

NOVADEL PHARMA INC
Form 10-K
October 27, 2006
UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

X ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended July 31, 2006

OR

**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES
EXCHANGE ACT OF 1934**

For the transition period from _____ to _____ .

COMMISSION FILE NO. 001-32177

NOVADEL PHARMA INC.

(Exact Name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation or organization)

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

Edgar Filing: NOVADEL PHARMA INC - Form 10-K

25 MINNEAKONING ROAD, FLEMINGTON, NEW JERSEY 08822

(Address of principal executive offices) (Zip Code)

(908) 782-3431

Registrant's telephone number, including area code

Securities registered pursuant to Section 12(b) of the Exchange Act:

Title of each class
COMMON STOCK, PAR VALUE \$.001 PER SHARE

Name of each exchange on which registered
American Stock Exchange

Securities registered pursuant to Section 12(g) of
the Exchange Act:

NONE

(Title of Class)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes No

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Edgar Filing: NOVADEL PHARMA INC - Form 10-K

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer Accelerated filer Non-accelerated filer

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes No

As of October 2, 2006, the aggregate market value of the voting and non-voting common equity of the issuer held by non-affiliates of the registrant was approximately \$45.7 million based upon the closing sale price of \$1.24 for the Registrant's common stock, \$.001 par value, as reported by the American Stock Exchange on that date. Common stock held by each officer and director and by each person known to the registrant who owned 5% or more of the outstanding common stock have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of October 2, 2006, the issuer had 49,236,369 shares of common stock, \$.001 par value, outstanding.

NOVADEL PHARMA INC.

ANNUAL REPORT ON FORM 10-K

FOR THE FISCAL YEAR ENDED JULY 31, 2006

TABLE OF CONTENTS

	PAGE
Item 1. PART I Business.	4
Item 1A. Risk Factors.	20
Item 1B. Unresolved Staff Comments.	38
Item 2. Properties.	39
Item 3. Legal Proceedings.	39
Item 4. Submission of Matters to a Vote of Security Holders.	39
Item 5. PART II Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchase of Equity Securities.	40
Item 6. Selected Consolidated Financial Data.	41
Item 7. Management's Discussion and Analysis of Financial Conditions and Results of Operations.	42
Item 7A. Quantitative and Qualitative Disclosures About Market Risk.	51
Item 8. Financial Statements and Supplementary Data.	51
Item 9. Changes In and Disagreements With Accountants on Accounting and Financial Disclosure.	51
Item 9A. Controls and Procedures.	51
Item 9B. Other Information.	51
Item 10. PART III Directors and Executive Officers of the Registrant.	52
Item 11. Executive Compensation.	55
Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.	63
Item 13. Certain Relationships and Related Transactions.	66
Item 14. Principal Accountant Fees and Services.	67
Item 15. PART IV Exhibits, Financial Statement Schedules.	69
Signatures	74

Edgar Filing: NOVADEL PHARMA INC - Form 10-K

Unless the context otherwise requires, all references to we, us, our, and the Company include NovaDel Pharma Inc. (NovaDel).

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

This Annual Report on Form 10-K includes forward-looking statements, including statements regarding NovaDel Pharma Inc.'s (the Company, we, us or NovaDel) expectations, beliefs, intentions or strategies for the future and the Company's internal controls and procedures and outstanding financial reporting obligations and other accounting issues. The Company intends that all forward-looking statements be subject to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are only predictions and reflect the Company's views as of the date they are made with respect to future events and financial performance. In particular, the Management's Discussion and Analysis of Financial Condition and Results of Operations section in Part II, Item 7 of this Annual Report includes forward-looking statements that reflect the Company's current views with respect to future events and financial performance. The Company uses words such as expect, anticipate, believe, intend and similar expressions to identify forward-looking statements. You can also identify forward-looking statements by the fact that they do not relate strictly to historical or current facts. A number of important risks and uncertainties could, individually or in the aggregate, cause actual results to differ materially from those expressed or implied in any forward-looking statements.

Examples of the risks and uncertainties include, but are not limited to: the inherent risks and uncertainties in developing products of the type the Company is developing (independently and through collaborative arrangements); the inherent risks and uncertainties in completing the pilot pharmacokinetic feasibility studies being conducted by the Company; possible changes in the Company's financial condition; the progress of the Company's research and development; clinical trials require adequate supplies of drug substance and drug product, which may be difficult or uneconomical to procure or manufacture; timely obtaining sufficient patient enrollment in the Company's clinical trials; the impact of development of competing therapies and/or technologies by other companies; the Company's ability to obtain additional required financing to fund its research programs; the Company's ability to enter into agreements with collaborators and the failure of collaborators to perform under their agreements with the Company; the progress of the Food and Drug Administration, or FDA, approvals in connection with the conduct of the Company's clinical trials and the marketing of the Company's products; the additional costs and delays which may result from requirements imposed by the FDA in connection with obtaining the required approvals; acceptance for filing by the FDA does not mean that the New Drug Application, or NDA, has been or will be approved, nor does it represent an evaluation of the adequacy of the data submitted; the risks related to the Company's internal controls and procedures; and the risks identified under the section entitled Risk Factors included as Item 1A in Part I of this Annual Report on Form 10-K and other reports, including this report and other filings filed with the Securities and Exchange Commission from time to time.

PART I

ITEM 1. BUSINESS.

GENERAL

NovaDel Pharma Inc., a Delaware corporation, 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

Edgar Filing: NOVADEL PHARMA INC - Form 10-K

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 52 patents which have been issued outside of the U.S. Additionally, we have over 80 patents pending around the world.

Edgar Filing: NOVADEL PHARMA INC - Form 10-K

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

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. Our principal business address is 25 Minneakoning Road, Flemington, New Jersey, 08822, and our telephone number is (908) 782-3431. We maintain a website at www.novadel.com.

On June 28, 2006, our Board of Directors approved a change of our fiscal year end from July 31 to December 31. Accordingly, the new fiscal year will begin on January 1, and end on December 31. We have filed this Annual Report on Form 10-K for the period ending July 31, 2006 and we intend to file a transition report on Form 10-K for the period ending December 31, 2006.

Highlights for our fiscal year ended July 31, 2006, and additionally through the date of filing of this Annual Report on Form 10-K, include the following product development and business achievements:

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

Announced that Dr. Henry Kwan would no longer serve as Head of Pharmaceutical Sciences on October 20, 2005.

Filed an IND for ondansetron (Zensana) through our partner, Hana Biosciences.

Announced through our partner, Hana Biosciences, positive study results of a pivotal clinical trial for Zensana ondansetron oral spray, a study which demonstrated Zensana 8mg dose is bioequivalent to the current commercially available 8mg tablet (Zofran®). Hana Biosciences filed an NDA for Zensana which was accepted for review by the FDA.

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

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

Completed a private placement in April 2006 of our common stock, raising gross proceeds of approximately \$11.8 million.

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

Received notice from the FDA indicating acceptance of our New Drug Application, or NDA, submission for our nitroglycerin lingual spray (NitroMist) as a complete response and an indicated target date of November 3, 2006 for action on the submission.

Edgar Filing: NOVADEL PHARMA INC - Form 10-K

Added two new central nervous system product candidates to our development pipeline, including tizanidine oral spray potentially for spasticity and ropinirole oral spray potentially for Parkinson's disease.

5

Edgar Filing: NOVADEL PHARMA INC - Form 10-K

Appointment of Mr. Steven B. Ratoff as Chairman of the Board effective September 15, 2006 with Dr. Egberts remaining a member of the Board of Directors.

Announcement of 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.

PRODUCT DEVELOPMENT

Drug development in the U.S. and most countries throughout the world is a process that includes several steps defined by the FDA or comparable regulatory authorities in foreign countries. The FDA approval processes relating to new drugs differ, depending on the nature of the particular drug for which approval is sought. With respect to any drug product with active ingredients not previously approved by the FDA, a prospective drug manufacturer is required to submit 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 IND, to obtain permission to begin clinical testing of the new drug. 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) NDA. We estimate that the development of new formulations of our pharmaceutical product candidates, including formulation, testing and obtaining FDA approval, will take two to three years for the 505(b)(2) NDA process and will require significantly lower investments in direct research and development expenditures than is the case for the discovery and development of new chemical entities. However, our estimates may prove to be inaccurate; or pre-marketing approval relating to our proposed products may not be obtained on a timely basis, if at all, and research and development expenditures may significantly exceed management's expectations.

It is not anticipated that we will generate any revenues from royalties or sales of our product candidates until regulatory approvals are obtained and marketing activities begin. Any one or more of our product candidates may not prove to be commercially viable, or if viable, may not reach the marketplace on a basis consistent with our desired timetables, if at all. The failure or the delay of any one or more of our proposed products to achieve commercial viability would have a material adverse effect on us.

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

the scope, rate of progress and expense of our clinical trials and other research and development activities;

results of future clinical trials;

the expense of clinical trials for additional indications;

the terms and timing of any collaborative, licensing and other arrangements that we may establish;

the expense and timing of regulatory approvals;

the expense of establishing clinical and commercial supplies of our product candidates and any products that we may develop;

the effect of competing technologies and market developments; and

the expense of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

6

Edgar Filing: NOVADEL PHARMA INC - Form 10-K

We expect to continue to spend significant amounts on the development of our product candidates and we expect our costs to increase as we continue to develop and ultimately commercialize our product candidates. Over the next fiscal year, we expect to devote the majority of our research and development resources to the following product candidates:

NitroMist (nitroglycerin lingual aerosol). This product candidate is 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 June 1, 2005, we received an approvable letter from the FDA regarding our NDA for NitroMist. The FDA is not requiring any additional clinical studies for approval, but has requested that we complete certain manufacturing process validation commitments. On April 30, 2006, we submitted the additional documentation to the FDA for the manufacturing process validation commitments. On May 26, 2006, we announced that the FDA had accepted our submission regarding our NDA as a complete response and, further, that the FDA indicated a target date of November 3, 2006 for action on the submission. We will receive a milestone payment from Par should final approval from the FDA be obtained. In addition, we will receive royalty payments based upon a percentage of net sales.

Zolpidem oral spray. Zolpidem is the active ingredient in Ambien®, the leading hypnotic marketed by Sanofi-Aventis. A pilot pharmacokinetic, or PK, study in zolpidem oral spray with 10 healthy subjects suggested that the formulation of zolpidem oral spray had a comparable PK profile to the Ambien® tablet but with a more rapid time to detectable drug levels. The study demonstrated a mean time to therapeutic concentration level that was 23 minutes shorter with the 10mg oral spray compared with the 10mg Ambien® tablet (15.5 min. and 38.5 min., respectively). This time was also approximately 16 minutes shorter for the 5mg dose of the oral spray. Zolpidem oral spray has the potential to provide patients with the meaningful benefit of faster onset of sleep as compared to existing sleep remedies should future studies validate the already completed Pilot PK study. 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. A pilot PK study of our sumatriptan oral spray with 9 healthy subjects, completed in the second half of calendar 2004, suggested that the formulation achieved serum concentrations of sumatriptan in the therapeutic range. In September 2006 we announced positive results from a pharmacokinetic study of our improved oral spray formulation of sumatriptan which demonstrated that sumatriptan oral spray achieves a statistically significant increase in absorption rate as compared with Imitrex® tablets. The rate of drug absorption is believed to be the most important predictor of the degree and speed of migraine relief. Sumatriptan oral spray was evaluated in a four-arm, crossover pharmacokinetic study comparing 50mg Imitrex® tablets to 20mg and 30mg of the oral spray in 10 healthy male volunteers under fasting conditions. Additionally, the pharmacokinetics of 20mg oral spray after a meal were evaluated. At least 90% of subjects receiving sumatriptan oral spray had detectable drug levels at three minutes post-dosing, while at the same timepoint, only 10% of subjects receiving 50mg Imitrex® tablets had detectable drug levels. These differences are statistically significant. At 3 to 6 minutes post dosing, all oral spray groups had statistically significantly higher mean concentration levels compared to 50mg Imitrex® tablets. Using published data for the currently marketed Imitrex® nasal spray as a proxy for therapeutic blood levels, we observed that by 6 minutes post-dosing, 100% of the 20mg oral spray users achieved these critical plasma concentration levels while none of the subjects from the Imitrex® tablet group did so by this timepoint. This result was also statistically significant. Furthermore, the study indicates up to a 50% increase in relative bioavailability of oral spray in comparison to the Imitrex® tablet. Sumatriptan oral spray was well tolerated.

Edgar Filing: NOVADEL PHARMA INC - Form 10-K

Comparison to Imitrex® Nasal Spray Published Data

Time to the first peak plasma concentration of sumatriptan -- which represents drug absorbed directly across the oral mucosa -- was approximately 70% faster with the 20mg oral spray than what has been reported in the literature for the same dose of the Imitrex® nasal spray (6 min. vs. 20 min.). The mean concentration level achieved during this critical first phase of absorption is approximately 30% greater for the oral spray than what was observed in published studies of the nasal spray (10.9 ng/mL vs. 8.5 ng/mL). Relative bioavailability after administration of 20mg oral spray appears to be greater than published estimates for the same dose of the Imitrex® nasal spray. Imitrex® nasal spray was not included in this clinical study.

Sumatriptan oral spray may provide clinical benefits to migraine sufferers including, possibly, faster relief than Imitrex® tablets as well as greater tolerability than triptan nasal sprays. Further, if proven to be safe and effective, sumatriptan oral spray may be attractive to patients who have trouble taking oral medications due to nausea and vomiting caused by the migraine attack. 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, which 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 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 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. We believe that Zensana is the only multidose oral spray product candidate currently in development which utilizes a spray technology to deliver full doses of ondansetron to patients experiencing chemo and radiotherapy-induced nausea and vomiting. Ondansetron, a selective blocking agent of the hormone serotonin, is an FDA-approved drug that is commonly used in tablet form to prevent chemotherapy and radiation-induced and post-operative nausea and vomiting. Many patients receiving chemo and radiation therapy have difficulty swallowing and are potentially unable to tolerate other forms of ondansetron and other therapies intended to prevent nausea and vomiting, known as anti-emetics. The convenience of drug delivery via a spray may offer a desirable alternative to tablets and other forms of ondansetron. 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 and 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. We retain the rights to our ondansetron oral spray outside of the U.S. and Canada.

Edgar Filing: NOVADEL PHARMA INC - Form 10-K

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

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

BUSINESS DEVELOPMENT

To date, we have entered into license agreements with (i) Hana Biosciences., for the marketing rights in the U.S. and Canada for our ondansetron oral spray, (ii) Par, for the marketing rights in the U.S. and Canada for our nitroglycerin lingual aerosol, (iii) Manhattan Pharmaceuticals, in connection with propofol, and (iv) Velcera, in connection with veterinary applications for currently marketed veterinary drugs. Lindsay A. Rosenwald, M.D., a significant stockholder, directly and indirectly, of us, is the Chairman and sole shareholder of Paramount BioCapital, Inc., 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. In addition, as of October 2, 2006, Dr. Rosenwald may be deemed to beneficially own approximately 16.8% 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 and Paramount may also be deemed to be affiliates of Manhattan Pharmaceuticals, Velcera and Hana Biosciences. See Item 13, Certain Relationships and Related Transactions . We intend to pursue additional strategic alliances, as well as to consider fully developing and commercializing product candidates internally. We have added two new central nervous system product candidates to our development pipeline, tizanidine oral spray for spasticity and ropinirole oral spray for Parkinson's disease. We intend to file NDAs on these products during 2008, with commercialization targeted for 2009. We intend to enter into additional license agreements and strategic alliances, including:

Marketing partners outside of North America for Zensano, for which we retain marketing rights outside of North America.

Marketing partners for our zolpidem oral spray and sumatriptan oral spray, to commercialize these products assuming that we are successful in attaining approval for these products from the FDA.

Additional marketing partners and strategic alliances as may be appropriate for future products in our development pipeline.

AGREEMENT WITH HANA BIOSCIENCES, INC.

In October 2004, we entered into a 20-year license and development agreement with Hana Biosciences. Hana Biosciences will develop and market our oral spray version of ondansetron, the most widely prescribed anti-emetic for preventing chemotherapy-induced nausea and vomiting. Under the agreement, Hana Biosciences has exclusive rights to market, sell and distribute our ondansetron oral spray in the U.S. and Canada. We are entitled to receive milestone payments at several junctures of development, including completion of a pharmacokinetic study, filing of an IND, FDA acceptance of the NDA and NDA approval. In August 2005, our license and development agreement with Hana Biosciences was amended to transfer the responsibility to Hana Biosciences of selecting and managing a contract manufacturer who will provide clinical and commercial quantities of the ondansetron oral spray product. Double-digit royalties on net sales of the product may be due to us if and when the product launches. In October 2004, in exchange for \$1 million, Hana Biosciences purchased 400,000 newly issued shares of our common stock, at a price of \$2.50 per share, and has issued to us, for no additional consideration, 73,121 shares of its common stock, valued at \$500,000 based upon the average price of Hana Biosciences' common stock during the 10 business days prior to the effective date of the agreement (\$6.84 per share).

LICENSE AND SUPPLY AGREEMENT WITH PAR PHARMACEUTICAL, INC.

In July 2004, we entered into a 10-year license and supply agreement with Par, a wholly owned subsidiary of Par Pharmaceutical Companies, Inc., whereby Par has the exclusive rights to market, sell and distribute our nitroglycerin lingual spray in the U.S. and Canada. The terms of the agreement call for an upfront license fee which was paid to us in July 2004, a milestone payment made to us upon the FDA's acceptance of an NDA for our nitroglycerin lingual spray for review in September 2004, another potential milestone payment if and when the NDA is approved for marketing in the U.S., and double-digit percentage royalties on net sales of the product in the U.S. and Canada. We are responsible for obtaining regulatory approval for the product and for supplying the product to Par.

AGREEMENT WITH MANHATTAN PHARMACEUTICALS, INC.

In April 2003, we entered into a 10-year license and development agreement with Manhattan Pharmaceuticals for the worldwide, exclusive rights to our oral spray technology to deliver propofol for pre-procedural sedation. Manhattan Pharmaceuticals is a development stage company and has no revenues to date. The terms of the agreement require Manhattan Pharmaceuticals to achieve certain milestones and to make certain up-front license fee payments to us, the first \$500,000 of which we received from June 2003 through November 2003.

AGREEMENT WITH VELCERA PHARMACEUTICALS, INC. (FORMERLY VETCO)

On September 14, 2004, we announced the granting of an exclusive worldwide 20-year license for our proprietary oral spray technology to Velcera, formerly known as Vetco Pharmaceuticals, for development of innovative veterinary medicines. We received an equity stake of 529,500 shares of common stock in Velcera, representing approximately 15% of its outstanding common stock as of October 23, 2003, along with an upfront cash technology fee of \$1,500,000 in September 2004. The agreement, which amends an earlier agreement, provides that Velcera shall make certain milestone payments to us upon the achievement of key events associated with product development. Velcera will be obligated to make additional similar payments to us for each product developed by it, and double-digit royalty payments on product sales will be due to us. Products will be formulated by Velcera, at Velcera's expense, and Velcera will fund all development and regulatory expenses. We will manufacture and supply Velcera with the resulting pharmaceutical products.

BUSINESS STRATEGY

Strategy

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;

Edgar Filing: NOVADEL PHARMA INC - Form 10-K

Increasing focus on products in targeted therapeutic areas (e.g., 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.

Products

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.

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 FDA.

In addition to our existing product candidates, we intend to continue to identify and pursue additional product candidates for development.

PATENTED AND PATENT PENDING DELIVERY SYSTEMS

We have certain patents and pending patent applications for our oral spray delivery system. FDA approval is not a prerequisite for patent approval. The expected year of marketability of a given product candidate will vary depending upon the specific drug product with which the delivery system will be utilized. Each individual use of the delivery system will require registration with and/or approval by the FDA or other relevant health authority prior to marketability, and the amount of regulatory oversight required by the FDA or other regulatory agencies will also depend on the specific type of drug product for which the delivery system is implemented. Our aerosol and pump spray formulations release drugs in the form of a fine mist into the buccal portion of the mouth for rapid absorption into the bloodstream via the mucosal membranes. We believe that this delivery system may offer certain advantages, including more rapid delivery of drugs to the bloodstream, improving the safety profile of certain drugs by lowering the required dosage to be administered, improving dose reliability, allowing medication to be taken without water, avoiding the need to swallow as is the case with many medications and improved patient convenience and compliance. Drug absorption through the mucosal membranes of the mouth is rapid and minimizes the first-pass metabolism effect (i.e., total or partial inactivation of a drug as it passes through the gastrointestinal tract and liver).

MARKETING AND DISTRIBUTION

To date, we have chosen to license products developed with our technology to other drug companies. We intend to pursue additional strategic alliances, as well as to consider fully developing and commercializing product candidates internally.

We anticipate that promotion of our product candidates, whether conducted by us or by a strategic partner, will be characterized by an emphasis on their distinguishing characteristics, such as dosage form and packaging, as well as possible therapeutic advantages of such product candidates. We intend to position our product candidates as alternatives or as line extensions to brand-name products. We believe that to the extent our formulated products are patent-protected, such formulations may offer brand-name manufacturers the opportunity to expand their product lines. Alternatively, products which are not patented may be offered to brand-name manufacturers as improved substitute products after patent protection on existing products expire.

Inasmuch as we do not have the financial or other resources to undertake extensive marketing activities, we generally intend to seek to enter into marketing arrangements, including possible joint ventures or license or distribution arrangements, with third parties. We believe that such third-party arrangements will permit us to maximize the promotion and distribution of pharmaceutical products while minimizing our direct marketing and distribution costs. If we are unable to enter into additional agreements, we may not be able to successfully market our product candidates.

Edgar Filing: NOVADEL PHARMA INC - Form 10-K

We have not yet determined strategies relating to marketing of our other proposed formulated products; these will be formulated in advance of anticipated completion of development activities relating to the particular formulated product. As a company, we have no experience in marketing or distribution of our product candidates, and our ability to fund such marketing activities will require us to raise additional funds and/or consummate a strategic alliance or combination with a well-funded business partner.

MANUFACTURING

We intend to both internalize and contract out the manufacturing of our product candidates. Our current facility does not yet have a pilot manufacturing operation that meets current Good Manufacturing Practices, or cGMP, and would require additional investment in order to attain that capability. We will have to contract out manufacturing and/or invest additional funds in the current facility in order to provide internal manufacturing capability. The manufacture of our pharmaceutical product candidates is subject to cGMP prescribed by the FDA and pre-approval inspections by the FDA and foreign authorities prior to the commercial manufacture of any such products. See Item 1, Business- Raw Materials and Suppliers and Government Regulation.

On November 18, 2004, we entered into a manufacturing and supply agreement with INyX USA, Ltd, or INyX, whereby INyX will manufacture and supply our nitroglycerin lingual spray. For a five-year period that began November 18, 2004, INyX will be the exclusive provider of the nitroglycerin lingual spray to us worldwide, excluding Poland, Byelorussia, the former Russian Republics of Ukraine, Latvia, Lithuania, Estonia and the United Arab Emirates. Pursuant to the terms and conditions of the agreement, it will be INyX's responsibility to manufacture, package and supply the nitroglycerin lingual spray in such territories. Thereafter, INyX will have a non-exclusive right to manufacture such spray for an additional five years.

RAW MATERIALS AND 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 and Japan and can be delivered to our manufacturing facility by such suppliers. We intend to enter into arrangements with such third-party suppliers for supplies of active and inactive pharmaceutical ingredients and packaging materials used in the manufacture of our product candidates. Accordingly, we may be subject to various import duties applicable to both finished products and raw materials and may be affected by various other import and export restrictions as well as other developments impacting upon international trade. These international trade factors will, under certain circumstances, have an impact on the manufacturing costs (which will, in turn, have an impact on the cost of our product candidates). To the extent that transactions relating to the purchase of raw materials involve currencies other than U.S. dollars, our operating results will be affected by fluctuations in foreign currency exchange rates.

Generally, certain raw materials, including inactive ingredients, are available from a limited number of suppliers and certain packaging materials intended for use in connection with our product candidates may be available only from sole source suppliers. Although we believe that we will not encounter difficulties in obtaining the inactive ingredients or packaging materials necessary for the manufacture of our products, we may not be able to enter into satisfactory agreements or arrangements for the purchase of commercial quantities of such materials. A failure to enter into agreements or otherwise arrange for adequate or timely supplies of principal raw materials and the possible inability to secure alternative sources of raw material supplies could have a material adverse effect on our ability to manufacture formulated products.

Development and regulatory approval of our product candidates 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 specified supplier, which could result in manufacturing delays. Accordingly, we intend to locate alternative FDA approved suppliers.

GOVERNMENT REGULATION

Edgar Filing: NOVADEL PHARMA INC - Form 10-K

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

Under the Federal Food, Drug and Cosmetic Act, or FDCA, 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 FDCA.

Edgar Filing: NOVADEL PHARMA INC - Form 10-K

The FDA approval process relating to a new drug differs, 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, including complete reports of pre-clinical, clinical and laboratory studies to prove such product's safety, quality and efficacy. Prior to submission of the NDA, it is necessary to submit an IND to obtain permission to begin clinical testing of the new drug. 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) NDA.

While the Abbreviated New Drug Application, or ANDA, process requires a manufacturer to establish bioequivalence to the previously approved drug, it permits the manufacturer to rely on the safety and efficacy studies contained in the NDA for the previously approved drug.

The NDA approval process generally requires between 10 to 24 months from NDA submission to pre-marketing approval, although in the case of an NDA submitted pursuant to Section 505(b)(2) of the FDCA this time frame may be significantly shorter. We believe that most products developed in oral spray delivery systems (dosage forms) usually will require submission of an NDA under Section 505(b)(2). This is because the safety and efficacy of the drug compound used in the oral spray formulation generally can be established in previous trials in NDA submissions and publications.

We estimate that the development of new formulations of pharmaceutical products, including formulation, testing and obtaining FDA approval, will take four to seven years for the NDA process, although NDAs submitted under Section 505(b)(2) of the FDCA are generally less complex than an ordinary NDA and may be acted upon by the FDA in a shorter period of time.

