiol and progesterone has been put on hold due to changes in the marketplace which have significantly reduced the market potential for these compounds.

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

—the number of clinical sites;
—the size of the patient population;

—the proximity of patients to the clinical sites;
—the eligibility criteria for the study;
—the existence of competing clinical trials; and
—the existence of alternative available products.

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

THERE ARE CERTAIN INTERLOCKING RELATIONSHIPS AND POTENTIAL CONFLICTS OF INTEREST.

Lindsay A. Rosenwald, M.D., a significant stockholder, directly and indirectly, of NovaDel, is the Chairman and sole shareholder of Paramount BioCapital. In the regular course of its business and the business of its affiliates, and outside of its arrangement with us, Paramount BioCapital and/or its affiliates identify, evaluate and pursue investment opportunities in biomedical and pharmaceutical products, technologies and companies. In addition, Dr. Rosenwald and his affiliates may be deemed to beneficially own approximately 25.5% of our outstanding common stock (assuming exercise of certain warrants beneficially owned by Dr. Rosenwald and his affiliates). As such, Dr. Rosenwald and Paramount BioCapital may be deemed to be our affiliates. Dr. Rosenwald and Paramount BioCapital may also be deemed to be affiliates of Manhattan Pharmaceuticals, Velcera Pharmaceuticals and Hana Biosciences. Generally, Delaware corporate law requires that any transactions between us and any of our affiliates be on terms that, when taken as a whole, are substantially as favorable to us as those then reasonably obtainable in an arms length transaction from a person who is not an affiliate. Nevertheless, neither Dr. Rosenwald nor Paramount BioCapital, nor their affiliates, are obligated pursuant to any agreement or understanding with us to make any additional products or technologies available to us, nor can there be any assurance, and we do not expect and our stockholders should not expect, that any biomedical or pharmaceutical product or technology identified by Dr. Rosenwald nor Paramount BioCapital, 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 outside counsel, Dickstein Shapiro Morin & Oshinsky LLP, who represented us in the private placement completed on May 26, 2005, also represents Dr. Rosenwald, Paramount BioCapital and certain of their affiliates from time to time, for which it has received, and will receive, customary fees and reimbursement of expenses.

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

Revenue received from our product development efforts consists of payments by pharmaceutical companies for research and bioavailability studies, pilot clinical trials and similar milestone-related payments. Our future growth and profitability will be dependent upon our ability successfully to raise additional funds to complete the development of, obtain regulatory approvals for and license out or market our proposed products. Accordingly, our prospects must be considered in light of the risks, expenses and difficulties frequently encountered in connection with the establishment of a new business in a highly competitive industry, characterized by frequent new product introductions. We anticipate that we will incur substantial operating expenses in connection with the development, testing and approval of our proposed products and expect these expenses to result in continuing and significant operating losses until such time, if ever, that we are able to achieve adequate levels of sales or license revenues. We may not be able to raise additional financing, increase revenues significantly, or achieve profitable operations. See “Risk Factors - We will require significant capital for product development and commercialization” and “- Our strategy is to enter into collaboration agreements with third parties and we may require additional collaboration agreements. If we fail to enter into these agreements or if we or the third parties do not perform under such agreements, it could impair our ability to

commercialize our proposed products".

WE DO NOT HAVE COMMERCIALLY AVAILABLE PRODUCTS.

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

WE HAVE NOT COMPLETED PRODUCT DEVELOPMENT.

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

WE DO NOT HAVE DIRECT CONSUMER MARKETING EXPERIENCE.

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

WE MUST COMPLY WITH GOOD MANUFACTURING PRACTICES.

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

WE ARE DEPENDENT ON OUR SUPPLIERS.

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

regulatory authorities.

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

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

If we cannot rectify these material weaknesses through remedial measures and improvements to our systems and procedures, management may encounter difficulties in timely assessing business performance and identifying incipient strategic and oversight issues. In December 2004, we hired a new Chief Financial Officer and in March 2005, we hired a Corporate Controller. We believe that these hirings will improve our internal controls, particularly with respect to our need to comply with Section 404 of the Sarbanes-Oxley Act of 2002. Management is currently focused on remedying internal control deficiencies, and this focus will require management from time to time to devote its attention away from other planning, oversight and performance functions.

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

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

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

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

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

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

WE FACE INTENSE COMPETITION.

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

Accordingly, our competitors may succeed in obtaining patent protection, receiving FDA or comparable foreign approval or commercializing products before us. If we commence commercial product sales, we will compete against companies with greater marketing and manufacturing capabilities who may successfully develop and commercialize products that are more effective or less expensive than ours. Our competitors may be more successful in receiving third party reimbursements from government agencies and others for their commercialized products which are 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 lingual spray products. First Horizon Pharmaceutical Corporation, headquartered in Alpharetta, Georgia, currently markets Nitrolingual® Pumpspray, a nitroglycerin lingual spray which is in an “air” propelled dispensing system (our nitroglycerin lingual spray is in a “propellant” based dispensing system). Generex Biotechnology Corporation, based in Toronto, Canada, is developing an insulin formulation that is delivered directly into the mouth via its RapidMist™ device. They also state that they have begun research on four specific target molecules for their RapidMist delivery system: morphine, fentanyl, heparin and flu vaccine. Generex is listed as the assignee on 15 United States patents. RapidMist™ is a pending trademark of Generex Biotechnology Corporation. Arakis Ltd., based in the United Kingdom, also claims to be developing an analgesic to be delivered sublingually via a non-pressurized metered dose spray formulation. There are several other companies that we are aware of that market lingual spray products containing vitamins and homeopathic ingredients.

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

LIMITED PRODUCT LIABILITY INSURANCE COVERAGE MAY AFFECT OUR BUSINESS.