Our product candidates are subjected to laboratory testing and stability studies and tested for therapeutic comparison to the originator's products by qualified laboratories and clinics. To the extent that two drug products with the same active ingredients are substantially identical in terms of their rate and extent of absorption in the human body (bioavailability), they are considered bioequivalent. If the accumulated data demonstrates bioequivalency and the product forms are identical, submission is then made to the FDA (through the filing of an ANDA), for its review and approval to manufacture and market. If the accumulated data demonstrates that there are differences in the two drugs' rate and extent of absorption into the human body, or if it is intended to make additional or different claims regarding therapeutic effect for the newly developed product, or if it is a different form or route of administration, submission is made to the FDA via an NDA for its review and approval under Section 505(b)(1) or Section 505(b)(2) of the FDCA. An NDA submitted under Section 505(b)(2) of the FDCA, is generally less complex than an ordinary Section 505(b)(1) NDA. We expect that the majority of our product candidates in development will require the filing of Section 505(b)(2) NDAs because, although such products are known chemical entities, we or our licensees may be making new claims as to therapeutic effects or lessened side effects, or both.

We estimate that development of our new formulations of pharmaceutical products, including formulation, testing and obtaining FDA approval, generally takes two to three years for the Section 505(b)(2) NDA or ANDA Section 505(j) process. Development of products requiring additional clinical studies under full NDAs, may take four to seven years. Our determination regarding the availability of ANDAs or Section 505(b)(2) NDAs for our product candidates under development may not be accurate and pre-marketing approval for our product candidates might not be obtained on a timely basis, if at all.

Our determinations regarding the availability of ANDAs and/or use of the Section 505(b)(2) regulatory path for our product candidates may not be accurate and pre-marketing approval for our product candidates might not be obtained on a timely basis, if at all. The FDA application procedure has become more rigorous and costly and the FDA currently performs pre-approval and periodic inspections of each finished dosage form and each active ingredient.

Section 505(b)(2) New Drug Applications

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.

Edgar Filing: NOVADEL PHARMA INC - Form 10-K

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 an NDA under Section 505(b)(2) for Zensana in June 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 will expire in June 2006, and that is subject to a period of pediatric exclusivity expiring 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.

The Hatch-Waxman Act

Under the Hatch-Waxman Act, newly-approved drugs and new conditions of use may benefit from a statutory period of non-patent marketing exclusivity. The Hatch-Waxman Act provides five-year marketing exclusivity to the first applicant to gain approval of an NDA for a new chemical entity, meaning that the FDA has not previously approved any other new drug containing the same active entity. The Hatch-Waxman Act prohibits the submission of an abbreviated NDA, or ANDA, or a Section 505(b)(2) NDA for another version of such drug during the five-year exclusive period; however, submission of a Section 505(b)(2) NDA or an ANDA for a generic version of a previously-approved drug containing a paragraph IV certification is permitted after four years, which may trigger a 30-month stay of approval of the ANDA or Section 505(b)(2) NDA. Protection under the Hatch-Waxman Act does not prevent the submission or approval of another full 505(b)(1) NDA; however, the applicant would be required to conduct its own preclinical and adequate and well-controlled clinical trials to demonstrate safety and effectiveness. The Hatch-Waxman Act also provides three years of marketing exclusivity for the approval of new and supplemental NDAs, including Section 505(b)(2) NDAs, for, among other things, new indications, dosages, or strengths of an existing drug, if new clinical investigations that were conducted or sponsored by the applicant are essential to the approval of the application. Some of our product candidates for which we may seek approval of new uses or indications may qualify for three (3) year non-patent marketing exclusivity under the Hatch-Waxman Act if we conduct clinical trials that are essential to the approval of the new indication.

Edgar Filing: NOVADEL PHARMA INC - Form 10-K

In addition to non-patent marketing exclusivity, the Hatch-Waxman Act amended the FDCA to require each NDA sponsor to submit with its application information on any patent that claims the drug for which the applicant submitted the NDA or that claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug. Generic applicants that wish to rely on the approval of a drug listed in the Orange Book must certify to each listed patent, as discussed above. We intend to submit for Orange Book listing all relevant patents for our product candidates.

Finally, the Hatch-Waxman Act amended the patent laws so that certain patents related to products regulated by the FDA are eligible for a patent term extension if patent life was lost during a period when the product was undergoing testing and regulatory review, and if certain criteria are met. We intend to seek patent term extensions, provided our patents and product candidates, if they are approved, meet applicable eligibility requirements.

Other Regulatory Requirements

The manufacture of our pharmaceutical product candidates will be subject to cGMP prescribed by the FDA, pre-approval inspection by the FDA before beginning commercial manufacture of such product candidates and periodic cGMP compliance inspections by the FDA thereafter.

Any drugs manufactured or distributed by us or our collaboration partners pursuant to future FDA approvals are subject to continuing regulation by the FDA, including recordkeeping requirements and reporting of adverse experiences associated with the drug. Drug manufacturers and their subcontractors are required to register with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with ongoing regulatory requirements, including cGMP, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Failure to comply with the statutory and regulatory requirements can subject a manufacturer to possible legal or regulatory action, such as warning letters, suspension of manufacturing, sales or use, seizure of product, injunctive action or possible civil penalties. We cannot be certain that we or our present or future third-party manufacturers or suppliers will be able to comply with the cGMP regulations and other ongoing FDA regulatory requirements. If our present or future third-party manufacturers or suppliers are not able to comply with these requirements, the FDA may halt our clinical trials, require us to recall a drug from distribution, or withdraw approval of the NDA for that drug.

The FDA closely regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the Internet. A company can make only those claims relating to safety and efficacy that are approved by the FDA. Failure to comply with these requirements can result in adverse publicity, warning and/or untitled letters, corrective advertising and potential civil and criminal penalties.

Foreign Regulation

In addition to regulations in the U.S., we will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our future product candidates. Whether or not we obtain FDA approval for a product candidate, we must obtain approval of a product candidate by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product candidate in those countries. The approval process varies from country to country, and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country.

Edgar Filing: NOVADEL PHARMA INC - Form 10-K

Under European Union regulatory systems, marketing authorizations may be submitted either under a centralized or mutual recognition procedure. The centralized procedure provides for the grant of a single marketing authorization that is valid for all European Union member states. The mutual recognition procedure provides for mutual recognition of national approval decisions. Under this procedure, the holder of a national marketing authorization may submit an application to the remaining member states. Within 90 days of receiving the applications and assessment report, each member state must decide whether to recognize approval.

In addition to regulations in Europe and the U.S., we will be subject to a variety of foreign regulations governing clinical trials and commercial distribution of our future product candidates.

Reimbursement

In many of the markets where we intend to commercialize a product candidate following regulatory approval, the prices of pharmaceutical products are subject to direct price controls by law and to drug reimbursement programs with varying price control mechanisms.

In the U.S., there has been an increased focus on drug pricing in recent years. Although there are currently no direct government price controls over private sector purchases in the U.S., federal legislation requires pharmaceutical manufacturers to pay rebates based on a set formula to state Medicaid agencies in order for such drugs to be eligible for reimbursement under certain public health care programs such as Medicaid. Various states have adopted further mechanisms under Medicaid and otherwise that seek to control drug prices, including creating formularies that favor lower cost drugs such as generics, requiring prior approval, and seeking supplemental rebates from manufacturers. Other federal purchases such as purchases by the Department of Veteran Affairs, the Department of Defense and purchases by covered entities under the 340B Program, use set formulas to determine the amount of reimbursement the government will pay, which may put downward pressure on prices for drugs sold to those entities. Managed care has also become a potent force in the marketplace that increases downward pressure on the prices of pharmaceutical products. Federal legislation, known as the Medicare Prescription Drug, Improvement and Modernization Act, or MMA, enacted in December 2003, created an outpatient prescription drug benefit called Medicare, Part D, which is provided through private entities, which are required to negotiate price concessions from pharmaceutical manufacturers. While Medicare Part D does not mandate which drugs may be included in a drug plan's formulary, the MMA mandates that formularies must contain at least one drug from each therapeutic category and class of drugs. In addition, Medicare Part D plans may structure the benefit using tiering or other methods that may encourage the use of lower cost drugs. Negotiated price concessions along with the risk of not being included in a formulary or being placed in a less favorable tier may negatively impact reimbursement under Medicare Part D.

Public and private health care payors control costs and influence drug pricing through a variety of mechanisms, including through negotiating discounts with the manufacturers and through the use of tiered formularies and other mechanisms that provide preferential access to certain drugs over others within a therapeutic class. Payors also set other criteria to govern the uses of a drug that will be deemed medically appropriate and therefore, covered and reimbursed. In particular, many public and private health care payors limit reimbursement and coverage to the uses of a drug that are either approved by the FDA or that are supported by other appropriate evidence (for example, published medical literature) and appear in a recognized drug compendium. Drug compendia are publications that summarize the available medical evidence for particular drug products and identify which uses of a drug are supported or not supported by the available evidence, whether or not such uses have been approved by the FDA.

Different pricing and reimbursement schemes exist in other countries. For example, in the European Union, governments influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national health care systems that fund a large part of the cost of such products to consumers. The approach taken varies from member state to member state. Some jurisdictions operate positive and/or negative list systems under which products may only be marketed once a reimbursement price has been agreed upon. Other member states allow companies to fix their own prices for medicines, but monitor and control company profits. The downward pressure on health care costs in general, particularly prescription drugs, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products, as exemplified by the National Institute for Clinical Excellence in the UK, which evaluates the data supporting new medicines and passes reimbursement recommendations to the government. In addition, in some countries cross-border imports from low-priced markets (parallel imports) exert a commercial pressure on pricing within a country.

COMPETITION

The markets which we intend to enter are characterized by intense competition, often from organizations which are larger and/or better capitalized than us. We will 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 delivery system technologies gain greater acceptance. Additionally, the markets for formulated products which we have targeted for development are intensely competitive, involving numerous competitors and products. We intend to enhance our competitive position by focusing our efforts on our novel dosage forms.

Edgar Filing: NOVADEL PHARMA INC - Form 10-K

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). Genex Biotechnology Corporation, based in Toronto, Canada, is developing an insulin formulation that is delivered directly into the mouth via its RapidMist® device. This product was approved in Ecuador. They also state that they have begun research on four specific target molecules for their RapidMist® delivery system: morphine, fentanyl, heparin and flu vaccine. Genex Biotechnology Corporation is listed as the assignee on 15 U.S. patents. RapidMist® is a pending trademark of Genex 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.

PATENTS AND PROTECTION OF PROPRIETARY INFORMATION

We have applied for U.S. and foreign patent protection for our buccal spray delivery systems which are the primary focus of our development activities as well as for our delayed contact allergy topical formulations. Eight U.S. patents, one Canadian patent and fifty-one European patents have been issued. The fifty-one patents in Europe consist of three unique patents which have been issued in seventeen different countries. We have over 80 patent applications pending in the U.S. and overseas. Additional patent applications may not be granted, or, if granted, may not provide adequate protection to us. We also intend to rely on whatever protection the law affords to trade secrets, including unpatented know-how. Other companies, however, may independently develop equivalent or superior technologies or processes and may obtain patents or similar rights with respect thereto.

Although we believe that we have developed our technology independently and have not infringed, and do not infringe, on the patents of others, third parties may make claims, however, that our technology does infringe on their patents or other intellectual property. In the event of infringement, we may, under certain circumstances, be required to modify our infringing product or process or obtain a license. We may not be able to do either of those things in a timely manner if at all, and failure to do so could have a material adverse effect on our business. In addition, we may not have the financial or other resources necessary to enforce a patent infringement or proprietary rights violation action or to defend ourselves against such actions brought by others. If any of the products we develop infringe upon the patent or proprietary rights of others, we could, under certain circumstances, be enjoined or become liable for damages, which would have a material adverse effect on our business.

We also rely on confidentiality and nondisclosure agreements with our licensees and potential development candidates to protect our technology, intellectual property and other proprietary property. Pursuant to the foregoing and for other reasons, we face the risk that our competitors may acquire information which we consider to be proprietary, that such parties may breach such agreements or that such agreements will be inadequate or unenforceable.

BUCCAL NONPOLAR SPRAYS. On April 12, 1996, we filed an application with the U.S. Patent and Trademark Office, or the USPTO, with claims directed to our buccal spray composition containing certain amounts of propellant, a non-polar solvent, and certain classes of drugs, as well as specific drugs within those classes. The application also included claims directed to soft-bite gelatin capsules containing these drugs. On September 1, 1998, the USPTO allowed the claims directed to buccal spray propellant compositions, but rejected the claims directed to the capsules. In November 1998, we deleted the capsule claims from this application to pursue issuance of a patent with claims directed to the buccal non-polar spray compositions and methods of administering the class of drugs using the buccal spray compositions. On September 21, 1999, U.S. Patent No. 5,955,098 was issued to us with claims directed to the above-described buccal non-polar spray propellant compositions and methods. This patent expires on April 12, 2016.

Edgar Filing: NOVADEL PHARMA INC - Form 10-K

On February 21, 1997, we filed an application under the Patent Cooperation Treaty, or the PCT, (PCT Application No. WO 97/38663) for the above-subject matter. The International Preliminary Examination Authority issued an International Preliminary Examination Report alleging that the subject matter of the invention lacked novelty and/or lacked an inventive step. This opinion, with which we disagree, is not dispositive.

With respect to the above PCT application, in October and November 1998, we entered the national phase in Canada and Europe, with claims directed to the above subject matter. On April 16, 2003, European Patent No. EP 0 904 055 was granted to us with claims directed to propellant containing buccal non-polar spray compositions containing similar drugs (i.e., anti-histamines, steroid hormones, non-steroidal anti-inflammatories, benzodiazepines, anti-depressants and nicotine) to those in the corresponding issued U.S. patent. This European patent has been validated in the UK, Germany, France, Italy, Belgium, Switzerland/Liechtenstein, Austria, Sweden, Denmark, Finland, Luxembourg, the Netherlands, Spain, Greece, Monaco, Portugal and Ireland so that there is patent protection in these countries. We have filed a divisional application based on this European patent with claims directed to a buccal spray composition containing a propellant, a non-polar solvent and an active compound selected from alkaloids and analgesics. With respect to the Canadian application, we filed a request for examination with the Canadian Patent Office on February 7, 2002. We received an Office Action from the Canadian Patent Office dated April 13, 2004, pursuant to which we were requested to elect for prosecution either claims directed to buccal spray compositions or claims to the soft-bite gelatin capsules. We elected to prosecute the claims directed to buccal spray compositions. The Canadian Patent Office granted the application on December 27, 2005 as Canadian Patent No. 2,252,050. The allowed claims are similar to those granted by the European Patent Office.

BUCCAL POLAR SPRAYS. On April 12, 1996, we filed an application with the USPTO with claims directed to propellant free buccal polar spray compositions containing certain amounts of a polar solvent and certain classes of drugs (i.e., non-steroidal anti-inflammatories, anti-histamines, steroid hormones, benzodiazepams, and anti-depressants), as well as specific drugs within those classes. The application also contained claims to soft-bite gelatin capsules containing such drugs. A continuation-in-part, or CIP, application was filed directed to this subject matter before the original application was allowed to go abandoned. The USPTO initially rejected the claims in the CIP application. We deleted the claims from this application (including the soft-bite capsule claims) and replaced them with claims directed to methods of using the above-described propellant free buccal polar spray compositions to administer the drugs. On August 29, 2000, U.S. Patent No. 6,110,486 was issued to us with claims directed to the above-described methods of administering the drugs. This patent expires on April 12, 2016.

On February 21, 1997, we filed an application under the PCT (PCT Application No. WO 97/38662) for the above-described subject matter. The International Preliminary Examination Authority issued an International Preliminary Examination Report alleging that the subject matter of the invention lacked novelty and/or lacked an inventive step. This opinion, with which we disagree, is not dispositive.

With respect to the above PCT application, in October and November 1998, we entered the national phase in Canada and Europe, respectively, with claims directed to the above subject matter. On February 2, 2005, European Patent No. 0 910 339 was granted to us with claims directed to use of polar solvent containing pump sprays containing similar drugs to those in the corresponding issued U.S. patent. This European patent has been validated in the UK, Germany, France, Italy, Belgium, Switzerland/Liechtenstein, Austria, Sweden, Denmark, Finland, Luxembourg, the Netherlands, Spain, Greece, Monaco, Portugal and Ireland so that there is patent protection in these countries. In November 2005, Akzo Nobel N.V. filed an opposition against this patent in the European Patent Office alleging lack of inventive step and insufficient disclosure. We have filed a Response to the Opposition. The Opposition Proceeding is currently pending before the European Patent Office. We have also filed a divisional application based on this European patent with claims directed to a buccal spray composition containing a propellant, a non-polar solvent and an active compound selected from alkaloids and analgesics. With respect to the Canadian application, we filed a request for examination with the Canadian Patent Office on February 7, 2002. We received an Office Action from the Canadian Patent Office dated April 13, 2004, pursuant to which we were requested to elect for prosecution either claims directed to buccal spray compositions or claims to the soft-bite gelatin capsules. We elected to prosecute the claims directed to buccal spray compositions. On February 10, 2006, the Canadian Patent Office issued a Notice of Allowance for this application.

BUCCAL NONPOLAR SPRAY FOR NITROGLYCERIN. On April 12, 1996, we filed an application with the USPTO with claims directed to a buccal spray containing certain amounts of nitroglycerin, a non-polar solvent, and a propellant. The claims were allowed and on February 9, 1999, the USPTO issued U.S. Patent No. 5,869,082 to us for said nitroglycerin buccal spray. This patent expires on April 12, 2016.

Edgar Filing: NOVADEL PHARMA INC - Form 10-K

On February 21, 1997, we filed a PCT application (PCT Application No. WO 97/38687) directed to the above-described subject matter. The International Preliminary Examination Authority issued an International Preliminary Examination Report alleging that the subject matter of the invention lacks an inventive step. This opinion, with which we disagree, is not dispositive. Nevertheless, Greek Patent, GRO904055 was issued on March 18, 2004, for our nitroglycerin buccal, non-polar spray or capsule.

In October 1998, we entered the national phase in Canada. We filed a request for examination on February 7, 2002. The Canadian Patent Office issued a second office action to us dated July 11, 2005. We responded to the office action on January 11, 2006 and await further communication from the Canadian Patent Office.

In November 1998, we entered the national phase in Europe. European Patent No. 0 927 032 was granted to us on April 16, 2003, with claims directed to a buccal spray containing certain amounts of nitroglycerin, a non-polar solvent and a propellant. This European patent has been validated in the UK, Germany, France, Italy, Belgium, Switzerland/Liechtenstein, Austria, Sweden, Denmark, Finland, Luxembourg, the Netherlands, Spain, Greece, Monaco, Portugal and Ireland so that there is patent protection in these countries.

BUCCAL POLAR/NONPOLAR SPRAYS OR CAPSULES. On October 1, 1997, we filed a PCT application (PCT Application No. WO 99/16417) designating a large number of countries including the U.S., directed to the buccal sprays and soft-bite capsules. The application included claims directed to: (A) a buccal spray composition containing either (1) a polar solvent with certain classes of drugs, as well as specific drugs in those classes with or without a propellant or (2) a non-polar solvent with or without a propellant with certain classes of drugs, as well as specific drugs in those classes; (B) buccal spray composition containing a non-polar solvent, a flavoring agent and certain classes of drugs; and (C) methods of administering these drugs using the buccal spray compositions. The application also contained claims to soft-bite gelatin capsules containing such drugs. This application differs from the first three applications, discussed above, in that the claimed compositions include different classes of drugs from those described in the first three applications. The International Preliminary Examination Authority issued an International Preliminary Examination Report alleging that the subject matter of the invention lacked novelty and/or lacked an inventive step. This opinion, with which we disagree, is not dispositive.

On March 29, 2000, we entered the national phase in the U.S. by filing a CIP of the above-identified PCT application with the USPTO. The CIP application included claims directed to propellant free buccal spray compositions containing certain amounts of polar or non-polar solvents, and certain classes of drugs, as well as specific drugs in those classes; buccal spray compositions containing certain amounts of a propellant, a polar or non-polar solvent and certain classes of drugs, as well as specific drugs in those classes; and methods of administering said drugs using these types of buccal spray compositions. The application is currently being prosecuted with claims directed to the propellant free buccal spray compositions and methods of administering said drugs using these types of buccal spray compositions. Subsequently, we filed two divisional applications claiming priority to the CIP. The first divisional application is currently being prosecuted with claims directed to the buccal spray compositions containing certain amounts of a propellant, a polar or non-polar solvent and certain classes of drugs, as well as specific drugs in those classes and methods of administering said drugs using these types of buccal spray compositions. The second divisional application was issued to us as U.S. Patent No. 6,676,931. This patent expires on October 1, 2017. The claims of this patent are directed to a propellant free pump spray composition containing certain amounts of a polar solvent, certain amounts of a flavoring agent and certain amounts of cyclosporin or ondansetron hydrochloride. Another application has been filed directed to the additional classes of drugs and specific drugs that were not included in the claims of U.S. Patent No. 6,676,931.

Based on the above-identified PCT application, we entered the national phase in Canada on March 29, 2000. We filed a request for examination in Canada on August 29, 2002. An office action has been received from the Canadian Patent Office and we have responded to that office action. Based on the above-identified PCT application, we also entered the national phase in Japan on April 3, 2000. We filed a request for examination of this Japanese application on September 30, 2004.

Edgar Filing: NOVADEL PHARMA INC - Form 10-K

Based on the above-identified PCT application, we also entered the national phase in Europe in April 2000. The European application includes claims directed to propellant free buccal spray compositions containing certain amounts of a polar solvent and certain classes of drugs, as well as specific drugs in those classes and the use thereof to prepare a medicament for use as a buccal spray for transmucosal administration. We have filed three applications related to this application in Europe. The first application included claims directed to buccal spray compositions containing certain amounts of a non-polar solvent, a propellant and certain classes of drugs as well as specific drugs in those classes and the use thereof to prepare a medicament for use as a buccal spray for transmucosal administration. The second application included claims directed to propellant free buccal spray compositions containing certain amounts of a non-polar solvent and certain classes of drugs, as well as specific drugs in those classes. The third application included claims directed to a buccal spray composition containing certain amounts of a polar solvent, a propellant and certain classes of drugs, as well as specific drugs in those classes. Each of the above-identified European applications is currently being prosecuted.

Furthermore, in August 2002, we filed a number of U.S. patent applications directed to buccal spray compositions containing certain classes of drugs as well as specific drugs for treating particular types of disorders. In August 2003, we filed PCT applications related to these U.S. applications. We have subsequently filed corresponding applications in Europe, Japan and Canada for the subject matter for a majority of these CIP applications.

ANTIHISTAMINE SYRUP AND OINTMENT. On November 10, 1997, we filed an application with the USPTO with claims directed to a spray composition for topical administration containing an antihistamine and a polar solvent or an antihistamine, a non-polar solvent and a propellant. In October 1998, the PTO rejected the claims. The claims were deleted and replaced with a claim directed to a method of controlling the occurrence of delayed contact dermatitis by applying a lotion composition containing certain amounts of certain antihistamines in certain amounts of a polar or non-polar solvent. On May 21, 2002, U.S. Patent No. 6,391,282 was issued to us for the above-described method. This patent expires on November 10, 2017.

GENERAL COMMENT WITH RESPECT TO ENTERING THE NATIONAL PHASE FOR EACH OF THE FOREGOING PCT APPLICATIONS. In addition to our patents and patent applications in the U.S., we are interested in entering the national phase and obtaining patent protection in Europe and Canada. At the present time, it is not possible to accurately predict the expenses involved in pursuing the foregoing applications in Canada and Europe. For example, we anticipate that, in the case of the European applications, it may become necessary to file appeals with the Board of Appeals in Munich. Expenses may exceed \$100,000 (in the aggregate) before a final disposition is obtained. We expect that this process may take between two and four years.

EMPLOYEES

As of October 2, 2006, we had 23 total employees, 21 of whom were full-time employees.

AVAILABLE INFORMATION

We file annual, quarterly and current reports, proxy statements and other information with the Securities and Exchange Commission, or the Commission. You may read and copy any document we file with the Commission at the Commission's public reference rooms at 450 Fifth Street, N.W., Washington, D.C. 20549. Please call the Commission at 1-800-SEC-0330 for further information on the public reference room. Our Commission filings are also available to the public from the 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 or contact Michael Spicer, our Chief Financial Officer at 25 Minneakoning Road, Flemington, New Jersey, 08822 or at 908-782-3431 ext. 2550.

Edgar Filing: NOVADEL PHARMA INC - Form 10-K

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 Annual Report on Form 10-K.

ITEM 1A. RISK FACTORS

This report contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those discussed in this report. Factors that could cause or contribute to these differences include, but are not limited to, those discussed below, elsewhere in this report, and in any documents incorporated in this report by reference.

20

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.

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 July 31, 2006 of approximately \$44.5 million. We incurred losses in each of our last ten fiscal years, including net losses of approximately \$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 flow from operations of approximately \$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 April 19, 2006, we completed an equity financing in which we received gross proceeds of \$11.8 million and approximate net proceeds of \$10.6 million. Although we expect to have sufficient cash to fund our operations through July 31, 2007, we would have to significantly reduce the pace of our ongoing development of our product candidates unless we can obtain additional working capital. Given the current and desired pace of product development of our product candidates, we estimate that we will need to raise additional capital during fiscal year 2007 in order to fully fund our development activities through July 31, 2007. This could include the securing of funds through new strategic partnerships and/or the sale of our common stock or other securities, in order to fund our research and development activities. There can be no assurance that such capital will be available to us on favorable terms, or at all. There are a number of risks and uncertainties related to our attempt to complete a financing or strategic partnering arrangement that are outside our control. We may not be able to successfully obtain additional financing on terms acceptable to us, or at all. If we are unsuccessful at obtaining additional financing as needed, we may be required to significantly curtail or cease operations. We will need additional financing thereafter until we achieve profitability, if ever.

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

The additional financings we require may be obtained through one or more transactions which effectively dilute the ownership interests of our 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 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 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.

We filed an NDA for our nitroglycerin lingual spray, NitroMist[®], on June 21, 2004, which was accepted for filing by the FDA on September 29, 2004. We received a Prescription Drug User Fee Act, or PDUFA, date of June 4, 2005, for NitroMist[®], and received an approvable letter from the FDA on June 1, 2005. In the June 1, 2005 letter, the FDA requested that we complete certain manufacturing process validation commitments. On April 30, 2006, we submitted the necessary documentation to the FDA for the manufacturing process validation commitments. On May 26, 2006, we announced that the FDA has accepted our submission regarding our NDA as a complete response and that the FDA indicated a target date of November 3, 2006 for action on the submission. NitroMist[®] is a trademark of Par Pharmaceuticals, Inc., or Par.

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

Edgar Filing: NOVADEL PHARMA INC - Form 10-K

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

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

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

THERE ARE CERTAIN INTERLOCKING RELATIONSHIPS AND POTENTIAL CONFLICTS OF INTEREST.

Lindsay A. Rosenwald, M.D., a significant stockholder, directly and indirectly, of us, is the Chairman and sole shareholder of Paramount. In the regular course of its business and the business of its affiliates, and outside of its arrangement with us, Paramount and/or its affiliates identify, evaluate and pursue investment opportunities in biomedical and pharmaceutical products, technologies and companies. As of October 2, 2006, Dr. Rosenwald beneficially owns approximately 16.8% of our outstanding common stock (assuming exercise of certain warrants beneficially owned by Dr. Rosenwald). As such, Dr. Rosenwald and Paramount may be deemed to be our affiliates. Dr. Rosenwald has the ability to designate an individual to serve on our Board of Directors, or the Board, and has exercised such ability by designating Mr. J. Jay Lobell to serve on the Board. On December 14, 2005 based upon the recommendation of the Corporate Governance and Nominating Committee, the Board elected Mr. Lobell as a member of the Board. Pursuant to the listing standards of the American Stock Exchange, or AMEX, Mr. Lobell 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 Item 13 Certain Relationships and Related Transactions 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 successfully to 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.

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 second half of calendar 2006 or the first half of calendar 2007 at the earliest. Accordingly, it is not anticipated that we will generate any revenues from royalties or sales of 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 second half of calendar 2006 or the first half of calendar 2007 at the earliest. Other potential products remain in the conceptual or very early development stage and remain subject to all the risks inherent in the development of pharmaceutical products, including unanticipated development problems and possible lack of funds to undertake or continue development. These factors could result in abandonment or substantial change in the development of a specific formulated product. We may not be able to successfully develop any one or more of our 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., who intends to manufacture our nitroglycerin lingual spray in its Manatee, Puerto Rico facility. With respect to other suppliers, we operate primarily on a purchase order basis beyond which there is no contract memorializing our purchasing arrangements. The inability to enter into agreements or otherwise arrange for adequate or timely supplies of principal raw materials and the possible inability to secure alternative sources of raw material supplies, or the failure of Dynamit Nobel or INyX USA, Ltd. to comply with their supply obligations to us, could have a material adverse effect on our ability to arrange for the manufacture of formulated products. In addition, development and regulatory approval of our products are dependent upon our ability to procure active ingredients and certain packaging materials from FDA-approved sources. Since the FDA approval process requires manufacturers to specify their proposed suppliers of active ingredients and certain packaging materials in their applications, FDA approval of a supplemental application to use a new supplier would be required if active ingredients or such packaging materials were no longer available from the originally specified supplier, which may result in manufacturing delays. If we do not maintain important manufacturing relationships, we may fail to find a replacement manufacturer or to develop our own manufacturing capabilities. If we cannot do so, it could delay or impair our ability to obtain regulatory approval for our products and substantially increase our costs or deplete any profit margins. If we do find replacement manufacturers, we may not be able to enter into agreements with them on terms and conditions favorable to us and, there could be a substantial delay before a new facility could be qualified and registered with the FDA and foreign regulatory authorities.

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 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 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 Annual Report on Form 10-K, 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 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 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.

Edgar Filing: NOVADEL PHARMA INC - Form 10-K

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). Genex 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. Genex Biotechnology Corporation is listed as the assignee on 15 U.S. patents. RapidMist® is a pending trademark of Genex 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 Act, 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 Act. 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 Act. 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 obtaining FDA approval, generally takes two to three years for the 505(b)(2) NDA process. Our determinations may prove to be inaccurate or pre-marketing approval relating to our proposed products may not be obtained on a timely basis, if at all. The failure by us to obtain necessary regulatory approvals, whether on a timely basis or at all, would have a material adverse effect on our business. The filing of an NDA with the FDA is an important step in the approval process in the 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. Over the next fiscal year, we expect to devote the majority of our internal research and development resources to the following product candidates:

NitroMist (nitroglycerin lingual aerosol). This product candidate is 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 June 1, 2005, we received an approvable letter from the FDA regarding our NDA for NitroMist. The FDA requested that we complete certain manufacturing process validation commitments. On April 30, 2006, we submitted the additional documentation to the FDA for the manufacturing process validation commitments. On May 26, 2006, we announced that the FDA had accepted our submission regarding our NDA as a complete response and that the FDA indicated a target date of November 3, 2006 for action on the submission. We will receive a milestone payment from Par should final approval from the FDA be obtained. In addition, we will receive royalty payments based upon a percentage of net sales.

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

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

Edgar Filing: NOVADEL PHARMA INC - Form 10-K

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

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

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

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

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

Edgar Filing: NOVADEL PHARMA INC - Form 10-K

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 expiring 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 52 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.

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. 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.

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

WE ARE CONTROLLED BY CURRENT STOCKHOLDERS, OFFICERS AND DIRECTORS.

Our directors, executive officers and principal stockholders and certain of our affiliates have the ability to influence the election of our directors and most other stockholder actions. Management and our affiliates currently beneficially own (including shares they have the right to acquire) greater than 35% of the common stock on a fully-diluted basis. Specifically, Dr. Rosenwald has the ability to exert significant influence over the election of the Board and other matters submitted to our stockholders for approval. Dr. Rosenwald has the ability to designate an individual to serve on our Board and has exercised such ability by designating Mr. J. Jay Lobell to serve on the Board. On December 14, 2005 based upon the recommendation of the Corporate Governance and Nominating Committee, the Board elected Mr. Lobell as a member of the Board. Pursuant to the listing standards of the AMEX, Mr. Lobell has been deemed to be an independent director by our Board of Directors on September 15, 2006.

Edgar Filing: NOVADEL PHARMA INC - Form 10-K

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 July 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 July 31, 2006, the average daily trading volume in our common stock was approximately 71,000 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.

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

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

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

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

Our management is aware of the abuses that have occurred historically in the penny stock market.

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

We are authorized to issue a total of 100,000,000 shares of common stock. As of October 2, 2006, there were 49,236,369 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 October 2, 2006, we had outstanding stock options and warrants to purchase approximately 30.6 million shares of common stock, the exercise price of which range between \$0.46 per share to \$3.18 per share, and we have reserved shares of our common stock for issuance in connection with the potential exercise thereof.

The following table provides an overview of our stock options and corresponding plans:

Plan	Shares Authorized	Options Outstanding at October 2, 2006	Remaining Shares Available for Issuance	Comments
1992 Stock Option Plan	500,000	80,000		Plan Closed
1997 Stock Option Plan	500,000	100,000		Plan Closed
1998 Stock Option Plan	3,400,000	2,629,000	471,000	
2006 Equity Incentive Plan	6,000,000	450,000	5,550,000	
Non-Plan	n/a	4,770,000		

Edgar Filing: NOVADEL PHARMA INC - Form 10-K

To the extent such options or warrants are exercised, the holders of our common stock will experience further dilution.

In addition, 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 and in amounts, 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 a result of such offerings current holders of our common stock will experience 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.

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.

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.

As of October 2, 2006, we have 49,236,369 shares of common stock issued and outstanding and 30.6 million shares of common stock issuable upon the exercise of outstanding stock options and warrants. In the event we wish to offer and sell shares of our common stock in excess of the 100,000,000 shares of common stock currently authorized by our certificate of incorporation, we will first need to receive stockholder approval. Such stockholder approval has the potential to adversely affect the timing of any potential transactions.

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

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

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

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

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

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

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

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

We have entered into agreements with the holders of our common stock that requires us to continuously maintain as effective, a registration statement covering the underlying shares of common stock. Such registration statements were declared effective on July 28, 2005 and May 30, 2006 and must continuously remain effective for a specified term. If we fail to continuously maintain such a registration statement as effective throughout the specified term, we may be subject to liability to pay liquidated damages.

ITEM 1B. UNRESOLVED STAFF COMMENTS.

None.

ITEM 2. PROPERTIES.

Our executive offices, laboratory, and warehousing space are located at 25 Minneakoning Road, Flemington, New Jersey, the New Facility. The facility, constituting approximately 31,800 square feet, is occupied under a 10-year lease, expiring in August 2013. Presently, we are only occupying a portion of our space in the building. Through December 31, 2005, we occupied approximately 4,500 square feet of laboratory and office space at 31 Route 12 West, Flemington, New Jersey, the Old Facility, which also formerly housed our executive offices. During the fiscal year ended July 31, 2006, we paid rent for both facilities of approximately \$495,000. The New Facility does not yet have a pilot manufacturing operation that meets current Good Manufacturing Practices, or cGMP, and would require additional investment in order to attain that capability. After the expiration of the lease on the Old Facility, we have contracted out manufacturing. We would have to invest additional funds in the New Facility in order to provide internal manufacturing capability. The manufacture of our pharmaceutical products is subject to cGMP prescribed by the FDA and pre-approval inspections by the FDA and foreign authorities prior to the commercial manufacture of any such products. See Item 1, Business- Raw Materials and Suppliers and Business-Government Regulations.

ITEM 3. LEGAL PROCEEDINGS.

We are not a named party in any material legal proceedings.

Lawrence J. Kessel, a former director who was not nominated by the Corporate Governance and Nominating Committee of the Board of the Directors to stand for re-election to the Board of Directors in January 2006, had alleged that in order to induce him not to stand for re-election to the Board of Directors, the Company promised to pay him compensation as a director and compensate him for options he lost by virtue of the end of his tenure on the Board of Directors. The Company denied these allegations. In June 2006, the Company and Dr. Kessel agreed that Dr. Kessel would not pursue the matter.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS.

None.

PART II**ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.**

Our common stock is traded on the American Stock Exchange; or AMEX, under the ticker symbol NVD. The following table sets forth the range of high and low closing sales prices of our common stock as reported by the AMEX for each fiscal quarter for the past two fiscal years.

	<u>CLOSING SALE PRICES</u>	
	-	
	(\$)	
	<u>HIGH</u>	<u>LOW</u>
FISCAL 2006		
First Quarter (August 1, 2005 through October 31, 2005)	1.85	1.21
Second Quarter (November 1, 2005 through January 31, 2006)	1.44	1.16
Third Quarter (February 1, 2006 through April 30, 2006)	1.90	1.22
Fourth Quarter (May 1, 2006 through July 31, 2006)	1.80	1.11
FISCAL 2005		
First Quarter (August 1, 2004 through October 31, 2004)	1.95	1.28
Second Quarter (November 1, 2004 through January 31, 2005)	1.65	1.40
Third Quarter (February 1, 2005 through April 30, 2005)	1.48	1.12
Fourth Quarter (May 1, 2005 through July 31, 2005)	1.39	1.09

The last closing sales price on the AMEX on October 2, 2006 was \$1.24. As of October 2, 2006 there were approximately 121 record holders of our common stock.

We have never declared or paid a dividend on our common stock and management expects that all or a substantial portion of our future earnings will be retained for expansion or development of our business. The decision to pay dividends, if any, in the future is within the discretion of our Board of Directors and will depend upon our earnings, capital requirements, financial condition and other relevant factors such as contractual obligations. Management does not anticipate that we will pay dividends on our common stock in the foreseeable future. Moreover, we may never issue dividends in the future.

RECENT SALES OF UNREGISTERED SECURITIES; USE OF PROCEEDS FROM REGISTERED SECURITIES.

On April 19, 2006, we completed a private placement to certain institutional and accredited investors of an aggregate of 8,092,796 shares of our common stock, at a purchase price of \$1.45 per share, and warrants to purchase up to approximately 2,427,839 shares of common stock, which will not be exercisable until the six (6) month anniversary of the date of issuance and shall expire five (5) years from the date they become exercisable, at an exercise price of \$1.60 per share pursuant to a certain securities purchase agreement. Our affiliates investing in this offering purchased shares of common stock at \$1.58 per share, which is the last closing sale price of our common stock on the day immediately prior to the execution of the securities purchase agreement. We received gross proceeds equal to \$11,773,963. In addition, we entered into a registration rights agreement with these purchasers. The registration rights agreement required us to file a registration statement on Form S-3 within 30 days of the closing date, and to have such registration statement declared effective within 90 days of the closing date, to register the securities acquired by the purchasers in the private placement. We intend to use the proceeds from this private placement to fund our research and development efforts as well as for general working capital.

Edgar Filing: NOVADEL PHARMA INC - Form 10-K

Griffin Securities, Inc., or Griffin, and Paramount BioCapital, Inc., or Paramount, have acted as the placement agents for this private placement. Griffin and Paramount shall be paid an aggregate fee for acting as placement agents of cash equal to 7% of the proceeds from the sale of the common stock, or \$792,400, and warrants equal to 6% of the shares of common stock purchased, subject to certain exclusions, or warrants to purchase 468,329 shares. Such warrants will have the same terms as those issued to the investors.

40

Edgar Filing: NOVADEL PHARMA INC - Form 10-K

We believe that the issuance of the foregoing securities was exempt from registration under Section 4(2) of the Securities Act of 1933, as amended, as transactions not involving a public offering. Each of the recipients was an accredited investor, acquired the securities for investment purposes only and not with a view to distribution and had adequate information about us. Additionally, the registration statement filed on May 11, 2006, and as amended on May 25, 2006, covering the resale of the securities, as required under the registration rights agreement, was declared effective by the Securities and Exchange Commission on May 30, 2006.

In addition, certain holders of our common stock, and warrants to purchase our common stock, listed as selling stockholders in our currently effective registration statements on Form SB-2 (SEC File Nos. 333-33201, 333-86262, 333-107122 and 333-112852), are entitled to cause us to register for resale certain shares owned by or issuable to the selling stockholders in the event that such registration statements are unavailable to the selling stockholders to sell all of the registrable shares.

ITEM 6. SELECTED CONSOLIDATED FINANCIAL DATA.

The following Selected Financial Data should be read in conjunction with our Financial Statements and the related Notes thereto, Management's Discussion and Analysis of Financial Condition and Results of Operations and other financial information included elsewhere in this Annual Report. The data set forth below with respect to our Statements of Operations for the fiscal years ended July 31, 2006, 2005 and 2004 and the Balance Sheet data as of July 31, 2006 and 2005 are derived from our Financial Statements which are included elsewhere in this Annual Report and are qualified by reference to such Financial Statements and related Notes thereto. The data set forth below with respect to our Statements of Operations for the years ended July 31, 2003 and 2002 and the Balance Sheets data as of July 31, 2004, 2003 and 2002 are derived from our Financial Statements, which are not included elsewhere in this Annual Report. Our historical results are not necessarily indicative of future results of operations.

	Years Ended				
	July 31,				
STATEMENT OF OPERATIONS DATA:	2006	2005	2004	2003	2002
Total Revenues	\$ 1,890,000	\$ 439,000	\$ 466,000	\$ 2,000	\$ 339,000
Total Expenses	12,454,000	10,217,000	7,119,000	7,091,000	6,592,000
Loss from Operations	(10,564,000)	(9,778,000)	(6,653,000)	(7,089,000)	(6,253,000)
Interest Income	224,000	87,000	98,000	49,000	44,000
Income Tax Benefit	256,000	241,000	214,000	84,000	88,000
Net Losses	\$(10,084,000)	\$(9,450,000)	\$(6,341,000)	\$(6,956,000)	\$(6,121,000)
Basic and Diluted Loss Per Common Share	\$(.23)	\$(.27)	\$(.24)	\$(.45)	\$(.54)
Weighted Average Number of Shares of Common Stock Used in Computation of Basic and Diluted Loss Per Share	43,000,000	34,808,000	26,269,000	15,419,000	11,361,000

	Years Ended				
	July 31,				
BALANCE SHEET DATA:	2006	2005	2004	2003	2002
Cash, cash equivalents, and short-term investments	\$ 10,138,000	\$ 8,223,000	\$ 8,377,000	\$ 3,086,000	\$ 3,314,000
Total Assets	14,822,000	13,028,000	11,486,000	4,327,000	3,839,000
Total Current Liabilities	2,200,000	2,405,000	1,086,000	457,000	316,000
Total Liabilities	4,777,000	5,079,000	1,463,000	457,000	316,000

Edgar Filing: NOVADEL PHARMA INC - Form 10-K

Accumulated deficit	(44,475,000) (34,391,000) (24,941,000) (18,600,000) (11,644,000)
Total Stockholders' Equity	\$ 10,045,000	\$ 7,949,000	\$ 10,023,000	\$ 3,870,000	\$ 3,523,000	

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

The following discussion of our financial condition and result of operations should be read in conjunction with the financial statements and the notes to those statements included elsewhere in this Annual Report. The discussion includes forward-looking statements that involve risks and uncertainties. As a result of many factors, such as those set forth in Item 1A. Risk Factors of this Annual Report, our actual results may differ materially from those anticipated in these forward looking statements.

GENERAL

NovaDel Pharma Inc. 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 systems 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, 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 52 patents which have been issued outside of the U.S. Additionally, we have over 80 patents pending around the world.

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

On June 28, 2006, our Board of Directors approved a change of our fiscal year end from July 31 to December 31. Accordingly, the new fiscal year will begin on January 1, and end on December 31. We have filed our Annual Report on Form 10-K for the period ending July 31, 2006, and we intend to file a transition report on Form 10-K for the period ending December 31, 2006.

Highlights for our fiscal year ended July 31, 2006, and additionally through the date of filing for this Annual Report on Form 10-K, include the following product development and business achievements:

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

Announced that Dr. Henry Kwan would no longer serve as Head of Pharmaceutical Sciences on October 20, 2005.

Filing an IND for ondansetron (Zensana) through our partner, Hana Biosciences.

Announced through our partner, Hana Biosciences, positive study results of a pivotal clinical trial for Zensana[®] ondansetron oral spray, a study which demonstrated Zensana[®] 8mg dose is bioequivalent to the current commercially available 8mg tablet (Zofran[®]). Hana Biosciences filed an NDA for Zensana[®] which was accepted for review by the FDA.

Edgar Filing: NOVADEL PHARMA INC - Form 10-K

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

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

Completed a private placement in April 2006 of our common stock, raising gross proceeds of approximately \$11.8 million.

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

Received notice from the FDA indicating acceptance of our New Drug Application, or NDA, submission for our nitroglycerin lingual spray (NitroMist) as a complete response and an indicated target date of November 3, 2006 for action on the submission.

Added two new central nervous system product candidates to our development pipeline, including tizanidine oral spray potentially for spasticity and ropinirole oral spray potentially for Parkinson's disease.

Appointment of Mr. Steven B. Ratoff as Chairman of the Board effective September 15, 2006 with Dr. Egberts remaining a member of the Board of Directors.

Announcement of 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.

Drug development in the U.S. and most countries throughout the world is a process that includes several steps defined by the FDA or comparable regulatory authorities in foreign countries. The FDA approval processes relating to new drugs differ, depending on the nature of the particular drug for which approval is sought. With respect to any drug product with active ingredients not previously approved by the FDA, a prospective drug manufacturer is required to submit 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 IND, to obtain permission to begin clinical testing of the new drug. 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) NDA. We estimate that the development of new formulations of our pharmaceutical product candidates, including formulation, testing and obtaining FDA approval, will take two to three years for the 505(b)(2) NDA process and will require significantly lower investments in direct research and development expenditures than is the case for the discovery and development of new chemical entities. However, our estimates may prove to be inaccurate; or pre-marketing approval relating to our proposed products may not be obtained on a timely basis, if at all, and research and development expenditures may significantly exceed management's expectations.

It is not anticipated that we will generate any revenues from royalties or sales of our product candidates until regulatory approvals are obtained and marketing activities begin. Any one or more of our product candidates may not prove to be commercially viable, or if viable, may not reach the marketplace on a basis consistent with our desired timetables, if at all. The failure or the delay of any one or more of our proposed products to achieve commercial viability would have a material adverse effect on us.

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

the scope, rate of progress and expense of our clinical trials and other research and development activities;

results of future clinical trials;

Edgar Filing: NOVADEL PHARMA INC - Form 10-K

the expense of clinical trials for additional indications;

the terms and timing of any collaborative, licensing and other arrangements that we may establish;

the expense and timing of regulatory approvals;

the expense of establishing clinical and commercial supplies of our product candidates and any products that we may develop;

the effect of competing technologies and market developments; and

the expense of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

We expect to continue to spend significant amounts on the development of our product candidates and we expect our costs to increase as we continue to develop and ultimately commercialize our product candidates. Over the next fiscal year, we expect to devote the majority of our research and development resources to the following product candidates:

NitroMist (nitroglycerin lingual aerosol). This product candidate is indicated for acute relief of an attack or acute prophylaxis of angina pectoris due to coronary artery disease. We have partnered with Par Pharmaceutical, Inc., or Par, who has exclusive rights to market, sell and distribute NitroMist in the U.S. and Canada. On June 1, 2005, we received an approvable letter from the FDA regarding our NDA for NitroMist. The FDA is not requiring any additional clinical studies for approval, but has requested that we complete certain manufacturing process validation commitments. On April 30, 2006, we submitted the additional documentation to the FDA for the manufacturing process validation commitments. On May 26, 2006, we announced that the FDA had accepted our submission regarding our NDA as a complete response and, further, that the FDA indicated a target date of November 3, 2006 for action on the submission. We will receive a milestone payment from Par should final approval from the FDA be obtained. In addition, we will receive royalty payments based upon a percentage of net sales.

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

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

Edgar Filing: NOVADEL PHARMA INC - Form 10-K

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

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

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

CRITICAL ACCOUNTING POLICIES

USE OF ESTIMATES - The accompanying financial statements have been prepared in conformity with accounting principles generally accepted in the U.S. This requires our management to make estimates about the future resolution of existing uncertainties that affect the reported amounts of assets, liabilities, revenues and expenses which in the normal course of business are subsequently adjusted to actual results. Actual results could differ from such estimates. In preparing these financial statements, management has made its best estimates and judgments of the amounts and disclosures included in the financial statements giving due regard to materiality.

REVENUE RECOGNITION We receive revenue from consulting services and license agreements. Consulting revenues from contract clinical research are recognized in the period in which the services are rendered, provided that collection is reasonably assured. Upfront license agreement payments are initially deferred and subsequently amortized into revenue over the contractual period. Milestone payments related to license agreements are recognized as revenue when earned.

Edgar Filing: NOVADEL PHARMA INC - Form 10-K

STOCK-BASED COMPENSATION In December 2004, the Financial Accounting Standards Board, or FASB, issued Statement of Financial Accounting Standards No. 123 (revised 2004), Share-Based Payment, SFAS 123R, which revises Accounting for Stock-Based Compensation, SFAS 123 and supersedes Accounting Principles Board APB Opinion No. 25, Accounting for Stock Issued to Employees, APB 25, which provided for the use of the intrinsic value method of accounting for employees stock options. SFAS 123R required all share-based payments to employees, including grants of employee stock options, to be recognized in the financial statements based on their fair values beginning with the first quarter of the first annual reporting period that began after June 15, 2005. Under SFAS 123R, the use of the intrinsic value method and pro forma disclosures previously permitted under SFAS 123 are no longer an alternative to financial statement recognition.

45

Edgar Filing: NOVADEL PHARMA INC - Form 10-K

We have adopted the provisions of SFAS 123R effective August 1, 2005 and have selected the Black-Scholes method of valuation for share-based compensation. We have adopted the modified prospective transition method which does not require restatement of prior periods. Instead, it requires that compensation cost be recorded as earned for all unvested stock options outstanding at the beginning of the first quarter of adoption of SFAS 123R. The charge is being recognized in research and development and consulting, selling, general and administrative expenses over the remaining service period after the adoption date based on the original estimate of fair value of the options as of the grant date. Prior to the adoption of SFAS 123R, we applied the intrinsic-value-based method of accounting prescribed by APB 25 and related interpretations, to account for its stock options granted to employees. Under this method, compensation cost was recorded only if the market price of the underlying common stock on the date of grant exceeded the exercise price. SFAS 123 established accounting and disclosure requirements using a fair-value-based method of accounting for share-based employee compensation plans. As permitted by SFAS 123, we elected to continue to apply the intrinsic-value-based method of accounting described above, and adopted only the disclosure requirements of SFAS 123, as amended. For the fiscal year ended July 31, 2006, we recorded share-based compensation of approximately \$1.2 million or \$0.03 per share. We will continue to incur share-based compensation charges in future periods. As of July 31, 2006, unamortized stock-based compensation expenses of approximately \$2.4 million remain to be recognized over a weighted-average period of 2.2 years.

As a result of cashless exercise provisions in our employee stock option agreements, we used variable accounting treatment under the Financial Accounting Standards Board's Interpretation 44, for issued and outstanding stock options from January 2002 through July 2005. On October 20, 2004, our Board of Directors rescinded the cashless exercise provision for all of our outstanding option grants. Through July 31, 2005, variable plan accounting continued to be applied for approximately 310,000 outstanding options, for which option exercise prices were modified from the original agreement.

The following table illustrates the pro forma effect on the Company's net loss and net loss per share as if the Company had adopted the fair-value-based method of accounting for share-based compensation under SFAS 123 for the fiscal years ended July 31, 2005 and 2004:

	Fiscal Year Ended July 31,	
	2005	2004
Net loss as reported	\$(9,450,000)	\$(6,341,000)
Compensation credit resulting from variable plan accounting	(106,000)	(736,000)
Total share-based employee compensation expense using the fair value based method for all awards	(854,000)	(795,000)
Pro forma net loss	\$(10,410,000)	\$(7,872,000)
Basic and diluted net loss per common share:		
As reported	\$(0.27)	\$(0.24)
Pro forma net loss	(0.30)	(0.30)

RESEARCH AND DEVELOPMENT EXPENSES - Research and development expenses are expensed as incurred.

RESULTS OF OPERATIONS

FISCAL YEARS ENDED JULY 31, 2006 AND 2005

Edgar Filing: NOVADEL PHARMA INC - Form 10-K

License fees and milestone fees earned from related parties for the fiscal year ended July 31, 2006 were \$1,622,000, as compared to \$141,000 for the fiscal year ended July 31, 2005. The increase is primarily due to milestone payments received in connection with our license and development agreement for ondansetron with Hana Biosciences.

Consulting revenues from related parties for the fiscal year ended July 31, 2006 were \$228,000 as compared to \$298,000 for the fiscal year ended July 31, 2005. The decrease is primarily attributable to lower levels of revenue from Velcera and Manhattan Pharmaceuticals, related to veterinary products and propofol, respectively.

Edgar Filing: NOVADEL PHARMA INC - Form 10-K

Research and development expenses for the fiscal year ended July 31, 2006 were \$5,275,000, as compared to \$3,826,000 for the fiscal year ended July 31, 2005. Research and development costs consist primarily of salaries and benefits, contractor and consulting fees, clinical drug supplies of preclinical and clinical development programs, consumable research supplies and allocated facility and administrative costs. Below is a summary of our research and development expenses for the fiscal years ended July 31, 2006 and 2005.

	2006	2005
NitroMist	\$ 1,084,000	\$ 689,000
Zolpidem	883,000	116,000
Sumatriptan	403,000	186,000
Zensana	221,000	99,000
Propofol		
Alprazolam		238,000
Tizanidine		
Ropinirole	15,000	
Other research and development costs	926,000	385,000
Internal costs	1,743,000	2,113,000
Total research and development expenses	\$ 5,275,000	\$ 3,826,000

In the preceding table, research and development expenses are set forth in the following categories:

NitroMist, Zolpidem, Sumatriptan, Tizanidine and Ropinirole - third-party direct project expenses relating to the development of the respective product candidates. We expect to devote the majority of our research and development resources to our zolpidem and sumatriptan product candidates and expect that costs associated with these product candidates should increase in future periods;

Zensana and Propofol - third-party direct project expenses relating to the development of Zensana. As our partners, Hana Biosciences and Manhattan Pharmaceuticals are overseeing all clinical development and regulatory approval activities for these product candidates, we do not expect to devote a significant amount of resources to these product candidates;

Alprazolam - third-party direct project expenses relating to the development of our alprazolam oral spray product candidate. We have determined that, in order to devote sufficient resources to other product candidates, it is appropriate to defer further efforts on alprazolam;

Other research and development costs - direct expenses not attributable to a specific product candidate; and

Internal costs - costs related primarily to personnel and overhead. We do not allocate these expenses to specific product candidates as these costs relate to all research and development activities.

Research and development expenses in the fiscal year ended July 31, 2006 increased primarily as a result of the following items:

\$395,000 increase related to process validation and method transfer activities for our NitroMist product candidate;

\$767,000 increase primarily related to product development costs for our zolpidem product candidate;

Edgar Filing: NOVADEL PHARMA INC - Form 10-K

\$217,000 increase primarily related to product development costs for our sumatriptan product candidate;

\$541,000 increase related to other research and development costs primarily as a result of higher lab supplies expense;

\$238,000 decrease related to our alprazolam product candidate as we have decided to defer further efforts on this product candidate;
and

\$370,000 decrease related to internal costs primarily as a result of lower headcount in the fiscal year ended July 31, 2006, as compared to the fiscal year ended July 31, 2005.

Edgar Filing: NOVADEL PHARMA INC - Form 10-K

Consulting, selling, general and administrative expenses for the fiscal year ended July 31, 2006 were \$7,179,000 as compared to \$6,391,000 for the fiscal year ended July 31, 2005. Consulting, selling, general and administrative expenses consist primarily of salaries and related expenses for executive, finance, legal and other administrative personnel, recruitment expenses, professional fees and other corporate expenses. The increase in consulting, selling, general and administrative costs is primarily related to the following items:

\$1,038,000 non-cash charge in the fiscal year ended July 31, 2006 for stock-compensation expense;

\$440,000 decrease in outside legal costs; and

\$307,000 decrease attributable to a non-cash charge recorded in the fiscal year ended July 31, 2005 for restricted shares of our common stock awarded to a consultant.

Total costs and expenses for the fiscal year ended July 31, 2006 were \$12,454,000 as compared to \$10,217,000 for the fiscal year ended July 31, 2005 primarily due to the net increases in research and development and selling general and administrative expenses noted above.

Interest income for the fiscal year ended July 31, 2006 was \$224,000 as compared to \$87,000 for fiscal year ended July 31, 2005 due to a general increase in interest rates.

Income tax benefit for the fiscal year ended July 31, 2006 was \$256,000 as compared to \$241,000 for the fiscal year ended July 31, 2005. These benefits resulted from the sale of our New Jersey Net Operating Losses.

The resulting net loss for the fiscal year ended July 31, 2006 was \$10,084,000 as compared to \$9,450,000 for the fiscal year ended July 31, 2005.

FISCAL YEARS ENDED JULY 31, 2005 AND 2004

License fees and milestone payments increased to \$141,000 in the fiscal year ended July 31, 2005 from \$13,000 in the fiscal year ended July 31, 2004 primarily due to the signing of new partnership agreements with Hana Biosciences and Velcera in the first quarter of the fiscal year ended July 31, 2005.

Consulting revenues for the fiscal year ended July 31, 2005 decreased to \$298,000 in the fiscal year ended July 31, 2005 from \$453,000 in the fiscal year ended July 31, 2004 primarily as a result of lower revenue from our arrangement with Manhattan Pharmaceuticals, partially offset by revenue associated with the Company's arrangement with Velcera.

Research and development expenses increased approximately \$1,334,000 to \$3,826,000 from \$2,492,000 for the fiscal year ended July 31, 2004. Research and development costs consist primarily of salaries and benefits, contractor fees, clinical drug supplies of preclinical and clinical development programs, consumable research supplies and allocated facility and administrative costs. The increase in research and development

expenses is primarily related to the following items:

Approximate \$264,000 increase, primarily related to pharmacokinetic studies completed in the fiscal year ended July 31, 2005 for three of our priority product candidates, including (i) zolpidem (Ambien®); (ii) ondansetron (Zofran®) and (iii) alprazolam (Xanax®);

Approximate \$670,000 increase, primarily related to outsourced manufacturing fees associated with process validation and method transfer activities for our NitroMist product candidate;

Approximate \$630,000 increase due to higher payroll and allocated facility and administrative costs, primarily as a result of an increase in R&D-related personnel in the fiscal year ended July 31, 2005; and

Approximate \$185,000 decrease in R&D-related consultants expense.

Consulting, selling, general and administrative expenses increased approximately \$1,764,000 to \$6,391,000 from \$4,627,000 for the fiscal year ended July 31, 2004. Consulting, selling, general and administrative expenses consist primarily of salaries and related expenses for executive, finance, legal and other administrative personnel, recruitment expenses, professional fees and other corporate expenses. The increase in consulting, selling, general and administrative costs is primarily related to the following items:

Approximate \$297,000 increase in outside legal costs, primarily related to the filing of additional patent applications in the fiscal year ended July 31, 2005;

Edgar Filing: NOVADEL PHARMA INC - Form 10-K

Approximate \$629,000 increase in compensation expense related to variable accounting for stock options. In the fiscal year ended July 31, 2005, we recognized a credit of \$106,000, as compared to a credit of \$736,000 in the fiscal year ended July 31, 2004. The decrease in the credit is primarily attributable to a significant reduction in the fiscal year ended July 31, 2005 of the number of stock options that are subject to variable accounting;

\$307,000 non-cash charge to consultants' expense in the fiscal year ended July 31, 2005 for restricted shares of our common stock awarded to a consultant; and

The remaining increase, net of individually offsetting items of lesser significance, is primarily attributable to higher payroll, recruiting and relocation expenses as a result of hiring additional employees.

Primarily as a result of the factors described above, total costs and expenses for the fiscal year ended July 31, 2005 increased approximately \$3,098,000 to approximately \$10,217,000 from \$7,119,000 for the fiscal year ended July 31, 2004.

Interest income decreased approximately \$11,000 to \$87,000 for the fiscal year ended July 31, 2005 from \$98,000 for the fiscal year ended July 31, 2004 due to lower average cash and investment balances.

Income tax benefit for the fiscal year ended July 31, 2005 was approximately \$241,000 compared to approximately \$214,000 for the fiscal year ended July 31, 2004. These benefits resulted from the sale of the Company's New Jersey net operating losses.

The resulting net loss for the fiscal year ended July 31, 2005 was \$9,450,000 compared to a net loss of \$6,341,000 for the fiscal year ended July 31, 2004.

LIQUIDITY AND CAPITAL RESOURCES

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 had a history of recurring losses, giving rise to an accumulated deficit at July 31, 2006 of \$44,475,000. We have had negative cash flow from operating activities of \$8,855,000, \$6,258,000, and \$6,120,000 for the fiscal years ended July 31, 2006, 2005 and 2004, respectively. As of July 31, 2006, we had working capital of approximately \$9,574,000 as compared to working capital of \$6,781,000 as of July 31, 2005, representing a net increase in working capital of approximately \$2,793,000. As explained further below, such increase is primarily attributable to a net increase in cash and short-term investments, an increase in investment in marketable equity security available for sale, and a decrease in accounts payable. In April 2006, we successfully closed an offering of our common stock and warrants to purchase shares of our common stock. The April 2006 Private Placement involved the sale of 8,092,796 shares of common stock and warrants to purchase 2,427,839 shares of common stock. We received proceeds, net of offering costs, of \$10,593,000. In May 2005, we successfully closed an offering of our common stock and warrants to purchase shares of our common stock, the May 2005 Private Placement. The May 2005 Private Placement involved the sale of approximately 6,733,024 shares of common stock, and warrants to purchase 2,356,559 shares of common stock. We received proceeds, net of offering costs, of approximately \$6,309,000.

Net cash used in operating activities was approximately \$8,855,000 for the fiscal year ended July 31, 2006, as compared to \$6,258,000 for the fiscal year ended July 31, 2005. The \$2,597,000 increase in net cash used in operating activities in the fiscal year ended July 31, 2006 compared with 2005 is due to the following:

\$634,000 increase in net loss in the fiscal year ended July 31, 2006 due to an increase in operating expenses;

Edgar Filing: NOVADEL PHARMA INC - Form 10-K

\$1,201,000 non-cash charge in the fiscal year ended July 31, 2006 to record stock-compensation expense pursuant to SFAS 123R;

\$1,974,000 increase in deferred revenue in the fiscal year ended July 31, 2005 attributable to payments received by us from our licensees, which payments are being amortized over the remaining terms of the agreements with the licensees;

\$549,000 increase in inventory in the fiscal year ended July 31, 2005 related to the purchase of raw materials for our nitroglycerin lingual spray product candidate;

\$938,000 increase in accounts payable in the fiscal year ended July 31, 2005 primarily related to costs incurred in conjunction with the manufacturing and process development of our nitroglycerin lingual spray product candidate; and

Edgar Filing: NOVADEL PHARMA INC - Form 10-K

\$307,000 non-cash charge recorded in the fiscal year ended July 31, 2005 for restricted shares of our common stock awarded to a consultant.

In the fiscal year ended July 31, 2006, \$1,038,000 was used in investing activities, principally due to purchases of short-term investments, net of maturities of short-term investments. In the fiscal year ended July 31, 2005, \$1,670,000 was provided by investing activities which related to \$9,155,000 of maturities of short-term and long-term investments, \$5,180,000 of purchases of short-term investments, and \$2,305,000 of capital expenditures. Capital expenditures for the fiscal year ended July 31, 2005 consisted primarily of leasehold improvements for our new laboratory facility and manufacturing equipment at INyX USA, Ltd. for the manufacture of our NitroMist product candidate.

Cash provided by financing activities was approximately \$10,900,000 in the fiscal year ended July 31, 2006, as compared to \$7,102,000 in the fiscal year ended July 31, 2005. This increase of \$3,798,000 is primarily due to \$10,593,000 in net proceeds relating to the April 2006 Private Placement, as compared to \$6,309,000 in net proceeds relating to the May 2005 Private Placement. Such increase was partially offset by \$636,000 of proceeds received from the shares of our common stock issued to Hana Biosciences in the fiscal year ended July 31, 2005.

Until and unless our operations generate significant revenues, we will attempt to continue to fund operations from cash on hand and through the sources of capital described below. Our long-term liquidity is contingent upon achieving sales and 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 and 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. Although we expect to have sufficient cash to fund our operations through the end of fiscal 2007, we would have to significantly reduce the pace of our ongoing development of our priority product candidates unless we can obtain additional working capital. Given the current and desired pace of product development of our priority product candidates, we estimate that we could need to raise additional capital during fiscal year 2007 in order to fully fund our development activities through July 31, 2007. This could include the securing of funds through new partnerships and/or the sale of our common stock or other securities, in order to fund our research and development activities. There can be no assurance that such capital will be available to us on favorable terms or at all. There are a number of risks and uncertainties related to our attempt to complete a financing or strategic partnering arrangement that are outside our control. We may not be able to successfully obtain additional financing on terms acceptable to us, or at all. If we are unsuccessful at obtaining additional financing as needed, we may be required to significantly curtail or cease operations. We will need additional financing thereafter until we achieve profitability, if ever.

OFF-BALANCE SHEET ARRANGEMENTS

We do not have any off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, results of operations, liquidity or capital resources.

CONTRACTUAL OBLIGATIONS

The following table sets forth our aggregate contractual cash obligations as of July 31, 2006.

	Total	<1 year	Payments Due By Period		
			1-3 years	3-5 years	5 years +
Capital leases	\$ 147,000	\$82,000	\$ 65,000	\$	\$
Operating leases	2,520,000	332,000	1,061,000	1,097,000	30,000
Employment agreements	925,000	765,000	160,000		

Edgar Filing: NOVADEL PHARMA INC - Form 10-K

Consulting agreements	167,000	167,000			
Total contractual cash obligations	\$3,759,000	\$1,346,000	\$1,286,000	\$1,097,000	\$30,000

We expect to continue to incur substantial additional operating losses from costs related to the continued development of our product candidates, clinical trials, and administrative activities. For a full discussion of risks and uncertainties regarding our need for additional financing, see Risk Factors-We will Require Significant Capital for Product Development and Commercialization.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

Our holdings of financial instruments consist of certificates of deposit and U.S. Treasury securities. Our market risk exposure consists principally of exposure to changes in interest rates.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

The financial statements required by this Item are included as a separate section of this report commencing on page F-1.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.

None.

ITEM 9A. CONTROLS AND PROCEDURES.

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures or controls and other procedures that are designed to ensure that the information required to be disclosed by us in the reports that we file or submit under the Securities Exchange Act of 1934, or Exchange Act, is recorded, processed, summarized and reported, within the time periods specified in the Securities and Exchange Commission's (SEC's) rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in the reports that a company files or submits under the Exchange Act is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

We carried out an evaluation, under the supervision and with the participation of our Chief Executive and Chief Financial Officers, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) and Rule 15d-15(e) of the Exchange Act) as of July 31, 2006. Based on this evaluation, our Chief Executive Officer and our Chief Financial Officer concluded that as of July 31, 2006, our disclosure controls and procedures were effective at providing reasonable assurance that the information required to be disclosed by us in reports filed under the Exchange Act is (i) recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms; and (ii) accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding disclosure.

Changes in Internal Controls over Financial Reporting

Edgar Filing: NOVADEL PHARMA INC - Form 10-K

During the fourth quarter of fiscal 2006, there were no changes in our internal control over financial reporting (as defined in Rule 13a-15(e) and Rule 15d-15(f) under the Exchange Act) that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION.

None.

51

PART III**ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT.**

The names and ages of our Directors and Executive Officers are set out below. All Directors are elected annually, to serve until the next annual meeting of stockholders and until their successors are duly elected and qualified. Executive Officers are elected annually by the Board of Directors and serve at the Board of Directors' pleasure. The Board of Directors has determined that the following individuals are the Executive Officers of the Company: Mr. Cohen, Dr. Egberts and Mr. Spicer.

NAME	AGE	POSITION WITH THE COMPANY
Thomas E. Bonney	41	Director
Jan H. Egberts, M.D.	48	President, Chief Executive Officer and Director
William F. Hamilton, Ph.D.	67	Director
J. Jay Lobell	44	Director
Charles Nemeroff, M.D., Ph.D.	57	Director
Steven B. Ratoff	64	Director and Chairman of the Board
Barry C. Cohen	44	Vice President, Business and New Product Development
Michael E. Spicer	53	Chief Financial Officer and Corporate Secretary

Committees of the Board

	Audit Committee	Compensation Committee	Corporate Governance and Nominating Committee
Thomas E. Bonney	C		M
William F. Hamilton, Ph.D.	M	M	C
J. Jay Lobell	M	C	
Charles Nemeroff, M.D., Ph.D.		M	M
Total meetings in fiscal year 2006	11	11	6

M = Committee Member

C = Committee Chair

Thomas E. Bonney, Director, CPA, 41. Mr. Bonney was elected to the Board of Directors in March 2005. From 2002 to the present, Mr. Bonney has been President of CMF Associates, LLC, a financial and management consulting firm. Since June 2005, Mr. Bonney has been Chief Financial Officer and a Director of Leblon Holdings LLC, a privately held beverage supplier. From 2001 to 2002 he was Chief Financial Officer of Akcelarent Holdings, Inc., a technology holding company. From 1995 to 2001, Mr. Bonney was President and a Director of Polaris Consulting & Information Technologies, a technology solutions provider. Mr. Bonney was at Deloitte & Touche from 1987 to 1995 in various positions including Senior Manager. Mr. Bonney received his B.S. in Accounting at the Pennsylvania State University and is a member of the Pennsylvania Institute of Certified Public Accountants. He is a member and chair of our Audit Committee and a member of our Corporate Governance and Nominating Committee.

Jan H. Egberts, M.D., Director and President and Chief Executive Officer, 48. Dr. Egberts was elected a director in January 2006. Dr. Egberts joined NovaDel in September 2005 as its Chief Operating Officer. Dr. Egberts assumed the position of President and Chief Executive Officer of NovaDel, effective as of December 23, 2005. On January 17, 2006, Dr. Egberts was elected a director of the Company. From January 2006 to September 2006, Dr. Egberts was Chairman of the Board of NovaDel. From August 2004 to September 2005, Dr. Egberts was Chief Operating Officer at Dynogen Pharmaceuticals, Inc. From February 2001 to January 2004, Dr. Egberts was Chairman of Molnlycke Healthcare, Inc., and concurrently served as President of the Barrier division from February 2001 through April 2002 and from April 2002 to January 2004 as Senior Vice President and Global Marketing Director of Molnlycke Healthcare Inc. From November 1996 to February 2001, Dr. Egberts served as Vice President, Business and Market Development Worldwide for Johnson & Johnson Medical. Dr. Egberts received his M.D. from Erasmus University Medical School in the Netherlands, and pursued his clinical training at Harvard Medical School. He also holds an M.B.A. degree from Stanford University.

Edgar Filing: NOVADEL PHARMA INC - Form 10-K

William F. Hamilton, Ph.D., Director, 67. Dr. Hamilton was elected to the Board of Directors in March 2003. In January 2006, Dr. Hamilton was appointed Lead Independent Director. Dr. Hamilton has served on the University of Pennsylvania faculty since 1967, and is the Landau Professor of Management and Technology, and Director of the Jerome Fisher Program in Management and Technology at The Wharton School and the School of Engineering and Applied Science. He serves as a director of Neose Technologies, Inc., a publicly-traded company developing proprietary drugs. Dr. Hamilton received his B.S. and M.S. in chemical engineering and his M.B.A. from the University of Pennsylvania, and his Ph.D. in applied economics from the London School of Economics. Dr. Hamilton is a member of the Audit Committee and Compensation Committee and a member and chair of our Corporate Governance and Nominating Committee.

J. Jay Lobell, Director, 44. Mr. Lobell was elected to the Board of Directors in December 2005. Mr. Lobell has served as Chief Executive Officer, Secretary and a member of the Board of Directors of Paramount Acquisition Corp. since October 2005. Mr. Lobell has served as President and Chief Operating Officer of Paramount BioCapital Asset Management, Inc. and Paramount Biosciences, LLC since January 2005, and is a registered representative of Paramount BioCapital, Inc. From 1996 through December 2004, Mr. Lobell was a partner at Covington & Burling, a law firm. Mr. Lobell received his B.A. from Queens College and his J.D. from Yale Law School. Mr. Lobell is a director of Innovive Pharmaceuticals, Inc., a publicly traded biopharmaceutical company. Mr. Lobell is a member and chair of our Compensation Committee and is a member of the Audit Committee.

Charles Nemeroff, M.D., Ph.D., Director, 57. Dr. Nemeroff was elected to the Board of Directors in September 2003. Dr. Nemeroff has been the Reunette W. Harris Professor and Chairman of the Department of Psychiatry and Behavioral Sciences at Emory University School of Medicine in Atlanta, Georgia, since 1991. Dr. Nemeroff serves on the Scientific Advisory Board of numerous publicly-traded pharmaceutical companies, including Cypress Bioscience Inc., Astra-Zeneca Pharmaceuticals, Forest Laboratories, Janssen, Organon, GlaxoSmithKline Beecham and Wyeth-Ayerst, and is a clinical advisor to Acadia Pharmaceutical. In 2002, he was elected to the Institute of Medicine. Dr. Nemeroff received his B.S. from the City College of New York, his M.S. from Northeastern University; his Ph.D. and Post doctorate from the University of North Carolina and his M.D. from the University of North Carolina. He is a member of our Compensation Committee and is a member of our Corporate Governance and Nominating Committee.

Steven B. Ratoff, Director, 64. Mr. Ratoff was elected to the Board of Directors in January 2006. Mr. Ratoff was elected Chairman of the Board on September 15, 2006. He is a private investor and since, December 2004, has served as a venture partner with ProQuest Investments, a health care venture capital firm. Mr. Ratoff has been a director, since May 2005, and Chairman of the Board, since September 2005, of Axonyx Inc, a NASDAQ development stage pharmaceutical company. Mr. Ratoff served as a director of Inkin Pharmaceuticals, Inc. from February 1998 to its sale to Salix, Inc. in September 2005. He also served as a board member since March 1995 and as Chairman of the Board and Interim Chief Executive Officer of CIMA Labs, Inc. from May 2003 to its sale to Cephalon, Inc. in August 2004. Mr. Ratoff also served as a director, since 1998 and as President and Chief Executive Officer of MacroMed, Inc. from February to December, 2001. From December 1994 to February 2001, Mr. Ratoff served as Executive Vice President and Chief Financial Officer of Brown-Forman Corporation, a public diversified manufacturer of consumer products. Mr. Ratoff received his B.S. in Business Administration from Boston University and an M.B.A. with Distinction from the University of Michigan. Mr. Ratoff is also a retired Certified Public Accountant.

Barry Cohen, M.B.A., Vice President of Business and New Product Development, 44. Mr. Cohen joined NovaDel in May 2003. From September 2001 to May 2003, he was Vice President-Business Development at Keryx Biopharmaceuticals Inc. From April 2000 to September 2001, Mr. Cohen served as Vice President-Marketing at Novartis Consumer Healthcare. From 1994 to April 2000, Mr. Cohen held several executive marketing and business development positions at Novartis Consumer Healthcare.

Michael E. B. Spicer, CPA, Chief Financial Officer and Corporate Secretary, 53. Mr. Spicer joined NovaDel as Chief Financial Officer in December 2004 and was named Corporate Secretary in April 2006. From December 2001 to December 2004, Mr. Spicer was Chief Financial Officer of Orchid Biosciences, Inc. (now known as Orchid Cellmark Inc.). From September 1998 to December 2001, Mr. Spicer served as Vice President, Chief Financial Officer of Lifecodes Corporation until it was acquired by Orchid.

AUDIT COMMITTEE

The Board of Directors has created an Audit Committee, which consists of Thomas E. Bonney, CPA (Chairman), J. Jay Lobell and Dr. William F. Hamilton. Each member of the Audit Committee meets the definition of independent director as defined by the listing standards of the American Stock Exchange. Among its responsibilities, the Audit Committee selects the independent registered public accounting firm, reviews the results and scope of the audit and other services provided by the Company's independent registered public accounting firm, and reviews and evaluates the Company's internal control functions.

The Board of Directors has determined that each member of the Audit Committee satisfies the independence standards for Audit Committee membership set forth in Section 10A(m)(3) of the Securities Exchange Act of 1934.

In addition, our Board of Directors has determined that Mr. Bonney qualifies as an audit committee financial expert as such term is defined by the Securities and Exchange Commission regulations and the listing standards of the American Stock Exchange.

SECTION 16(a) BENEFICIAL OWNERSHIP REPORTING COMPLIANCE

Directors, Executive Officers and beneficial owners of more than 10% of our common stock are required by Section 16(a) of the Securities Exchange Act of 1934 and related regulations to file ownership reports on Forms 3, 4 and 5 with the Securities and Exchange Commission and the principal exchange upon which such securities are traded or quoted and to furnish us with copies of the reports. Based solely on a review of the copies of such forms furnished to us, we believe that from August 1, 2005, to July 31, 2006, that all Section 16(a) filing requirements applicable to our Executive Officers, with the exception of Mr. Spicer, Directors and greater than 10% holders of our common stock were in compliance. Mr. Spicer was not in compliance with his respective Section 16(a) filing requirements as one Form 4 reporting one transaction was filed late. The Company has revised its administrative procedures to enhance the ability of the Company's Executive Officers and Directors to comply with such requirements.

COMPENSATION COMMITTEE INTERLOCKS

From August 1, 2005 through January 17, 2006, the members of the Compensation Committee of the Board of Directors were Dr. William F. Hamilton, Dr. Lawrence J. Kessel and Dr. Charles Nemeroff. From January 17, 2006 through July 31, 2006 the members of the Compensation Committee were Dr. William F. Hamilton, Dr. Charles Nemeroff and Mr. Steven B. Ratoff. None of these individuals was at any time during or at any other time an officer or employee of ours. Jan H. Egberts, our President and Chief Executive Officer, and Gary A. Shangold, our former President and Chief Executive Officer, participated in discussions and decisions regarding salaries and incentive compensation for all of our executive officers, except they were excluded from discussions regarding their own salary and incentive stock compensation.

CODE OF ETHICS

Our Board of Directors adopted a Business Conduct Policy that is applicable to all employees, officers and directors of the Company. The Business Conduct Policy is intended to be designed to deter wrong-doing and promote honest and ethical behavior, full, fair, timely, accurate and understandable disclosure, and compliance with applicable laws. The Business Conduct Policy satisfies the definition of code of ethics under the rules and regulations of the Securities and Exchange Commission and standards of the American Stock Exchange. The Board of

Edgar Filing: NOVADEL PHARMA INC - Form 10-K

Directors adopted the Business Conduct Policy before the end of calendar year 2003 and a subsequent revised Business Conduct Policy was adopted by the Board of Directors in 2004. A copy of the Business Conduct Policy can be obtained and will be provided to any person without charge upon written request to our Corporate Secretary at our executive offices, 25 Minneakoning Road, Flemington, New Jersey 08822.

The Business Conduct Policy can also be obtained on our website, 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 Annual Report on Form 10-K.

ITEM 11. EXECUTIVE COMPENSATION.

The following table sets forth a summary for the fiscal years ended July 31, 2006, 2005 and 2004 of the cash and non-cash compensation awarded, paid or accrued by the Company to our Chief Executive Officer, our former Chief Executive Officer and our four most highly compensated officers other than the CEO who served in such capacities in 2006 (collectively, the Named Executive Officers). There were no restricted stock awards, long-term incentive plan payouts or other compensation paid during fiscal 2006, 2005 and 2004 to the Named Executive Officers, except as set forth below:

SUMMARY COMPENSATION TABLE

Name and Principal Position	Fiscal Year	Annual Compensation			Long-Term Compensation			All Other Compensation (\$)
		Salary (\$)	Bonus (\$)	Other Annual Compensation (\$)(2)	Awards Restricted Stock Award(s) (\$)	Securities Underlying Options (1) (#)	Payouts LTIP Payouts (\$)(3)	
Jan H. Egberts, M. D. <i>President & CEO</i>	2006	297,000	93,000(4)	10,000		1,622,700		12,000
	2005							
	2004							
Gary A. Shangold, M.D.(5) <i>Former President & CEO</i>	2006	125,000		168,000				6,000
	2005	350,000	150,000	15,000		100,000		13,000
	2004	350,000	150,000	14,000		125,000		12,000
Michael E. Spicer, CPA <i>Chief Financial Officer and Corporate Secretary</i>	2006	240,000	66,000	41,000		450,000		10,000
	2005	147,000		17,000		100,000		6,000
	2004							
Jean W. Frydman, Esq.(6) <i>Former Vice President, General Counsel and Corporate Secretary</i>	2006	230,000	75,000	6,000				7,000
	2005	215,000	50,000	5,000		50,000		8,000
	2004	42,000		1,000		100,000		5,000
Barry C. Cohen <i>Vice President-Business & New Product Development</i>	2006	224,000		34,000				9,000
	2005	219,000	50,000	30,000		50,000		8,000
	2004	194,000		27,000		75,000		8,000
Henry Kwan(7) <i>Former Head of Pharmaceutical Sciences</i>	2006	170,000		13,000				2,000
	2005	157,000		12,000		150,000		6,000
	2004							

(1) No Stock Appreciation Rights have been issued.

(2) Other Annual Compensation amounts represent (i) automobile allowances as reimbursement for business usage of personal automobiles for Mr. Cohen, \$12,000; (ii) living expenses for Mr. Spicer, \$19,000; (iii) employer contributions for medical, dental and life insurance benefits for Dr. Egberts, \$10,000; Dr. Shangold, \$18,000; Mr. Cohen, \$22,000; Ms. Frydman, \$6,000; Dr. Kwan, \$13,000; Mr. Spicer, \$22,000; and (iv) a lump sum separation payment for Dr. Shangold, \$150,000.

(3) All Other Compensation amounts represent employer contributions to 401(k) savings plan.

Edgar Filing: NOVADEL PHARMA INC - Form 10-K

- (4) Dr. Egberts was inadvertently overpaid his fiscal 2006 cash bonus by approximately \$47,000 or \$26,000, net of taxes and other withholdings. Dr. Egberts brought the overpayment to the attention of the Board of Directors and the Audit Committee of the Board of Directors. After review by the full Board of Directors, Dr. Egberts promptly made full restitution of such overpayment.
- (5) Ceased to be President and Chief Executive Officer on December 22, 2005.
- (6) Ceased to be Vice President, General Counsel and Corporate Secretary on April 24, 2006.
- (7) Ceased to be Head of Pharmaceutical Sciences on October 20, 2005.

Edgar Filing: NOVADEL PHARMA INC - Form 10-K

OPTION GRANTS IN LAST FISCAL YEAR

The following table sets forth information with respect to the Named Executive Officers concerning grants of options during the fiscal year ended July 31, 2006:

Name	Number of Securities Underlying Options Granted (a)	% of Total Options Granted to Employees in Fiscal Year	Exercise or Base Price (\$/Sh)	Expiration Date	Grant Date Present Value (b)
Jan H. Egberts, M.D.	1,622,700	67%	\$1.70	9/26/2010	\$1,441,000
Gary A. Shangold, M.D.					
Michael E. Spicer	450,000	19%	\$1.65	4/18/2016	\$491,000
Jean W. Frydman, Esq.					
Barry C. Cohen					
Henry Kwan, Ph. D.					

- (a) Options granted to Dr. Egberts and Mr. Spicer have an exercise price equal to the market price on the date of grant and a three-year vesting period with one-third of the option grant vesting on each annual anniversary of the grant date. Dr. Egberts and Mr. Spicer's options have five-year and ten-year contractual terms, respectively.
- (b) Options are valued using a Black-Scholes option pricing model that assumes the following: (i) For Dr. Egberts: expected volatility of 64%; dividend yield of 0%; expected term until exercise of 4 years; and a risk-free interest rate of 4.1% and (ii) For Mr. Spicer: expected volatility of 64%; dividend yield of 0%; expected term until exercise of 6.5 years; and a risk-free interest rate of 4.9%.

AGGREGATED OPTION EXERCISES IN LAST FISCAL YEAR

AND FISCAL YEAR-END OPTION VALUES

The following table sets forth information with respect to the Named Executive Officers concerning the exercise of options during the fiscal year ended July 31, 2006 and the number and value of unexercised options held as of July 31, 2006.

Name of Executive Officer	Shares Acquired on Exercise (#)	Value Realized (\$)	Number of Securities Underlying Unexercised Options at Fiscal Year End; (Exercisable/Unexercisable)	Value of Unexercised In-the-Money Options at Fiscal Year End (\$); (Exercisable/ Unexercisable)
Jan H. Egberts, M.D.			0/1,622,700	0/0
Gary A. Shangold, M.D.			1,158,333/66,667	0/0
Michael E. Spicer			33,333/516,667	0/0
Jean W. Frydman, Esq.			33,333/0	0/0
Barry C. Cohen			166,666/33,334	0/0
Henry Kwan, Ph. D.				

EMPLOYMENT AGREEMENTS AND CHANGE IN CONTROL ARRANGEMENTS

Jan H. Egberts, M.D. On September 26, 2005, the Company entered into a two-year employment agreement with Dr. Jan H. Egberts pursuant to which he agreed to serve as the Company's Chief Operating Officer. Pursuant to the agreement, Dr. Egberts assumed the positions of President and Chief Executive Office on December 23, 2005. Pursuant to the agreement, Dr. Egberts receives a base salary of \$350,000 and is eligible for an annual bonus of up to 50% of his base salary. On the date he assumes the position of President and Chief Executive Officer, he received an interim bonus for the period from September 26, 2005 through the date he assumed the positions of President and Chief Executive Officer, in an amount equal to 50% of his pro-rated base salary for such period. In addition, Dr. Egberts was also granted non-plan options to purchase 1,622,700 shares of common stock (at an exercise price of \$1.70 per share) on September 26, 2005. The options vest in three annual installments, subject to certain conditions, on September 25, 2006, September 25, 2007 and September 25, 2008. Such options have a five-year term and expire on September 24, 2010. In addition, the Company has also agreed to grant Dr. Egberts options to purchase an additional 400,000 shares of common stock of the Company upon the signing of a third-party agreement which provides milestone opportunities in excess of \$30 million in revenue, but no earlier than March 26, 2006. Such stock option grant will have a term of five (5) years and will vest ratably over a three-year period ending on the third anniversary of the grant. In the event Dr. Egberts' employment is terminated by reason of death or disability, the agreement provides for the following benefits to be paid to his estate, as applicable: (i) base salary and any accrued and unpaid bonus and expense reimbursement amounts through the date of his death or disability and the pro rata portion of his guaranteed bonus and stock options earned by him during the year of his death or disability; and (ii) for the longer of twelve (12) months following his death, disability or the balance of the term of the agreement the Company will provide continued coverage to the members of his family and, in the case of termination for disability, for Dr. Egberts, under all major medical and other health, accident, life or other disability plans and programs in which such family members and, in the case of termination for disability, for Dr. Egberts, participated immediately prior to his death or disability. All stock options that are scheduled to vest by the end of the calendar year in which such termination occurs shall be accelerated and deemed to have vested as of the termination date. All stock options that have not vested (or been deemed pursuant to the preceding sentence to have vested) as of the date of termination shall be deemed to have expired. Any stock options that have vested as of the date of his death or disability shall remain exercisable for a period of 90 days after the date of his death or disability. In the event that Dr. Egberts' employment is terminated upon a change-in-control of the Company, the agreement provides for the following benefits: (i) continuation of the payment of Dr. Egberts' base salary for a period of one year following such termination; (ii) payment of any accrued and unpaid bonus through the date of termination; and (iii) payment of any accrued and unpaid expense reimbursements owed to Dr. Egberts through the date of termination. In addition, all stock options that have not vested as of such termination date shall be accelerated and deemed to have vested as of the date of termination.

Gary A. Shangold, M.D. On November 29, 2005, the Company entered into a Confidential Separation Agreement and General Release (the Separation Agreement) and a Consulting Agreement (the Consulting Agreement) with Gary Shangold, M.D. Dr. Shangold is the former President and Chief Executive Officer of the Company. Pursuant to the Separation Agreement, the Company paid to Dr. Shangold a separation payment of \$150,000, will pay Dr. Shangold's COBRA health insurance premium less any active employee contribution for up to one year from December 23, 2005, enter into the Consulting Agreement with Dr. Shangold, and permit Dr. Shangold's 100,000 stock options issued pursuant to the Nonqualified Stock Option and Incentive Stock Option Agreements, dated January 24, 2005, to vest as if Dr. Shangold were still an employee of the Company for as long as he provides consulting services to the Company pursuant to the Consulting Agreement and, in the event that the Consulting Agreement expires at the end of one year, to allow the 33,334 stock options that would otherwise vest on January 24, 2007, to vest on the expiration date of the Consulting Agreement. The Company will extend the post-termination exercise period applicable to Dr. Shangold's vested options (other than non-plan options) to a date that is 90 days after the termination of the Consulting Agreement. In exchange for the Company's agreement to provide the aforementioned consideration to Dr. Shangold, Dr. Shangold will release the Company from any and all claims he may have against the Company. In addition, Dr. Shangold will refrain from competition with the Company until the later of June 22, 2007 or 6 months after termination of the Consulting Agreement. Pursuant to the Consulting Agreement, the Company will retain Dr. Shangold as an independent contractor to provide the Company with consulting services related to the drug regulatory and approval process. The Company will pay to Dr. Shangold an amount equal to \$2,500 per day worked, with a minimum guaranteed payment of \$25,000 per month in which he provides service to the Company regardless of whether the Company has requested his services for ten (10) days during the month, provided that the Company need not pay the entire \$25,000, but rather an amount for days worked at the per day rate, for any month in which the Company requested 10 or more days of service and Dr. Shangold was unavailable to provide his services after good faith efforts by both parties to accommodate the scheduling of services. In addition, the Company will reimburse Dr. Shangold for expenses incurred in the performance of these services. The Consulting Agreement commenced on December 23, 2005 and will continue for a period of 1 year, unless terminated earlier in accordance with the terms of the Consulting Agreement. The Consulting Agreement may be extended by mutual consent of the parties.

Michael E.B. Spicer. Effective December 20, 2004, the Company entered into a three-year employment agreement with Michael E.B. Spicer pursuant to which he agreed to serve as the Company's Chief Financial Officer. Mr. Spicer assumed the position of Corporate Secretary on April 24, 2006. The Company agreed to pay Mr. Spicer an annual base salary of \$235,000, plus incentive bonuses up to 30% of his annual salary. In January 2006, Mr. Spicer's annual base salary was increased to approximately \$244,000 per year and, pursuant to the terms of his agreement, was granted non-qualified options to purchase 100,000 shares of the Company's common stock at an exercise price of \$1.57 per share (110% of the fair market value on the grant date) from the 1998 Plan. The options vest in three annual installments, subject to certain conditions, on December 20, 2005, December 20, 2006, and December 20, 2007. Such options have a term of 10 years and expire on December 19, 2014. In April 2006, Mr. Spicer was granted non-qualified stock options to purchase 389,394 shares of the Company's common stock and incentive stock options to purchase 60,606 shares of the Company's common stock at an exercise price of \$1.65. The options vest in three equal installments, subject to certain conditions, on April 18, 2007, April 18, 2008 and April 18, 2009. Such options have a term of ten years, and expire on April 18, 2016. On September 2, 2005, the Company entered into an amendment to its employment agreement with Mr. Spicer. The amendment provides that Mr. Spicer will receive remuneration for relocation expenses and for expenses for temporary housing and commuting to and from his residence prior to his relocation. In the event Mr. Spicer's employment is terminated by reason of death, the agreement provides for the following benefits to be paid to his estate: (i) base salary and any accrued and unpaid bonus and expense reimbursement amounts through the date of his death; (ii) for the shorter of six months following his death or the balance of the term of the agreement, the Company will provide continued coverage to the members of his family under all major medical and other health, accident, life or other disability plans and programs in which such family members participated immediately prior to his death. Any stock options granted to Mr. Spicer that have not vested as of the date of his death shall be deemed to have expired as of such date. Should Mr. Spicer's employment be terminated due to disability, the agreement provides that the Company shall pay his base salary and any accrued bonus and expense reimbursement amounts through the date of termination. In addition, the agreement provides for the following benefits: for the shorter of six (6) months following such termination or the balance of the term of the agreement, the Company shall (i) continue to pay his base salary in effect at the time of such termination, less the amount, if any, then payable under any disability benefits of the Company and (ii) provide continued coverage under all major medical and other health, accident, life or other disability plans and programs in which Mr. Spicer participated immediately prior to such termination. All stock options that have not vested as of the date of termination shall be deemed to have expired as of such date. In the event that Mr. Spicer's employment is terminated upon a change-in-control of the Company, the agreement provides for the following benefits: (i) continuation of the payment of Mr. Spicer's base salary for a period of one year following such termination (which shall be reduced by any amounts actually earned by Mr. Spicer during the one-year period following such termination); (ii) payment of any accrued and unpaid bonus through the date of termination; and (iii) payment of any accrued and unpaid expense reimbursement amounts owed to Mr. Spicer through the date of termination. In addition, all stock options that have not vested as of such termination date shall be accelerated and deemed to have vested as of the date of termination.

Jean W. Frydman. On June 6, 2006, the Employment Agreement, as amended, between Ms. Frydman and the Company, was terminated in connection with Ms. Frydman entering into a Settlement/Release Agreement with the Company. The Settlement/Release Agreement will provide Ms. Frydman with severance payments of approximately \$120,000 over a six-month period, paid on a bi-weekly basis. The Employment Agreement was scheduled to expire on May 17, 2007.

Barry C. Cohen. In May 2003, the Company entered into a three-year employment agreement with Mr. Cohen, who was appointed Vice President-New Business and Product Development. Pursuant to the agreement, Mr. Cohen receives a base salary of \$185,000, plus incentive bonuses. In addition, Mr. Cohen was issued options to purchase 75,000 shares of common stock at \$2.04 per share under the 1998 Plan and all such options are currently exercisable. These options expire in May 2008. In January 2005, Mr. Cohen was given an increase of salary to approximately \$219,000 per year and, in January 2006, Mr. Cohen was given a salary increase to approximately \$228,000 per year. In the event Mr. Cohen's employment is terminated by reason of death, the agreement provides for the following benefits to be paid to his estate: (i) base salary and any accrued and unpaid bonus and expense reimbursement amounts through the date of his death; (ii) continue to pay to his estate his base salary for three (3) months following his death; and (iii) for the shorter of six months following his death or the balance of the term of the agreement, the Company will provide continued coverage to the members of his family under all major medical and other health, accident, life or other disability plans and programs in which such family members participated immediately prior to his death. Any stock options granted to Mr. Cohen that have not vested as of the date of his death shall vest upon the date of Mr. Cohen's death. Should Mr. Cohen's employment be terminated due to disability, the agreement provides that the Company shall pay his base salary and any accrued bonus and expense reimbursement amounts through the date of termination. In addition, the agreement provides for the following benefits: for the shorter of six (6) months following such termination or the balance of the term of the agreement, the Company shall (i) continue to pay his base salary in effect at the time of such termination, less the amount, if any, then payable under any disability benefits of the Company and (ii) provide continued coverage under all major medical and other health, accident, life or other disability plans and programs in which Mr. Cohen participated immediately prior to such termination. All outstanding stock options, except unvested stock options, shall vest upon the effective date of his termination due to disability. In the event that Mr. Cohen's employment is terminated upon a change-in-control of the Company, the agreement provides for the following benefits: (i) continuation of the payment of Mr. Cohen's base salary for a period of six months following such termination (which shall be reduced by any amounts actually earned by Mr. Cohen during the six-month period following such termination); (ii) payment of any accrued and unpaid bonus through the date of termination; and (iii) payment of any accrued and unpaid expense reimbursement amounts owed to Mr. Cohen through the date of termination. In addition, all stock options that have not vested as of such termination date shall be accelerated and deemed to have vested as of the date of termination. Lastly, for the shorter of six months following such termination and the balance of the term of Mr. Cohen's agreement, the Company shall provide Mr. Cohen continued coverage under all major medical and other health, accident, life or other disability plans or programs in which Mr. Cohen participated immediately prior to such termination.

Dr. Henry Kwan. Dr. Henry Kwan, Head of Pharmaceutical Sciences, was terminated without cause from employment with the Company on October 20, 2005. Dr. Kwan had been employed by the Company pursuant to a written employment agreement dated as of December 21, 2004 (the Employment Agreement). The Employment Agreement provided for an initial term of three years. In connection with Dr. Kwan's termination from employment, the Employment Agreement was terminated, effective as of October 20, 2005. Pursuant to the employment agreement, the Company paid to Dr. Kwan his base salary for a period of six (6) months from October 20, 2005 and any accrued and unpaid bonus and expense reimbursement amounts through the date of termination. Such amounts were reduced by any amounts otherwise actually earned during the six-month period following the termination of his employment. In addition, for a period of one year from October 20, 2005, the Company shall provide continuation coverage under all major medical and other health, accident, life or other disability plans or programs in which Dr. Kwan participated immediately prior to his termination. All stock options granted by the Company to Dr. Kwan that had not vested as of October 20, 2005 expired on October 20, 2005 pursuant to the terms of the Employment Agreement.

The foregoing agreements also provide for certain non-competition and non-disclosure covenants on the part of such executive. However, with respect to the non-competition covenants, a court may determine not to enforce such provisions or only partially enforce such provisions. Additionally, each of the foregoing agreements provides for certain fringe benefits, such as inclusion in pension, profit sharing, stock option, savings, hospitalization and other benefit plans at such times as the Company may adopt them.

COMPENSATION OF DIRECTORS

For the fiscal year ended July 31, 2006, directors who are not employees and are independent received fees of \$2,000 for each meeting of the Board of Directors attended in person or \$1,000 if participated in by telephone. Non-employee independent Directors were also compensated \$3,000 per annum for serving, or \$5,000 per annum for chairing, a committee of the Board of Directors. Each non-employee independent Director was also awarded options to purchase 100,000 shares of common stock upon their election to the Board of Directors, to vest in three equal annual installments beginning on the first anniversary of their appointment. In addition, non-employee independent Directors were awarded annually options to purchase 50,000 shares of common stock at the time of their re-election to the Board of Directors. Such annually awarded options vest over a three-year period. Non-employee independent Directors are also reimbursed for expenses incurred in connection with their attendance at meetings of the Board of Directors or committees thereof.

The following table shows amounts earned by each Director in the fiscal year ended July 31, 2006:

Name	Total	Cash Fees	Stock Awards	Option Awards(a)	Non-Stock Incentive Plan	
					Compensation	All Other Compensation
Thomas E. Bonney	\$60,000	\$24,000	\$	\$36,000	\$	\$
William F. Hamilton	68,000	32,000		36,000		
J. Jay Lobell	67,000	1,000		66,000		
Charles Nemeroff	54,000	18,000		36,000		
Steven B. Ratoff	87,000	16,000		71,000		

(a) Represents estimated fair value of the option award on the grant date using a Black-Scholes option pricing model that assumes the following: expected volatility of 64%; dividend yield of 0%; expected term until exercise of 4 years; and a risk-free interest rate of 4.3%. Options granted to non-employee directors generally have the following terms: (i) exercise price equal to market price on the date of grant; (ii) vesting period of three years with one-third of the option grant vesting on each annual anniversary of the grant date; and (iii) contractual term of five years.

On August 16, 2006, at a meeting of the Board of Directors of the Company, the Board, based upon the recommendation of the Compensation Committee of the Board, unanimously approved certain changes to the compensation arrangements for non-employee directors. Summarized below are the terms of the compensation for non-employee directors, effective September 1, 2006. All amounts will be prorated for the remainder of 2006.

Equity Compensation

Each new non-employee director will, upon initially joining the Board, receive options to purchase 150,000 shares of the Company's common stock pursuant to the Company's 2006 Equity Incentive Plan (the "Plan"), and thereafter, each non-employee director will receive an annual grant of options to purchase 50,000 shares of the Company's common stock upon reelection to the Board, commencing with the upcoming annual meeting.

Edgar Filing: NOVADEL PHARMA INC - Form 10-K

Cash Compensation

Each non-employee director will be paid an annual retainer fee of \$35,000. In addition, each non-employee director will receive certain additional annual retainers for chairing or serving as a member of the committees of the Board, as follows:

Chairman of the Audit Committee	\$ 10,500
Member of the Audit Committee	\$ 7,500
Chairman of the Compensation Committee	\$ 7,500
Member of the Compensation Committee	\$ 5,000
Chairman of the Corporate Governance and Nominating Committee	\$ 7,500
Member of the Corporate Governance and Nominating Committee	\$ 5,000

The Board has agreed to permit each non-employee director to elect to receive any cash compensation in the form of an option grant under the Plan. Such election will be made on an annual basis and valued at the time of grant. Option grants will be received by such non-employee directors when cash compensation payments are due.

On October 25, 2006, at a meeting of the Board of Directors of the Company, the Board, based upon the recommendation of the Compensation Committee of the Board, unanimously approved certain changes to the compensation arrangements for non-employee directors. Summarized below are the terms of the compensation for non-employee directors, effective October 25, 2006. All amounts will be prorated for the remainder of 2006.

Equity Compensation

Each new non-employee director will, upon initially joining the Board, receive options to purchase 100,000 shares of the Company's common stock pursuant to the Company's 2006 Equity Incentive Plan (the "Plan"), and thereafter, each non-employee director will receive an annual grant of options to purchase 50,000 shares of the Company's common stock upon reelection to the Board, commencing with the upcoming annual meeting.

Cash Compensation

Each non-employee director will be paid an annual retainer fee of \$20,000 and \$2,000 for in-person and \$1,000 for telephonic meetings of the Board. The lead independent director will be paid a \$2,500 retainer for such role. In addition, each non-employee director will receive certain additional annual retainers and meeting fees for chairing or serving as a member of the committees of the Board, as follows:

Chairman of the Audit Committee	\$ 7,500
Member of the Audit Committee	\$ 2,500

Edgar Filing: NOVADEL PHARMA INC - Form 10-K

Chairman of the Compensation Committee	\$ 5,000
Member of the Compensation Committee	\$ 2,500
Chairman of the Corporate Governance and Nominating Committee	\$ 5,000
Member of the Corporate Governance and Nominating Committee	\$ 2,500

In addition, each non-employee director will be paid \$1,000 for in-person and \$500 for telephonic committee meetings. The Board has agreed to permit each non-employee director to elect to receive any cash compensation in the form of equity under the Plan. Such election will be made on an annual basis and valued at the time of grant. Equity grants will be received by such non-employee directors when cash compensation payments are due.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED MATTERS.**SHAREHOLDER APPROVAL OF EQUITY COMPENSATION PLANS**

The following table sets forth information as of July 31, 2006 with respect to the number of shares of our common stock issuable pursuant to equity compensation plans which have and have not been approved by our stockholders.

Equity Compensation Plan Information

Plan Category	Number of securities to be issued upon exercise of outstanding options (a)	Weighted average exercise price of outstanding options (b)	Number of securities remaining available for future issuance (c)
Equity compensation plans approved by security holders	3,298,000	1.51	5,988,000
Equity compensation plans not approved by security holders	4,863,000	1.73	N/A
TOTAL	8,161,000	1.65	5,988,000

As of July 31, 2006, we had outstanding warrants to purchase approximately 22.6 million shares of our common stock, the exercise price of which ranged from \$0.46 per share to \$2.00 per share.

STOCK OPTION PLANS

As of July 31, 2006, we had outstanding stock options to purchase approximately 8.1 million shares of common stock, the exercise price of which range between \$0.63 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 plans are administered by the Compensation Committee of the Board of Directors. The Committee has sole discretion and authority, consistent with the provisions of the Plans, to select the eligible participants to whom options will be granted under the Plans, the number of shares which will be covered by each option and the form and terms of the agreement to be used. All of the Company's employees and officers are eligible to participate in the Plans.

Plan	Shares Authorized	Options Outstanding at July 31, 2006	Remaining Shares Available for Issuance	Comments
1992 Stock Option Plan	500,000	80,000		Plan Closed
1997 Stock Option Plan	500,000	100,000		Plan Closed
1998 Stock Option Plan	3,400,000	2,668,000	438,000	
2006 Equity Incentive Plan	6,000,000	450,000	5,550,000	
Non-Plan	n/a	4,863,000		

Edgar Filing: NOVADEL PHARMA INC - Form 10-K

The Committee is empowered to determine the exercise price of options granted under the Plans, but the exercise price of incentive stock options (ISOs) issued under the 1998 Plan and the 2006 Equity Incentive Plan must be equal to or greater than the fair market value of a share of common stock on the date the option is granted (110% with respect to optionees who own at least 10% of the Company's outstanding common stock). The Committee has the authority to determine the time or times at which options granted under the Plans become exercisable, but options expire no later than 5 and 10 years from the date of grant. Options are nontransferable, other than by will and the laws of descent, and generally may be exercised only by an employee while employed by the Company or within 90 days after termination of employment (one year from termination resulting from death or disability).

Edgar Filing: NOVADEL PHARMA INC - Form 10-K

No ISO may be granted to an employee if, as the result of such grant, the aggregate fair market value (determined at the time each option was granted) of the shares with respect to which ISOs are exercisable for the first time by such employee during any calendar year (under all such Plans) exceeds \$100,000. The Plans do not confer upon any employee any right with respect to the continuation of employment by the Company, nor do the Plans interfere in any way with the employee's right or the Company's right to terminate the employee's employment at any time.

Stock Ownership of Directors, Management and Certain Beneficial Owners

Stock Ownership of Certain Beneficial Owners

The following table sets forth information, as of October 2, 2006, regarding beneficial ownership of the common stock to the extent known to us by each person known to be the beneficial owner of 5% or more of the common stock. Except as otherwise noted, each person has sole voting and investment power as to his or her shares.

<u>Title of Class</u>	<u>Name and Address or Number in Group</u>	<u>Amount and Nature of Beneficial Ownership</u>	<u>Percentage of Class</u>
Common Stock	Lindsay A. Rosenwald, M.D. (1)	9,491,924 (2)	16.8%
Common Stock	ProQuest Investment II Advisors Fund, L.P. (3)	7,128,152 (4)	14.0%
Common Stock	ProQuest Investments, II, L.P. (3)	7,128,152 (5)	14.0%
Common Stock	ProQuest Investments, III, L.P.(3)	7,128,152 (6)	14.0%
Common Stock	Caisse De DePot Et Placement Du Quebec (7)	5,837,931 (8)	11.5%

(1) The address for Dr. Rosenwald is: c/o Paramount BioCapital, Inc., 787 Seventh Avenue, 48th Floor, New York, NY 10019.

(2) Includes 2,155,660 shares of common stock and warrants to purchase 7,336,264 shares of common stock. Does not include 2,900,000 shares of common stock owned by the Lindsay A. Rosenwald 2000 (Delaware) Irrevocable Indenture of Trust dated May 24, 2000 which is a trust established for the benefit of Dr. Rosenwald. Dr. Rosenwald is not a trustee of this trust and disclaims beneficial ownership of such shares, except to any pecuniary interest therein. Does not include warrants which are convertible into 1,331,424 shares of common stock (the Trust Shares) and are owned by certain trusts for the benefit of Dr. Rosenwald's children. Dr. Rosenwald is not a trustee of these trusts and disclaims beneficial ownership of the Trust Shares, except to any pecuniary interest therein.

(3) The address for ProQuest Investments III, L.P., ProQuest Investments II, L.P., and ProQuest Investments II Advisors Fund, LP is 90 Nassau Street, 5th Floor, Princeton, NJ 08542.

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

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

Edgar Filing: NOVADEL PHARMA INC - Form 10-K

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

(7) The address for Caisse De DePot Et Placement Du Quebec is: 1000 Place Jean-Paul-Riopelle, Montreal, Quebec, Canada H22 263.

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

Stock Ownership of Directors and Management

The following table sets forth information, as of October 2, 2006, regarding beneficial ownership of the common stock to the extent known to the Company, by (i) each person who is a nominee for Director; (ii) each Executive Officer named in the Summary Compensation Table see Item 11, Executive Compensation; and (iii) all Directors and Executive Officers as a group. Except as otherwise noted, each person has sole voting and investment power as to his or her shares.

Title of	Name and Address or	Amount and Nature of	Percentage of
<u>Class</u>	<u>Number in Group (1)</u>	<u>Beneficial Ownership(2)</u>	<u>Class</u>
Common Stock	Thomas E. Bonney	52,833	*
Common Stock	Barry C. Cohen	171,666	*
Common Stock	Jan H. Egberts, M.D.	540,900	1.1%
Common Stock	Jean W. Frydman, Esq.	33,333	*
Common Stock	William F. Hamilton, Ph.D.	149,999	*
Common Stock	Henry Kwan, Ph.D.	0	*
Common Stock	J. Jay Lobell	273,149(3)	*
Common Stock	Charles Nemeroff, M.D., Ph.D.	150,999	*
Common Stock	Steven B. Ratoff	167,817(4)	*
Common Stock	Gary Shangold, M.D.	1,234,332	2.4%
Common Stock	Michael E. B. Spicer, CPA	42,333	*
	All Executive Officers and Directors as a group (11 persons)	2,817,361	5.5%

Edgar Filing: NOVADEL PHARMA INC - Form 10-K

*less than 1%.

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

65

Edgar Filing: NOVADEL PHARMA INC - Form 10-K

(2) For each of the following persons, the numbers set forth in this column includes the number of shares of common stock immediately succeeding such person's name, which such person has the right to acquire within 60 days through the exercise of stock options: Mr. Bonney, 33,333; Mr. Cohen, 166,666; Dr. Egberts, 540,900; Ms. Frydman, 33,333; Dr. Hamilton, 149,999; Dr. Nemeroff, 150,999; Dr. Shangold, 1,158,332; Mr. Spicer, 33,333; and all Directors and Executive Officers as a group, 2,266,895.

(3) Includes warrants to purchase 95,685 shares of common stock.

(4) Includes warrants to purchase 38,727 shares of common stock.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS.

To the best of management's knowledge, other than (i) compensation for services as Executive Officers and Directors or (ii) as set forth below, there were no material transactions, or series of similar transactions, or any currently proposed transactions, or series of similar transactions, to which the Company was or was to be a party, in which the amount involved exceeds \$60,000 during fiscal 2005 or fiscal 2006, and in which any Director or Executive Officer, or any security holder who is known by the Company to own of record or beneficially more than 5% of any class of the common stock, or any member of the immediate family of any of the foregoing persons, has an interest.

In April 2003, the Company entered into a license and development agreement with Manhattan Pharmaceuticals, Inc., or Manhattan Pharmaceuticals, for the worldwide, exclusive rights to its oral spray technology to deliver propofol for pre-procedural sedation. In November 2003, the Company received \$375,000 from Manhattan Pharmaceuticals, for license fees. The Company has included these license fees in deferred revenue and is recognizing these license fees over the 20-year term of the license. During the fiscal years ended July 31, 2006 and 2005, the Company invoiced Manhattan Pharmaceuticals approximately \$0 and \$119,000, respectively, for the Company's reimbursable expenses. Dr. Rosenwald may be deemed to be an affiliate of Manhattan Pharmaceuticals.

In September 2004, the Company entered into a license and development agreement with Velcera Pharmaceuticals Inc., or Velcera, in connection with veterinary applications for currently marketed veterinary drugs. In September 2004, the Company received \$1,500,000 from Velcera as an upfront payment in connection with the commercialization agreement. The Company may receive additional milestone payments and royalty payments over the 20-year term of the agreement. During the fiscal years ended July 31, 2006 and 2005, the Company invoiced Velcera approximately \$228,000 and \$183,000, respectively, for reimbursable expenses. Additionally, during the year ended July 31, 2005, the Company invoiced Velcera \$50,000 for a contractual milestone that was reached. Dr. Rosenwald may be deemed to be an affiliate of Velcera.

In October 2004, the Company entered into a license agreement with Hana Biosciences Inc., or Hana Biosciences, for the marketing rights in the U.S. and Canada for the Company's ondansetron oral spray technology. Pursuant to the terms of the agreement, in exchange for \$1,000,000, Hana Biosciences purchased 400,000 shares of the Company's common stock at a per share price equal to \$2.50, a premium of \$.91 per share or \$364,000 over the then market value of the Company's common stock. The Company accounted for this premium as deferred revenue related to the license. In connection with the agreement, Hana Biosciences issued to the Company \$500,000 worth of common stock of Hana Biosciences (73,121 shares based on a market value of \$6.84 per share). The proceeds received from Hana Biosciences attributable to the premium are included in deferred revenue and are being recognized over the period of the agreement. During the fiscal year ended July 31, 2006, the Company received approximately \$1.5 million in milestone payments from Hana Biosciences. The Company may receive additional license fees and royalties over the 20-year term of the agreement. During the fiscal years ended July 31, 2006 and July 31, 2005, the Company invoiced Hana Biosciences approximately \$13,000 and \$84,000, respectively, for pass-through expenses incurred by the Company on behalf of Hana Biosciences. Dr. Rosenwald may be deemed to be an affiliate of Hana Biosciences.

Edgar Filing: NOVADEL PHARMA INC - Form 10-K

In April 2005, the Company engaged Paramount BioCapital Inc., or Paramount, to assist it in the placement of shares in connection with a private placement. In connection with the offering, the Company paid a cash commission equal to approximately \$495,000 and issued a warrant to purchase 336,651 shares of common stock to Paramount, who acted as its placement agent. Such warrant is exercisable at an initial exercise price equal to \$1.30 per share (subject to adjustment). Paramount 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 offering. The Company agreed to indemnify Paramount against certain liabilities, including liabilities under the Securities Act of 1933, incurred in connection with the offering. Paramount and its affiliates are beneficial owners of approximately 9.9 million shares of common stock and securities exercisable for shares of common stock and, accordingly, Paramount may be deemed to be an affiliate of the Company. In connection with any future offering by the Company of its debt or equity securities for gross proceeds of greater than \$1 million that is intended to be exempt from Section 5 of the Securities Act of 1933 on or before May 27, 2006, the Company had granted Paramount the right of first refusal to act as a placement agent or co-agent. Prior to engaging in any such offering, the Company was to offer Paramount the opportunity to match the terms, conditions and limitations of any such proposed future private offering (including, but not limited to, cash fees and placement warrant coverage, if any; offering price of securities, including warrants, if any, as well as any applicable warrant exercise price and percentage of warrant coverage; and the quality and suitability of any proposed investors as shareholders of the Company). Had Paramount been unwilling to match or propose superior terms, conditions and limitations than those offered by an alternate placement agent, the Company would have been allowed to engage an alternate placement agent as its exclusive placement agent, investment banker, finder or broker-dealer, as applicable, and Paramount would have had no right to participate in the subsequent private offering. Had Paramount matched or proposed superior terms, conditions and limitations than those originally proposed by the alternate placement agent, after providing the alternate placement agent with the opportunity to match Paramount's offer, then either (i) Paramount and the alternate placement agent would each be allowed to participate in equal amounts toward the final total capital raise, as co-agents, or (ii) Paramount would be engaged by the Company to act as the exclusive placement agent for the subsequent private offering. The Board of Directors of the Company, at its sole discretion, would have made the final and binding determination as to whether proposals are equal, substantially similar or superior to each other.

In November 2005, the Company entered into a Confidential Separation Agreement and General Release (the Separation Agreement) and a Consulting Agreement (the Consulting Agreement) with Gary Shangold, M.D. Dr. Shangold is the former Chief Executive Officer of the Company. For the fiscal year ended July 31, 2006, pursuant to the Separation Agreement, the Company paid Dr. Shangold a separation payment of \$150,000. For the fiscal year ended July 31, 2006, pursuant to the Consulting Agreement, the Company paid Dr. Shangold \$175,000. See Item 11, Executive Compensation for more information.

In March 2006, the Company engaged Griffin Securities, Inc. (Griffin) and Paramount to assist it in the placement of shares in connection with a private placement. Griffin and Paramount were paid an aggregate fee for acting as placement agents of cash equal to 7% of the proceeds from the sale of the common stock, or \$792,400, and warrants equal to 6% of the shares of common stock purchased, subject to certain exclusions, or warrants to purchase 468,329 shares. Such warrants have the same terms as those issued to the investors. In conjunction with the March 2006 placement agent execution agreement, Paramount waived its right of first refusal privileges that it received as part of the April 2005 placement agent agreement.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES.

The following table sets forth fees billed to the Company by its independent registered public accounting firm during the fiscal years ended July 31, 2006 and 2005 for: (i) services rendered for the audit of its annual financial statements and the review of its quarterly financial statements; (ii) services by its independent registered public accounting firm that are reasonably related to the performance of the audit or review of its financial statements and that are not reported as Audit Fees; (iii) services rendered in connection with tax compliance, tax advice and tax planning; and (iv) all other fees for services rendered.

	J.H. Cohn LLP	
	FY 2006	FY 2005
Audit Fees	\$99,000	\$95,000
Audit Related Fees	12,000	3,000

Edgar Filing: NOVADEL PHARMA INC - Form 10-K

Tax Fees	4,000	9,000
All Other Fees		

67

Policy on Audit Committee Pre-Approval of Audit and Permissible Non-Audit Services of Independent Auditors

The Audit Committee has adopted a policy for the pre-approval of all audit and permitted non-audit services that may be performed by our independent registered public accounting firm. Under this policy, unless a type of service to be provided by the independent registered public accounting firm has received general pre-approval, it will require specific pre-approval by the Audit Committee. Any proposed services exceeding pre-approved cost levels will require specific pre-approval by the Audit Committee. The term of any pre-approval is 12 months from the date of pre-approval, unless the Audit Committee specifically provides for a different period. The Audit Committee periodically will revise the list of pre-approved services, based on subsequent determinations. The Audit Committee delegates pre-approval authority to its chairperson and may delegate such authority to one or more of its members, whose activities are reported to the Audit Committee at each regularly scheduled meeting.

The Audit Committee has approved for fiscal year 2006 the following services with the following fee limits:

Audit Services

Service	Range of Fees
1. Statutory audits or financial audits for affiliates of the Company for annual financial statements and review of financial statements included in quarterly reports in Form 10-Q.	Not to exceed \$5,000
2. Services associated with SEC registration statements, periodic reports and other documents filed with the SEC or other documents issued in connection with securities offerings (e.g. comfort letters, consents) and assistance in responding to SEC comment letters	Not to exceed \$5,000
3. Consultations by the Company's management as to the accounting or disclosure treatment of transactions or events and/or other actual or potential impact of final or proposed rules, standards or interpretations by the SEC, FASB, or other regulatory or standard setting bodies (Note: Under SEC rules, some consultations may be audit-related services rather than audit services)	Not to exceed \$10,000

Audit Related Services

Service	Range of Fees
1. Due diligence services pertaining to potential business acquisitions/dispositions	Not to exceed \$5,000
2. Agreed-upon or expanded audit procedures related to accounting and/or billing records required to respond or comply with financial, accounting or regulatory reporting matters	Not to exceed \$10,000
3. Consultations by the Company's management as to the accounting or disclosure treatment of transactions or events and/or the actual or potential impact of final or proposed rules, standards or interpretations by the SEC, FASB, or other regulatory or standard-setting bodies (Note: Under SEC rules, some consultations may be audit services rather than audit-related services)	Not to exceed \$10,000
4. Attest services not required by statute or regulation	Not to exceed \$5,000

Tax Services

Edgar Filing: NOVADEL PHARMA INC - Form 10-K

Service

1. U.S. federal, state and local tax planning and advice
2. U.S. federal, state and local tax compliance
3. International tax planning and advice
4. International tax compliance

Range of Fees

- Not to exceed \$5,000
Not to exceed \$5,000
Not to exceed \$5,000
Not to exceed \$5,000

68

All Other Services

Service

No such services are pre-approved

Range of Fees

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES.

(a) Financial Statements and Schedules:

1. Financial Statements

The following financial statements and report of independent registered public accounting firm are included herein:

Report of Independent Registered Public Accounting Firm	F-1
Balance Sheets	F-2
Statements of Operations	F-3
Statements of Changes in Stockholders' Equity	F-4
Statements of Cash Flows	F-5
Notes to Financial Statements	F-6

2. Financial Statement Schedules
Not applicable.

3. List of Exhibits

Edgar Filing: NOVADEL PHARMA INC - Form 10-K

INDEX TO EXHIBITS

The following exhibits are included with this Annual Report. All management contracts or compensatory plans or arrangements are marked with an asterisk.

EXHIBIT NO.	DESCRIPTION	METHOD OF FILING
3.1	Restated Certificate of Incorporation of the Company	Incorporated by reference to Exhibit 3.1 of the Company's Quarterly Report on Form 10-QSB, as filed with the SEC on June 14, 2004
3.2	Amended and Restated By-laws of the Company	Incorporated by reference to Exhibit 3.1 of the Company's Form 8-K, as filed with the SEC on September 9, 2005
4.1	Form of Class C Warrant for the Purchase of Shares of Common Stock	Incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K, as filed with the SEC on January 12, 2004
4.2	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 April 17, 2006
10.1*	1992 Stock Option Plan	Incorporated by reference to the Company's Registration Statement on Form SB-2, as filed with the SEC on August 8, 1997 (File No. 333-33201)
10.2*	Form of Incentive Stock Option Agreement under the 1992 Stock Option Plan	Incorporated by reference to the Company's Registration Statement on Form SB-2, as filed with the SEC on August 8, 1997 (File No. 333-33201)
10.3*	1997 Stock Option Plan	Incorporated by reference to Exhibit 10.8 to the Company's Registration Statement on Form SB-2, as filed with the SEC on August 8, 1997 (File No. 333-33201)
10.4*	Form of Non-Qualified Option Agreement under the 1997 Stock Option Plan	Incorporated by reference to the Company's Registration Statement on Form SB-2, as filed with the SEC on August 8, 1997 (File No. 333-33201)
10.5*	1998 Stock Option Plan	Incorporated by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-8, as filed with the SEC on June 18, 2004 (File No. 333-116665)
10.6*	Form of Stock Option Agreement under the 1998 Stock Option Plan	Incorporated by reference to Exhibit 4.2 to the Company's Registration Statement on Form S-8, as filed with the SEC on June 18, 2004 (File No. 333-116665)
10.7*	Form of Non-Qualified Stock Option Agreement	Incorporated by reference to Exhibit 4.3 to the Company's Registration Statement on Form S-8, as filed with the SEC on June 18, 2004 (File No. 333-116665)
10.8	Common Stock and Warrant Purchase Agreement, dated December 12, 2001, by and among the Company and certain purchasers	Incorporated by reference to Exhibit A to the Schedule 13D as filed by Lindsay A. Rosenwald with the SEC on December 21, 2001

Edgar Filing: NOVADEL PHARMA INC - Form 10-K

10.10	Lease Agreement, dated March 19, 2003, by and between the Company and Macedo Business Park, II, L.L.C.	Incorporated by reference to Exhibit 10.28 to the Company's Quarterly Report on Form 10-QSB for the period ended April 30, 2003, as filed with the SEC on June 19, 2003
10.11	Amendment Number 1 to Lease Agreement dated March 19, 2003 between Macedo Business Park, II, L.L.C. and the Company, dated as of March 19, 2003	Incorporated by reference to Exhibit 10.29 to the Company's Quarterly Report on Form 10-QSB for the period ended April 30, 2003, as filed with the SEC on June 19, 2003
10.12	License and Development Agreement, effective as of April 4, 2003, by and between the Company and Manhattan Pharmaceuticals, Inc.	Incorporated by reference to Exhibit 10.31 to the Amendment No. 1 to the Company's Annual Report on Form 10-KSB, as filed with the SEC on March 11, 2004
10.13	Development, Manufacturing and Supply Agreement, dated July 28, 2004, by and between the Company and Par Pharmaceutical, Inc.	Incorporated by reference to Exhibit 10.13 to the Company's Annual Report on Form 10-KSB, as filed with the SEC on November 15, 2004
10.14	Second Amendment to License and Development Agreement, dated as of June 22, 2004, by and between the Company and the Veterinary Company, Inc.	Incorporated by reference to Exhibit 10.14 to the Company's Annual Report on Form 10-KSB, as filed with the SEC on November 15, 2004
10.15*	Employment Agreement, dated as of May 23, 2003, by and between the Company and Barry Cohen	Incorporated by reference to Exhibit 10.30 to the Company's Quarterly Report on Form 10-QSB for the period ending April 30, 2003, as filed with the SEC on June 19, 2003
10.16*	Disclosure and Release Agreement Related to the Exchange of Non-Plan Options for Stock Options under the NovaDel Pharma Inc. 1998 Stock Option Plan by and between the Company and Thomas E. Bonney	Incorporated by reference to Exhibit 10.3 of the Company's Form 8-K, as filed with the SEC on August 2, 2005
10.17*	Disclosure and Release Agreement Related to the Exchange of Non-Plan Options for Stock Options under the NovaDel Pharma Inc. 1998 Stock Option Plan by and between the Company and William F. Hamilton	Incorporated by reference to Exhibit 10.2 of the Company's Form 8-K, as filed with the SEC on August 2, 2005
10.18*	Disclosure and Release Agreement Related to the Exchange of Non-Plan Options for Stock Options under the NovaDel Pharma Inc. 1998 Stock Option Plan by and between the Company and Charles Nemeroff	Incorporated by reference to Exhibit 10.4 of the Company's Form 8-K, as filed with the SEC on August 2, 2005
10.19*	Employment Agreement, dated as of December 20, 2004, by and between the Company and Michael Spicer	Incorporated by reference to Exhibit 10.35 of the Company's Form 8-K, as filed with the SEC on December 23, 2004
10.20*	Amendment to Employment Agreement dated September 2, 2005, by and between the Company and Michael E.B. Spicer	Incorporated by reference to Exhibit 10.2 of the Company's Form 8-K, as filed with the SEC on September 9, 2005
10.21*	1998 Stock Option Plan Nonqualified Stock Option Agreement dated July 28, 2005, by and between the Company and Thomas E. Bonney	Incorporated by reference to Exhibit 10.25 of the Company's Annual Report on Form 10-KSB for the period ended July 31, 2005, as filed with the SEC on October 31, 2005
10.22*	1998 Stock Option Plan Nonqualified Stock Option Agreement dated July 28, 2005, by and between the Company and William F. Hamilton	Incorporated by reference to Exhibit 10.27 to the Company's Annual Report on Form 10-KSB for the period ended July 31, 2005, as filed with the SEC on October 31, 2005

Edgar Filing: NOVADEL PHARMA INC - Form 10-K

10.23*	1998 Stock Option Plan Nonqualified Stock Option Agreement dated July 28, 2005, by and between the Company and Charles Nemeroff	Incorporated by reference to Exhibit 10.29 of the Company's Annual Report on Form 10-KSB for the period ended July 31, 2005, as filed with the SEC on October 31, 2005
10.24	Amendment No. 1 to License and Development Agreement dated as of August 8, 2005, by and between the Company and Hana Biosciences Inc.	Incorporated by reference to Exhibit 99.1 of the Company's Form 8-K, as filed with the SEC on August 12, 2005
10.25*	Employment Agreement, dated as of September 26, 2005, by and between the Company and Jan H. Egberts, M.D.	Incorporated by reference to Exhibit 10.1 of the Company's Form 8-K, as filed with the SEC on September 28, 2005
10.26*	Nonqualified Stock Option Agreement dated September 26, 2005, by and between the Company and Jan H. Egberts, M.D.	Incorporated by reference to Exhibit 10.2 of the Company's Form 8-K, as filed with the SEC on September 28, 2005
10.27	Confidential Separation Agreement and General Release dated November 29, 2005, by and between the Company and Gary Shangold, M.D.	Incorporated by reference to Exhibit 10.1 of the Company's Form 8-K, as filed with the SEC on December 2, 2005
10.28	Consulting Agreement dated November 29, 2005, by and between the Company and Gary Shangold, M.D.	Incorporated by reference to Exhibit 10.2 of the Company's Form 8-K, as filed with the SEC on December 2, 2005
10.29*	NovaDel Pharma Inc. 2006 Equity Incentive Plan	Incorporated by reference to Exhibit 10.1 of the Company's Form 8-K, as filed with the SEC on January 23, 2006
10.30*	1998 Stock Option Plan Nonqualified Stock Option Agreement dated January 17, 2006, by and between the Company and Thomas Bonney	Incorporated by reference to Exhibit 10.2 of the Company's Quarterly Report on Form 10-Q, as filed with the SEC on March 15, 2006
10.31*	1998 Stock Option Plan Nonqualified Stock Option Agreement dated January 17, 2006, by and between the Company and William Hamilton	Incorporated by reference to Exhibit 10.3 of the Company's Quarterly Report on Form 10-Q, as filed with the SEC on March 15, 2006
10.32*	1998 Stock Option Plan Nonqualified Stock Option Agreement dated December 14, 2005, by and between the Company and J. Jay Lobell	Incorporated by reference to Exhibit 10.4 of the Company's Quarterly Report on Form 10-Q, as filed with the SEC on March 15, 2006
10.33*	1998 Stock Option Plan Nonqualified Stock Option Agreement dated January 17, 2006, by and between the Company and Charles Nemeroff	Incorporated by reference to Exhibit 10.5 of the Company's Quarterly Report on Form 10-Q, as filed with the SEC on March 15, 2006
10.34*	1998 Stock Option Plan Nonqualified Stock Option Agreement dated January 17, 2006, by and between the Company and Steven Ratoff	Incorporated by reference to Exhibit 10.6 of the Company's Quarterly Report on Form 10-Q, as filed with the SEC on March 15, 2006
10.35	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 April 17, 2006
10.36	Registration Rights Agreement by and between the Company and certain accredited investors (with attached schedule of parties and terms thereto)	Incorporated by reference to Exhibit 10.2 of the Company's Form 8-K, as filed with the SEC on April 17, 2006
10.37	Placement Agent Agreement, dated March 15, 2006, by and between the Company, Griffin Securities, Inc. and Paramount BioCapital, Inc.	Incorporated by reference to Exhibit 10.1 of the Company's Form 8-K, as filed with the SEC on April 20, 2006

Edgar Filing: NOVADEL PHARMA INC - Form 10-K

21.1	Subsidiaries of the Registrant	The registrant has no subsidiaries
23.1	Consent of J.H. Cohn LLP	Filed herewith
31.1	Certification of Chief Executive Officer under Rule 13a-14(a)	Filed herewith

72

Edgar Filing: NOVADEL PHARMA INC - Form 10-K

31.2	Certification of Principal Financial Officer under Rules 13a-14(a)	Filed herewith
32.1	Certifications of the Chief Executive Officer and Chief Financial Officer under 18 USC 1350	Filed herewith

(b) Exhibits.
See Item 15(a)(3) above.

(c) Financial Statement Schedules.
See Item 15(a)(2) above.

73

SIGNATURES

In accordance with Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

NovaDel Pharma Inc.

Date: October 27, 2006

By:

/S/JAN H. EGBERTS
Jan H. Egberts, M.D.
President and Chief Executive Officer

Edgar Filing: NOVADEL PHARMA INC - Form 10-K

In accordance with the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

<u>SIGNATURES</u>	<u>TITLE</u>	<u>DATE</u>
-		
/S/ JAN H. EGBERTS Jan H. Egberts, M.D.	Director, President and Chief Executive Officer (Principal Executive Officer)	October 27, 2006
/S/ MICHAEL E. SPICER Michael E. Spicer	Chief Financial Officer (Principal Financial and Accounting Officer)	October 27, 2006
/S/ THOMAS E. BONNEY Thomas E. Bonney	Director	October 27, 2006
/S/ WILLIAM F. HAMILTON William F. Hamilton, Ph.D.	Director	October 27, 2006
/S/ J. JAY LOBELL J. Jay Lobell	Director	October 27, 2006
/S/ CHARLES NEMEROFF Charles Nemeroff	Director	October 27, 2006
/S/ STEVEN B. RATOFF Steven B. Ratoff	Director and Chairman of the Board	October 27, 2006

INDEX TO FINANCIAL STATEMENTS

The following financial statements are included in Part II, Item 8:

Report of Independent Registered Public Accounting Firm	F-1
Balance Sheets	F-2
Statements of Operations	F-3
Statements of Changes in Stockholders' Equity	F-4
Statements of Cash Flows	F-5
Notes to Financial Statements	F-6

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Stockholders and

Board of Directors

NovaDel Pharma Inc.

We have audited the accompanying balance sheets of NovaDel Pharma Inc. as of July 31, 2006 and 2005, and the related statements of operations, changes in stockholders' equity and cash flows for each of the years in the three-year period ended July 31, 2006. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of NovaDel Pharma Inc. as of July 31, 2006 and 2005, and its results of operations and cash flows for each of the years in the three-year period ended July 31, 2006, in conformity with accounting principles generally accepted in the United States of America.

As discussed in Note 3 to the financial statements, the Company changed the manner in which it accounts for share-based compensation in fiscal 2006.

/S/ J.H. COHN LLP

Roseland, New Jersey

September 15, 2006

NOVADEL PHARMA INC.

BALANCE SHEETS

AS OF JULY 31, 2006 AND 2005

ASSETS	July 31, 2006	July 31, 2005
Current Assets:		
Cash and cash equivalents	\$5,687,000	\$4,680,000
Short-term investments	4,451,000	3,543,000
Accounts receivable from related parties, net of allowances:		
\$54,000 as of July 31, 2006 and 2005		108,000
Inventories	585,000	549,000
Investment in marketable equity security available for sale	560,000	
Prepaid expenses and other current assets	491,000	306,000
Total Current Assets	11,774,000	9,186,000
Property and equipment, net	2,704,000	2,991,000
Other assets	344,000	351,000
Investment in non-marketable equity security, at cost		500,000
TOTAL ASSETS	\$ 14,822,000	\$ 13,028,000
LIABILITIES AND STOCKHOLDERS EQUITY		
Current Liabilities:		
Accounts payable	\$845,000	\$1,179,000
Accrued expenses and other current liabilities	1,111,000	1,064,000
Current portion of deferred revenue	162,000	162,000
Current portion of capitalized lease obligation	82,000	
Total Current Liabilities	2,200,000	2,405,000
Non-current portion of deferred revenue	2,512,000	2,674,000
Non-current portion of capitalized lease obligation	65,000	
Total Liabilities	4,777,000	5,079,000
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS EQUITY		
Preferred stock, \$.001 par value:		
Authorized 1,000,000 shares, none issued		
Common stock, \$.001 par value:		
Authorized 100,000,000 shares, Issued 49,123,869 and 40,597,318 shares at July 31, 2006 and 2005, respectively	49,000	41,000
Additional paid-in capital	54,417,000	42,305,000
Accumulated deficit	(44,475,000)	(34,391,000)
Accumulated other comprehensive income	60,000	
Less: Treasury stock, at cost, 3,012 shares	(6,000)	(6,000)
Total Stockholders Equity	10,045,000	7,949,000
TOTAL LIABILITIES AND STOCKHOLDERS EQUITY	\$ 14,822,000	\$ 13,028,000

See accompanying notes to financial statements.

NOVADEL PHARMA INC.

STATEMENTS OF OPERATIONS

FOR THE YEARS ENDED JULY 31, 2006, 2005 AND 2004

	2006		2005		2004
License Fees and Milestone Payments Earned from Related Parties	\$ 1,662,000		\$ 141,000		\$ 13,000
Consulting Revenues from Related Parties	228,000		298,000		453,000
Total Revenues	1,890,000		439,000		466,000
Research and Development Expenses	5,275,000		3,826,000		2,492,000
Consulting, Selling, General and Administrative Expenses	7,179,000		6,391,000		4,627,000
Total Expenses	12,454,000		10,217,000		7,119,000
Loss From Operations	(10,564,000)		(9,778,000)		(6,653,000)
Interest Income	224,000		87,000		98,000
Loss Before Income Tax Benefit	(10,340,000)		(9,691,000)		(6,555,000)
Income Tax Benefit	(256,000)		(241,000)		(214,000)
Net Loss	\$ (10,084,000)		\$ (9,450,000)		\$ (6,341,000)
Basic and Diluted Loss Per Common Share	\$ (.23)		\$ (.27)		\$ (.24)
Weighted Average Number of Common Shares Used in Computation of Basic and Diluted Loss Per Share	43,000,000		34,808,000		26,269,000

See accompanying notes to financial statements.

NOVADEL PHARMA INC.

STATEMENTS OF CHANGES IN STOCKHOLDERS EQUITY

FOR THE YEARS ENDED JULY 31, 2006, 2005 AND 2004

	Common Stock			Accumulated Deficit	Accumulated Other Comprehensive Income	Treasury Stock	Total Stockholders Equity
	Shares	Amount	Additional Paid-In Capital				
BALANCE, August 1, 2003	17,972,730	\$ 18,000	\$ 22,452,000	\$(18,600,000)	\$	\$	\$ 3,870,000
Stock issued in connection with private placements, net of costs	13,333,333	14,000	12,771,000				12,785,000
Stock issued to 2003 private investors in connection with reset provision	1,371,549	1,000	(1,000)				
Stock issued for options and warrants exercised	413,825		451,000			(6,000)	445,000
Impact of variable plan accounting			(736,000)				(736,000)
Net Loss				(6,341,000)			(6,341,000)
BALANCE, July 31, 2004	33,091,437	33,000	34,937,000	(24,941,000)		(6,000)	10,023,000
Stock issued in connection with private placements, net of costs	6,733,024	7,000	6,302,000				6,309,000
Stock issued to Hana Biosciences Inc. per license agreement	400,000		636,000				636,000
Stock issued for options and warrants exercised	172,857		219,000				219,000
Stock issued for services	200,000	1,000	306,000				307,000
Warrants issued for services			11,000				11,000
Impact of variable plan accounting			(106,000)				(106,000)
Net Loss				(9,450,000)			(9,450,000)
BALANCE, July 31, 2005	40,597,318	41,000	42,305,000	(34,391,000)		(6,000)	7,949,000
Share-based compensation expense			1,201,000				1,201,000
Stock issued in connection with private placement, net of costs	8,092,796	8,000	10,585,000				10,593,000
Stock issued for options and warrants exercised	433,755		326,000				326,000
Comprehensive income (loss):							
Unrealized gain on investment in marketable equity security					60,000		60,000
Net loss				(10,084,000)			(10,084,000)
Total comprehensive loss							(10,024,000)
BALANCE, July 31, 2006	49,123,869	\$ 49,000	\$ 54,417,000	\$(44,475,000)	\$ 60,000	\$(6,000)	\$ 10,045,000

See accompanying notes to financial statements.

NOVADEL PHARMA INC.

STATEMENTS OF CASH FLOWS

FOR THE YEARS ENDED JULY 31, 2006, 2005 AND 2004

	2006		2005		2004
CASH FLOWS FROM OPERATING ACTIVITIES					
Net loss	\$ (10,084,000)	\$ (9,450,000)	\$ (6,341,000
Adjustments to reconcile net loss to net cash used in operating activities:					
Stock issued for services			307,000		
Warrants issued for services			11,000		
Share-based compensation expense	1,201,000				
Impact of variable plan accounting			(106,000)	(736,000
Depreciation and amortization	583,000		380,000		222,000
Changes in operating assets and liabilities:					
Accounts receivable from related parties	108,000		22,000		(128,000
Inventories	(36,000)	(549,000)	
Prepaid expenses and other current assets	(185,000)	(51,000)	(87,000
Other Assets	7,000				6,000
Accounts payable	(334,000)	938,000		102,000
Accrued expenses and other current liabilities	47,000		266,000		480,000
Deferred revenue	(162,000)	1,974,000		362,000
Net cash used in operating activities	(8,855,000)	(6,258,000)	(6,120,000
CASH FLOWS FROM INVESTING ACTIVITIES:					
Purchases of property and equipment	(130,000)	(2,305,000)	(487,000
Purchases of short-term and long-term investments	(5,751,000)	(5,180,000)	(9,560,000
Maturities of short-term and long-term investments	4,843,000		9,155,000		2,042,000
Net cash provided by (used in) investing activities	(1,038,000)	1,670,000		(8,005,000
CASH FLOWS FROM FINANCING ACTIVITIES:					
Proceeds from issuance of common stock through private placements	10,593,000		6,309,000		12,785,000
Proceeds from options and warrants exercised	326,000		219,000		445,000
Proceeds from shares of common stock issued to Hana Biosciences, Inc.			636,000		
Payments of capitalized lease obligations	(19,000)	(62,000)	(25,000
Net cash provided by financing activities	10,900,000		7,102,000		13,205,000
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	1,007,000		2,514,000		(920,000
CASH AND CASH EQUIVALENTS, BEGINNING OF YEAR	4,680,000		2,166,000		3,086,000
CASH AND CASH EQUIVALENTS, END OF YEAR	\$ 5,687,000		\$ 4,680,000		\$ 2,166,000
SUPPLEMENTAL DISCLOSURE OF NONCASH INVESTING AND FINANCING ACTIVITIES:					
Investment in Hana Biosciences, Inc. common stock received in connection with license agreement	\$		\$ 500,000		\$
Equipment acquired under capitalized lease obligation	\$ 166,000		\$		\$ 87,000
Treasury stock acquired	\$		\$		\$ 6,000

See accompanying notes to financial statements.

NOVADEL PHARMA INC.

NOTES TO FINANCIAL STATEMENTS

NOTE 1 - NATURE OF THE BUSINESS

NovaDel Pharma Inc. (the Company) is a specialty pharmaceutical company engaged in the development of novel drug delivery systems for prescription and over-the-counter (OTC) drugs. The Company's oral spray therapeutics are administered by a novel application drug delivery system for presently marketed prescription, OTC, and veterinary drugs. The Company's patented and patent-pending delivery system is an oral spray potentially enabling drug absorption through the oral mucosa, increasing the benefits of clinically proven compounds, including more rapid absorption into the bloodstream than presently available oral delivery systems.

Through July 31, 2006, the Company has entered into strategic license agreements with (i) Hana Biosciences Inc. (Hana Biosciences), for the marketing rights in the U.S. and Canada for the Company's ondansetron oral spray, (ii) Par Pharmaceutical, Inc. (Par), for the marketing rights in the U.S. and Canada for the Company's nitroglycerin oral spray, (iii) Manhattan Pharmaceuticals, Inc. (Manhattan Pharmaceuticals), in connection with propofol, and (iv) Velcera Pharmaceuticals, Inc. (Velcera), in connection with veterinary applications for currently marketed veterinary drugs.

On November 18, 2004, the Company entered into a manufacturing and supply agreement with INyX USA, Ltd. (INyX), whereby INyX manufactures and supplies the Company's nitroglycerin lingual spray. For a five-year period that began November 18, 2004, INyX is the exclusive provider substantially worldwide of the nitroglycerin lingual spray to the Company.

On June 28, 2006, the Company's Board of Directors approved a change of the Company's fiscal year end from July 31 to December 31. Accordingly, the new fiscal year will begin on January 1, and end on December 31.

NOTE 2 - LIQUIDITY AND BASIS OF PRESENTATION

The Company has reported a net loss of \$10,084,000, \$9,450,000 and \$6,341,000 and negative cash flows from operating activities of \$8,855,000, \$6,258,000, and \$6,120,000 for the fiscal years ended July 31, 2006, 2005, and 2004, respectively. As of July 31, 2006, the Company had working capital of \$9,574,000, cash and cash equivalents of \$5,687,000 and short-term investments of \$4,451,000. Until and unless the Company's operations generate significant revenues, the Company will attempt to continue to fund operations from cash on hand and through the sources of capital described below. The Company's long-term liquidity is contingent upon achieving sales and/or obtaining additional financing. The most likely sources of financing include private placements of its equity or debt securities or bridge loans to the Company from third party lenders, license payments from existing and current and future partners, and royalty payments from sales of approved drugs by partners. The Company can give no assurances that any additional capital that the Company is able to obtain will be sufficient to meet its needs. On April 19, 2006, the Company completed an equity financing in which the Company received gross proceeds of \$11.8 million and net proceeds of \$10.6 million. Although the Company expects to have sufficient cash to fund its operations through the end of fiscal 2007, the Company would have to significantly reduce the pace of its ongoing development of its product candidates unless it can obtain additional working capital. Given the current and desired pace of product development of our product candidates, the Company estimates that it will need to raise additional capital during fiscal year 2007 in order to fully fund its development activities through July 31, 2007. This could include the securing of funds through new partnerships and/or the sale of our common stock or other securities, in order to fund our research and development activities. There can be no assurance that such capital will be available to the Company 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. The Company may not be able to successfully obtain additional financing on terms acceptable to it, or at all. If the Company is unsuccessful at obtaining additional financing as needed, the Company may be required to significantly curtail or cease operations. The Company will need additional financing thereafter until it achieves profitability, if ever.

NOTE 3 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

REVENUE RECOGNITION The Company receives revenue from consulting services and license agreements. Consulting revenues from contract clinical research are recognized in the period in which the services are rendered, provided that collection is reasonably assured. Upfront license agreement payments are initially deferred and subsequently amortized into revenue over the contractual period. Milestone payments related to license agreements are recognized as revenue when earned.

F-6

Edgar Filing: NOVADEL PHARMA INC - Form 10-K

CASH EQUIVALENTS AND INVESTMENTS - Cash equivalents include certificates of deposit and money market instruments with original maturities of three months or less when purchased. Investments include short-term investments, long-term investments and an investment in marketable common stock received from a licensee (See Notes 7 and 8). Short-term investments are carried at amortized cost, which approximates fair market value, and consist of certificates of deposit and US treasury securities with original maturities greater than three months and less than one year.

FINANCIAL INSTRUMENTS - Financial instruments include cash and cash equivalents, short-term investments, long-term investments, accounts receivable and accounts payable. The amounts reported for financial instruments are considered to be reasonable approximations of their fair values.

PROPERTY AND EQUIPMENT - Property and equipment, including leasehold improvements, are stated at cost. The Company provides for depreciation and amortization using the straight-line method, based upon estimated useful lives of five to ten years or the lease term, if shorter.

RESEARCH AND DEVELOPMENT COSTS - Research and development costs are expensed as incurred.

INCOME TAXES - Deferred tax assets and liabilities are recognized for the future tax consequences attributable to temporary differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Temporary differences between financial statement and income tax reporting result primarily from net operating losses. As a result of these temporary differences, the Company has recorded a deferred tax asset with an offsetting valuation allowance for the same amount. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. Valuation allowances are established when it is considered more likely than not that some portion or all of the deferred tax asset will not be realized.

DEFINED CONTRIBUTION RETIREMENT PLANS - During January 2004, the Company established a 401(k) retirement plan that is available to all employees and requires matching contributions by the Company. During the years ended July 31, 2006, 2005 and 2004, the Company contributed approximately \$101,000, \$101,000 and \$56,000, respectively, to this plan. Prior to January 2004, the Company had a Simple IRA retirement plan, available to all employees that provided for contributions at management's discretion. During the year ended July 31, 2004, the Company made contributions to this Simple IRA of approximately \$37,000.

INVENTORIES - Inventories, consisting of raw materials, are carried at the lower of cost or market. Cost is determined using the first-in, first-out (FIFO) method.

Inventories at July 31, 2006 and 2005 primarily consisted of inventory related to the Company's nitroglycerin lingual aerosol product candidate. Through outsourcing to INyX, the Company is in the process of starting to make commercial quantities for this product candidate prior to the date that such product candidate may receive final U.S. Food and Drug Administration (FDA) marketing approval (i.e., pre-launch inventory). On June 1, 2005, the Company received an approvable letter from the FDA regarding its New Drug Application (NDA) for NitroMist (nitroglycerin lingual aerosol). The FDA is not requiring any additional clinical studies for approval but has requested that the Company complete certain manufacturing process validation commitments. On April 30, 2006, the Company submitted the necessary documentation to the FDA for the completed process validation commitments. On May 26, 2006, the Company announced that the FDA had accepted the Company's submission regarding its NDA as a complete response and that the FDA indicated a target date of November 3, 2006 for action on the submission. If final approval of this product candidate is not received, or approval is not received timely compared to our estimates for product shelf-life, the Company will write-off the related amounts of pre-launch inventory in the period of that determination. If the Company had been required to write-off the \$585,000 recorded as pre-launch inventory at July 31, 2006, the charge would have been considered by the Company to have been material to its operating results and is likely to be considered material if such a write-off is required in a subsequent period.

RECLASSIFICATION Certain prior year amounts have been reclassified to conform to the current year's presentation.

F-7

Edgar Filing: NOVADEL PHARMA INC - Form 10-K

USE OF ESTIMATES The accompanying financial statements have been prepared in conformity with accounting principles generally accepted in the U.S. This requires our management to make estimates about the future resolution of existing uncertainties that affect the reported amounts of assets, liabilities, revenues and expenses which in the normal course of business are subsequently adjusted to actual results. Actual results could differ from such estimates. In preparing these financial statements, management has made its best estimates and judgments of the amounts and disclosures included in the financial statements giving due regard to materiality.

LOSS PER SHARE Loss per common share is computed pursuant to SFAS No. 128, Earnings Per Share. Basic loss per share is computed as net loss divided by the weighted average number of common shares outstanding for the period. Diluted net loss per common share is the same as basic net loss per common share, since potentially dilutive securities from the assumed exercise of all outstanding options and warrants would have an antidilutive effect because the Company incurred a net loss during each period presented. As of July 31, 2006, 2005 and 2004, there were 30.7 million, 26.2 million and 20.0 million common shares, respectively, issuable upon exercise of options and warrants which were excluded from the diluted loss per share computation.

STOCK-BASED COMPENSATION - In December 2004, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards (SFAS) No. 123 (revised 2004), Share-Based Payment (SFAS 123R), which revises Accounting for Stock-Based Compensation, (SFAS 123) and supersedes Accounting Principles Board (APB) Opinion No. 25, Accounting for Stock Issued to Employees, (APB 25), which provided for the use of the intrinsic value method of accounting for employees stock options. SFAS 123R required all share-based payments to employees, including grants of employee stock options, to be recognized in the financial statements based on their fair values beginning with the first quarter of the first annual reporting period that began after June 15, 2005. Under SFAS 123R, the use of the intrinsic value method and pro forma disclosures previously permitted under SFAS 123 are no longer an alternative to financial statement recognition.

The Company adopted the provisions of SFAS 123R effective August 1, 2005 and selected the Black-Scholes method of valuation for share-based compensation. The Company adopted the modified prospective transition method which does not require restatement of prior periods. Instead, it requires that compensation cost be recorded as earned for all unvested stock options outstanding at the beginning of the first quarter of adoption of SFAS 123R. The charge is being recognized in research and development and consulting, selling, general and administrative expenses over the remaining service period after the adoption date based on the original estimate of fair value of the options as of the grant date. Prior to the adoption of SFAS 123R, the Company applied the intrinsic-value-based method of accounting prescribed by APB 25 and related interpretations, to account for its stock options granted to employees. Under this method, compensation cost was recorded only if the market price of the underlying common stock on the date of grant exceeded the exercise price. SFAS 123 established accounting and disclosure requirements using a fair-value-based method of accounting for share-based employee compensation plans. As permitted by SFAS 123, the Company elected to continue to apply the intrinsic-value-based method of accounting described above, and adopted only the disclosure requirements of SFAS 123, as amended. For the fiscal year ended July 31, 2006, the Company recorded share-based compensation of approximately \$1,201,000 or \$0.03 per share. The Company will continue to incur share-based compensation charges in future periods. As of July 31, 2006, unamortized stock-based compensation expenses of approximately \$2.4 million remain to be recognized over a weighted-average period of 2.2 years.

As a result of cashless exercise provisions in our employee stock option agreements, the Company used variable accounting treatment under the Financial Accounting Standards Board's Interpretation 44, for issued and outstanding stock options from January 2002 through July 2005. On October 20, 2004, the Company's Board of Directors rescinded the cashless exercise provision for all of its outstanding option grants. Through July 31, 2005, variable plan accounting continued to be applied for approximately 310,000 outstanding options, for which option exercise prices were modified from the original agreement.

Edgar Filing: NOVADEL PHARMA INC - Form 10-K

The following table illustrates the pro forma effect on the Company's net loss and net loss per share as if the Company had adopted the fair-value-based method of accounting for share-based compensation under SFAS 123 for the fiscal years ended July 31, 2005 and 2004:

	Fiscal Year Ended July 31,	
	2005	2004
Net loss as reported	\$(9,450,000)	\$(6,341,000)
Compensation credit resulting from variable plan accounting	(106,000)	(736,000)
Total share-based employee compensation expense using the fair value based method for all awards	(854,000)	(795,000)
Pro forma net loss	\$(10,410,000)	\$(7,872,000)
Basic and diluted net loss per common share:		
As reported	\$(0.27)	\$(0.24)
Pro forma net loss	(0.30)	(0.30)

The fair values of options granted during the fiscal years ended July 31, 2005 and 2004 were estimated at the date of grant using a Black-Scholes option pricing model with the following weighted-average assumptions, respectively: risk-free interest rates of 4.0%, dividend yield of 0.0%, volatility factors of the expected market price of the Company's common stock of 66% in 2005 and 56% in 2004, and an expected life of the options of five to ten years.

NOTE 4 - PROPERTY AND EQUIPMENT

Property and equipment are summarized as follows:

	July 31, 2006	July 31, 2005
Equipment	\$ 2,215,000	\$ 1,912,000
Furniture and fixtures	455,000	455,000
Leasehold improvements	1,472,000	1,479,000
	4,142,000	3,846,000
Less: Accumulated depreciation and amortization	1,438,000	855,000
	\$ 2,704,000	\$ 2,991,000

The Company had total fixed assets of \$570,000 and inventories of \$585,000 at the facilities of INyX as of July 31, 2006. Such assets are the property of the Company and cannot be used by INyX for any other business. In the event that the Company's contract with INyX is terminated for any reason, such assets are to be returned to the Company. As of July 31, 2006, the Company had total gross fixed assets of \$166,000, with an accumulated depreciation of \$8,000, recorded under a capital lease.

NOTE 5 - RELATED PARTY TRANSACTIONS

PLACEMENT AGENT AGREEMENTS (see Note 6) In January 2004, May 2005 and April 2006, the Company completed private placements for which it utilized Paramount BioCapital, Inc., or Paramount, as its placement agent or co-placement agent. Paramount and its affiliates are beneficial owners of a significant amount of shares of common stock and options and warrants for the purchase of shares of common stock of the Company and, accordingly, Paramount is a related party to the Company.

LEGAL FEES - The Company has incurred legal fees charged by a former officer and director of the Company. These fees approximated \$0, \$1,000 and \$195,000 for the years ended July 31, 2006, 2005 and 2004, respectively.

CONSULTING AGREEMENTS - Mr. John H. Klein, the former Chairman of the Company's Board of Directors, consulting agreement ceased on January 31, 2004. The Company paid Mr. Klein approximately \$0, \$1,000 and \$186,000, pursuant to its consulting agreement with Mr. Klein (including finder fees relating to the Company's licensing agreements) for the years ended July 31, 2006, 2005 and 2004, respectively. The amount of the fees is determined according to the net revenue received by the Company in connection with the Par Pharmaceutical agreement.

In November 2005, the Company entered into a Confidential Separation Agreement and General Release (the Separation Agreement) and a Consulting Agreement (the Consulting Agreement) with Gary Shangold, M.D. Dr. Shangold is the former President and Chief Executive Officer of the Company. For the fiscal year ended July 31, 2006, pursuant to the Separation Agreement, the Company paid Dr. Shangold a separation payment of \$150,000. For the fiscal year ended July 31, 2006, pursuant to the Consulting Agreement, the Company paid Dr. Shangold \$175,000. As of July 31, 2006, the Company is obligated to pay Dr. Shangold approximately \$125,000 pursuant to the Consulting Agreement, all of which will be paid in fiscal 2007.

LICENSE AND DEVELOPMENT AGREEMENTS WITH RELATED PARTIES - In April 2003, the Company entered into a license and development agreement with Manhattan Pharmaceuticals for the worldwide, exclusive rights to the Company's proprietary oral spray technology to deliver propofol for pre-procedural sedation.

In June 2004, the Company entered into a 20-year worldwide exclusive license agreement with Velcera, a veterinary company. The license agreement is for the exclusive rights to the Company's proprietary oral spray technology in animals.

In October 2004, the Company entered into a license and development agreement (as amended in August 2005) with Hana to develop and market the Company's oral spray version of ondansetron. The agreement is an exclusive license for the U.S. and Canada.

Lindsay A. Rosenwald, M.D., a significant stockholder of the Company, may be deemed to be an affiliate of the Company, Manhattan Pharmaceuticals, Velcera, and Hana Biosciences. Companies affiliated with Dr. Rosenwald have provided financial and other services unrelated to the Company's agreements with the parties to such agreements from time to time.

NOTE 6 - STOCKHOLDERS' EQUITY

Edgar Filing: NOVADEL PHARMA INC - Form 10-K

PRIVATE PLACEMENTS - In April 2006, the Company closed a private placement of 8,092,796 shares of common stock, and warrants to purchase a total of 2,427,839 shares of common stock with an exercise price of \$1.60 per share of common stock. The Company received proceeds, net of offering costs, of approximately \$10,593,000. Griffin Securities, Inc. and Paramount, a NASD broker-dealer, acted as the Placement Agents for this private placement. The Placement Agents were paid an aggregate fee for acting as placement agents of cash equal to 7% of the gross proceeds from the sale of the common stock, or \$792,400, and warrants equal to 6% of the shares of common stock purchased, subject to certain exclusions, or warrants to purchase 468,329 shares of common stock. Such warrants have the same terms as those issued to the investors. The Placement Agents were also entitled to a non-accountable expense allowance of up to \$55,000 as reimbursement for out of pocket expenses incurred in connection with the offering. The Company agreed to indemnify the Placement Agents against certain liabilities, including liabilities under the Securities Act of 1933, incurred in connection with the offering.

F-10

Edgar Filing: NOVADEL PHARMA INC - Form 10-K

In May 2005, the Company closed a private placement of 6,733,024 shares of common stock and Class D warrants to purchase a total of 2,356,559 shares of common stock, with an initial exercise price equal to \$1.30 per share of common stock, subject to adjustment. The Company received net proceeds of approximately \$6,309,000 from the Offering. The financing was led by ProQuest Investments and included Caisse de dépôt et placement du Québec and others. In connection with the private placement, the Company paid a cash commission equal to 7% of the gross proceeds from the private placement, or approximately \$495,000, to Paramount, who acted as its placement agent, and issued to Paramount a warrant to purchase 336,651 shares of common stock (the Placement Warrant). The Placement Warrant is exercisable at an initial exercise price equal to \$1.30 per share (subject to adjustment). Paramount was also entitled to a non-accountable expense allowance of up to \$50,000 to reimburse it for out-of-pocket expenses incurred in connection with the private placement. The Company agreed to indemnify Paramount against certain liabilities, including liabilities under the Securities Act of 1933, incurred in connection with the Offering.

In January 2004, the Company completed a private placement and received net proceeds of \$12,785,000 from the sale of a total of 140 units of the Company's securities. Each unit consisted of 95,238 common shares, and 28,571 warrants. Each warrant entitles the holder to purchase an additional share of the Company's common stock at an exercise price of \$1.40 per share through January 2009. The sale price of each unit was \$100,000. A total of 13,333,333 shares and approximately 4,000,000 warrants were issued. The securities were sold through Paramount. For its services as placement agent, the Company paid Paramount a commission of 7% of the aggregate amount raised, or approximately \$1,000,000, and also issued to Paramount (and its designees) unit purchase options to purchase 1,330,303 shares of common stock at an exercise price of \$1.40 per share and warrants to purchase an additional 399,091 shares of common stock at an exercise price of \$1.40 per share. The Company also paid Paramount a non-accountable expense allowance of \$25,000 to reimburse Paramount for its out-of-pocket expenses.

The Company has entered into registration rights agreements with certain holders of our common stock that require us to continuously maintain an effective registration statement covering the underlying shares of common stock. Such registration statements have been declared effective and must continuously remain effective for a specified term. If we fail to continuously maintain such registration statements as effective throughout the specified terms, the Company may be subject to liability to pay liquidated damages.

PREFERRED STOCK - The Company's Certificate of Incorporation authorizes the issuance of up to 1,000,000 shares of Preferred Stock. None of the Preferred Stock has been designated or issued through July 31, 2006. The Board is authorized to issue shares of Preferred Stock from time to time in one or more series and to establish and designate any such series and to fix the number of shares and the relative conversion and voting rights, and terms of redemption and liquidation.

NOTE 7 - COMMITMENTS AND CONTINGENCIES

EMPLOYMENT AGREEMENTS - At July 31, 2006, the Company had employment agreements with three officers of the Company providing for an aggregate salary of \$765,000 in fiscal 2007 and \$160,000 in fiscal 2008, excluding potential Company matching contributions to the officers' 401(k) plan. The remaining terms of the officers' employment agreements are outlined below. Generally in the event an officer is terminated prior to the end of such agreement, the officer is entitled to severance payments equal to the officer's salary for the shorter of six months or the remaining term of the officer's employment agreement.

The employment agreements with the Company's officers are due to expire on the following schedule: Dr. Egberts' agreement in September 2007, Mr. Spicer's agreement in December 2007, and Mr. Cohen's agreement expired in May 2006. The employment agreement of Mr. Cohen automatically extends for additional one-year periods unless either party to the agreement advises the other to the contrary in writing at least 90 days prior to the expiration of the term.

All of the foregoing employment agreements provide for the potential issuance of bonuses based on certain factors. Such agreements also provide for the grant of options to purchase shares of the Company's common stock, vesting ratably over the term of the agreement.

F-11

Edgar Filing: NOVADEL PHARMA INC - Form 10-K

LICENSE AND DEVELOPMENT AGREEMENTS - In April 2003, the Company entered into a license and development agreement with Manhattan Pharmaceuticals for the worldwide, exclusive rights to the Company's proprietary oral spray technology to deliver propofol for pre-procedural sedation. The terms of the agreement call for certain milestone and other payments, the first \$125,000 of which was partially received during June 2003. In November 2003, the Company received \$375,000 from Manhattan Pharmaceuticals for license fees. The Company has included these license fees in deferred revenue and is recognizing these license fees over the 20-year term of the license. During the years ended July 31, 2006, 2005 and 2004, the Company invoiced Manhattan Pharmaceuticals approximately \$0, \$65,000 and \$400,000, respectively, for the Company's reimbursable expenses.

In June 2004, the Company entered into a 20-year worldwide exclusive license agreement with Velcera, a veterinary company. The license agreement is for the exclusive rights to the Company's proprietary oral spray technology in animals. In September 2004, the Company received \$1,500,000 from Velcera as an upfront payment in connection with the commercialization agreement. The upfront payment has been included in deferred revenue and will be recognized in income over the 20-year term of the agreement. In addition, the Company received an equity stake of 529,500 shares of common stock, approximately 15% at the time the shares were issued, in Velcera which did not have a material value. The Company may receive additional milestone payments and royalty payments over the 20-year term of the agreement. During the years ended July 31, 2006, 2005 and 2004, the Company invoiced Velcera approximately \$228,000, \$183,000, and \$0, respectively, for reimbursable expenses. Additionally, during the year ended July 31, 2005, the Company invoiced Velcera \$50,000 for a contractual milestone that was reached.

In July 2004, the Company entered into a licensing agreement with Par for the exclusive right to market, sell and distribute nitroglycerin lingual spray in the U.S. and Canada. The Company has received \$250,000 in upfront and milestone payments and may receive additional fees and royalty payments over the 10-year term of the license. The upfront payment has been included in deferred revenue and will be recognized in income over the 10-year term of the agreement.

In October 2004, the Company entered into a license and development agreement pursuant to which the Company granted to Hana Biosciences an exclusive license to develop and market the Company's oral spray version of ondansetron in the U.S. and Canada. Pursuant to the terms of the agreement, in exchange for \$1,000,000, Hana Biosciences purchased 400,000 shares of the Company's common stock at a per share price equal to \$2.50, a premium of \$.91 per share or \$364,000 over the then market value of the Company's common stock. The Company accounted for this premium as deferred revenue related to the license. In connection with the agreement, Hana Biosciences issued to the Company \$500,000 worth of common stock of Hana Biosciences (73,121 shares based on a market value of \$6.84 per share). The proceeds received from Hana Biosciences attributable to the premium are included in deferred revenue and are being recognized over the 20-year term of the agreement. The Company may receive additional license fees and royalties over the 20-year term of the agreement. During the years ended July 31, 2006, 2005, and 2004, the Company invoiced Hana Biosciences approximately \$13,000, \$84,000, and \$0, respectively, for pass-through expenses incurred by the Company on behalf of Hana Biosciences. In the fiscal year ended July 31, 2006, the Company received \$1,500,000 in milestone payments from Hana Biosciences.

On November 18, 2004, the Company entered into a manufacturing and supply agreement with INyX whereby INyX manufactures and supplies the Company's nitroglycerin lingual spray. For a five-year period that began November 18, 2004, INyX is the exclusive provider of the nitroglycerin lingual spray to the Company substantially worldwide. Pursuant to the terms and conditions of the agreement, it will be INyX's responsibility to manufacture, package and supply the nitroglycerin lingual spray in such territories. Thereafter, INyX will have a non-exclusive right to manufacture such spray for an additional five years.

CAPITAL LEASE OBLIGATIONS As of July 31, 2006, the Company has aggregate capital lease obligations of \$147,000 of which \$82,000 and \$65,000 are scheduled to be paid in fiscal 2007 and 2008, respectively.

OPERATING LEASES - In March 2003, the Company entered into a 10-year lease for office, laboratory, manufacturing and warehouse space. During the first five years of the lease, the annual rent is approximately \$332,000 plus a proportionate share of real estate taxes and common areas. Beginning in the sixth year and continuing through the tenth year of the lease, the annual rent will be approximately \$365,000 plus a proportionate share of real estate taxes and common areas. Through December 31, 2005, the Company occupied office and laboratory space at a

second location. During the fiscal years ended July 31, 2006, 2005 and 2004, the Company paid rent of approximately \$495,000, \$521,000, and 477,000, respectively.

F-12

Edgar Filing: NOVADEL PHARMA INC - Form 10-K

Future minimum rental payments subsequent to July 31, 2006 are as follows:

Years Ending July 31,

2007	\$332,000
2008	\$332,000
2009	\$363,000
2010	\$366,000
2011	\$366,000
Thereafter	\$761,000
	\$2,520,000

NOTE 8 INVESTMENT IN EQUITY SECURITY

As explained in Note 7, in October 2004, as part of the license agreement with Hana Biosciences, the Company received \$500,000 of common stock of Hana Biosciences (73,121 shares based on a market value of \$6.84 per share at the date of the agreement). As a result of restrictions on its ability to sell the shares, the Company was required by SFAS No. 115, Accounting for Certain Investments in Debt and Equity Securities, to account for those shares using the cost method through October 2005 and thereafter as marketable equity securities. At July 31, 2006, the Company has classified the shares as available for sale and is recording changes in their value as part of its comprehensive income. Such shares had a market value of \$560,000 at July 31, 2006 and, accordingly, the Company has included its \$60,000 unrealized gain in accumulated comprehensive income, a separate component of stockholders' equity, as of July 31, 2006.

NOTE 9 ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES

Accrued expenses and other current liabilities are comprised of the following at July 31, 2006 and 2005:

	2006	2005
Accrued compensation	\$ 396,000	\$ 383,000
Professional fees	70,000	244,000
Accrued milestone payments	312,000	312,000
Product development costs	112,000	
Insurance premiums	127,000	
Property and equipment		70,000
Other	94,000	55,000
	\$ 1,111,000	\$ 1,064,000

NOTE 10 - INCOME TAXES

The significant components of the Company's net deferred tax asset are summarized as follows:

	July 31 2006	2005
Stock options	\$ 397,000	\$
Net operating loss carryforwards	14,511,000	10,671,000
Deferred revenue	1,070,000	1,196,000
Property and equipment	(157,000)	(36,000)
Other	49,000	21,000
Total gross deferred tax assets	15,870,000	11,852,000
Valuation allowance	(15,870,000)	(11,852,000)
Net deferred tax assets	\$	\$

At July 31, 2006, the Company had federal and state net operating loss carryforwards for financial reporting and income tax purposes of approximately \$38.3 million and \$25.2 million, respectively, which can be used to offset current and future federal and state taxable income, if any, through 2026 and 2013, respectively. A valuation allowance is provided when it is more likely than not that some portion or all of the deferred tax assets will not be realized. The Company has provided valuation allowances to offset its deferred tax assets due to the significant uncertainties related to its ability to generate future taxable income. The net increases in the total valuation allowance for fiscal 2006, 2005 and 2004 were \$4.0 million, \$3.8 million and \$2.7 million, respectively.

The tax benefits expected based on the Company's pre-tax loss in fiscal 2006, 2005 and 2004, utilizing the applicable statutory rates, have been reduced to an actual benefit of \$256,000, \$241,000 and \$214,000, respectively, due principally to the aforementioned increases in the valuation allowance. The benefit recognized in such fiscal years relates solely to the sale of certain of the Company's state net operating loss carryforwards.

The following is a reconciliation of the income tax benefit computed at the statutory rate to the provision for income taxes:

	Year Ended July 31,		
	2006	2005	2004
Federal tax at statutory rate	(34.0%)	(34.0%)	(34.0%)
State income tax	(6.0%)	(6.0%)	(6.0%)
Other		0.3%	(4.5%)
Sale of net operating losses	(2.5%)	(2.5%)	(3.3%)
Increase in valuation allowance	40.0%	39.7%	44.5%
	(2.5%)	(2.5%)	(3.3%)

The Tax Reform Act of 1986 (the Act) provides for a limitation on the annual use of NOL carryforwards (following certain ownership changes, as defined by the Act) which could significantly limit the Company's ability to utilize these carryforwards. The Company may have experienced various ownership changes, as defined by the Act, as a result of past financings and may experience others in connection with future financings. Accordingly, the Company's ability to utilize the aforementioned federal operating loss carryforwards will be limited. The Company is in the

Edgar Filing: NOVADEL PHARMA INC - Form 10-K

process of determining if ownership changes, as defined by the Act, have occurred. Additionally, because U.S. tax laws limit the time during which these carryforwards may be applied against future taxes, the Company may not be able to take full advantage of these attributes for federal income tax purposes.

F-14

Edgar Filing: NOVADEL PHARMA INC - Form 10-K

SALE OF NET OPERATING LOSS CARRYFORWARDS: The State of New Jersey has enacted legislation permitting certain corporations located in New Jersey to sell state tax loss carryforwards and state research and development credits, or net operating loss carryforwards, in order to obtain tax benefits. The Company recorded an income tax benefit of \$256,000, \$241,000 and \$214,000 for the fiscal years ended July 31, 2006, 2005, and 2004, respectively, from the sale of its New Jersey net operating loss carryforwards. If still available under New Jersey law, the Company may attempt to sell its remaining New Jersey net operating loss carryforwards of \$25.2 million as of July 31, 2006. The Company cannot estimate, however, what percentage of its saleable net operating loss carryforwards New Jersey will permit it to sell, how much money will be received in connection with the sale, if the Company will be able to find a buyer for its net operating loss carryforwards or if such funds will be available in a timely manner.

NOTE 11 - STOCK OPTIONS AND WARRANTS

At July 31, 2006, the Company had two plans which allow for the issuance of stock options and other awards: the 1998 Stock Option Plan and the 2006 Equity Incentive Plan (the Plans). On January 17, 2006, the stockholders of the Company, upon recommendation of the Board of Directors of the Company, approved the NovaDel Pharma Inc. 2006 Equity Incentive Plan (the 2006 Plan). The 2006 Plan authorizes the grant of several types of stock-based awards, including stock options, stock appreciation rights and stock (including restricted stock). The amount of shares of common stock originally reserved for issuance under the 2006 Plan was 6 million shares. These Plans are administered by the Compensation Committee of the Board of Directors. Incentive Stock Options (ISOs) may be granted to employees and officers of the Company and non-qualified options may be granted to consultants, directors, employees and officers of the Company. Options to purchase the Company's common stock may not be granted at a price less than the fair market value of the common stock at the date of grant and will expire not more than 10 years from the date of grant, and vesting is determined by the Compensation Committee of the Board of Directors. ISOs granted to a 10% or more stockholder may not be for less than 110% of fair market value or for a term of more than five years. As of July 31, 2006, there was approximately 6.0 million shares available for issuance under the Plans.

Information with respect to stock option activity for the fiscal year ended July 31, 2006 is as follows:

Options	Shares (000)	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Terms (Years)	Aggregate Intrinsic Value (\$000)
Outstanding at August 1, 2005	6,474	\$ 1.64		\$
Grants	3,280	1.58		
Exercises	(360)	.75		
Cancellations	(1,217)	1.66		
Outstanding at July 31, 2006	8,177	\$ 1.65	4.4	\$ 492
Exercisable at July 31, 2006	4,710	\$ 1.69	3.3	\$ 492

Edgar Filing: NOVADEL PHARMA INC - Form 10-K

In the fiscal year ended July 31, 2006, the Company recorded share-based compensation for options using the fair value method required by FAS 123R of approximately \$1,201,000, or \$0.03 per share, respectively, which is included in the Company's net loss for each period. As of July 31, 2006, unamortized stock-based compensation expenses of approximately \$2.4 million remain to be recognized over a weighted-average period of 2.2 years. For grants during the fiscal year ended July 31, 2006, the Company used the following weighted average assumptions in determining fair value under the Black-Scholes model: expected volatility of 64%; dividend yield of 0%; expected term until exercise of 4.5 years; and risk-free interest rate of 4.3%. Expected volatility is based on historical volatility of the Company's common stock. The expected term of options is estimated based on the average of the vesting period and contractual term of the option. The risk-free rate is based on U.S. Treasury yields for securities in effect at the time of grant with terms approximating the expected term until exercise of the option. In addition, under SFAS 123R, the fair value of stock options granted is recognized as expense over the service period, net of estimated forfeitures. The Company is utilizing a 5% forfeiture rate, which it believes is a reasonable assumption to estimate forfeitures. However, the estimation of forfeitures requires significant judgment, and to the extent actual results or updated estimates differ from our current estimates, such resulting adjustment will be recorded in the period estimates are revised. The weighted average grant date fair value of options granted during the fiscal year ended July 31, 2006 was \$0.86. The total intrinsic value of options exercised during the fiscal year ended July 31, 2006 was approximately \$261,000.

At July 31, 2006, there were 4,863,000 non-plan options reserved for issuance.

The following table summarizes information related to warrants outstanding at July 31, 2006:

Price Range	Number of Warrants Outstanding and Exercisable 000's	Remaining Contractual Life (Years)
\$0.01 - 0.99	10,267	1.8
\$1.00 - 1.99	11,391	3.4
\$2.00	900	1.6
Totals	22,558	

NOTE 12 THREATENED LITIGATION

Lawrence J. Kessel, a former director who was not nominated by the Corporate Governance and Nominating Committee of the Board of Directors to stand for re-election to the Board of Directors in January 2006, had alleged that in order to induce him not to stand for re-election to the Board of Directors, the Company promised to pay him compensation as a director and compensate him for options he lost by virtue of the end of his tenure on the Board of Directors. The Company denied these allegations. In June 2006, the Company and Dr. Kessel agreed that Dr. Kessel would not pursue the matter.

NOTE 13 VALUATION AND QUALIFYING ACCOUNTS

Accounts	Balance Beginning of Year	Additions		Balance End of Year
		Charged to Cost and Expense	Charged to Other Accounts	
Year ended July 31, 2006				
Allowance for doubtful accounts	\$ 54,000	\$	\$	\$54,000
Deferred tax valuation allowance	11,852,000	4,018,000		15,870,000
Allowance for inventory obsolescence		55,000		55,000
Year ended July 31, 2005				
Allowance for doubtful accounts		54,000		54,000
Deferred tax valuation allowance	8,001,000	3,851,000		11,852,000
Year ended July 31, 2004				
Deferred tax valuation allowance	5,300,000	2,701,000		8,001,000

NOTE 14 QUARTERLY RESULTS OF OPERATIONS (UNAUDITED)

Unaudited quarterly financial data for the years ended July 31, 2006 and 2005 follows:

Three Months Ended

	October 31, 2005	January 31, 2006	April 30, 2006	July 31, 2006	Fiscal Year Ended July 31, 2006
Total Revenues	\$ 150,000	\$541,000	\$ 1,159,000	\$ 40,000	\$1,890,000
Total Expenses	2,768,000	3,658,000	3,307,000	2,721,000	12,454,000
Loss from Operations	(2,618,000)	(3,117,000)	(2,148,000)	(2,681,000)	(10,564,000)
Interest Income	43,000	30,000	19,000	132,000	224,000
Income Tax Benefit		256,000			256,000
Net Loss	\$ (2,575,000)	\$(2,831,000)	\$ (2,129,000)	\$(2,549,000)	\$(10,084,000)
Basic and Diluted Loss Per Common Share	\$ (0.06)	\$(0.07)	\$ (0.05)	\$(0.05)	\$(0.23)
Weighted Average Number of Shares of Common Stock Used in Computation of Basic and Diluted Loss Per Share	40,606,000	40,648,000	41,715,000	48,991,000	43,000,000

Edgar Filing: NOVADEL PHARMA INC - Form 10-K

Three Months Ended

	October 31, 2004	January 31, 2005	April 30, 2005	July 31, 2005	Fiscal Year Ended July 31, 2005
Total Revenues	\$ 118,000	\$ 124,000	\$ 102,000	\$ 95,000	\$ 439,000
Total Expenses	2,396,000	2,928,000	2,758,000	2,135,000	10,217,000
Loss from Operations	(2,278,000)	(2,804,000)	(2,656,000)	(2,040,000)	(9,778,000)
Interest Income	22,000	13,000	14,000	38,000	87,000
Income Tax Benefit		241,000			241,000
Net Loss	\$ (2,256,000)	\$(2,550,000)	\$ (2,642,000)	\$(2,002,000)	\$(9,450,000)
Basic and Diluted Loss Per Common Share	\$ (0.07)	\$(0.08)	\$ (0.08)	\$(0.05)	\$(0.27)
Weighted Average Number of Shares of Common Stock Used in Computation of Basic and Diluted Loss Per Share	33,100,000	33,596,000	33,834,000	38,671,000	34,808,000

The sum of the quarters may not equal the full year basic and diluted loss per share since each period is calculated separately.

Edgar Filing: NOVADEL PHARMA INC - Form 10-K

INDEX TO EXHIBITS

The following exhibits are included with this Annual Report. All management contracts or compensatory plans or arrangements are marked with an asterisk.

EXHIBIT NO.	DESCRIPTION	METHOD OF FILING
3.1	Restated Certificate of Incorporation of the Company	Incorporated by reference to Exhibit 3.1 of the Company's Quarterly Report on Form 10-QSB, as filed with the SEC on June 14, 2004
3.2	Amended and Restated By-laws of the Company	Incorporated by reference to Exhibit 3.1 of the Company's Form 8-K, as filed with the SEC on September 9, 2005
4.1	Form of Class C Warrant for the Purchase of Shares of Common Stock	Incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K, as filed with the SEC on January 12, 2004
4.2	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 April 17, 2006
10.1*	1992 Stock Option Plan	Incorporated by reference to the Company's Registration Statement on Form SB-2, as filed with the SEC on August 8, 1997 (File No. 333-33201)
10.2*	Form of Incentive Stock Option Agreement under the 1992 Stock Option Plan	Incorporated by reference to the Company's Registration Statement on Form SB-2, as filed with the SEC on August 8, 1997 (File No. 333-33201)
10.3*	1997 Stock Option Plan	Incorporated by reference to Exhibit 10.8 to the Company's Registration Statement on Form SB-2, as filed with the SEC on August 8, 1997 (File No. 333-33201)
10.4*	Form of Non-Qualified Option Agreement under the 1997 Stock Option Plan	Incorporated by reference to the Company's Registration Statement on Form SB-2, as filed with the SEC on August 8, 1997 (File No. 333-33201)
10.5*	1998 Stock Option Plan	Incorporated by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-8, as filed with the SEC on June 18, 2004 (File No. 333-116665)
10.6*	Form of Stock Option Agreement under the 1998 Stock Option Plan	Incorporated by reference to Exhibit 4.2 to the Company's Registration Statement on Form S-8, as filed with the SEC on June 18, 2004 (File No. 333-116665)
10.7*	Form of Non-Qualified Stock Option Agreement	Incorporated by reference to Exhibit 4.3 to the Company's Registration Statement on Form S-8, as filed with the SEC on June 18, 2004 (File No. 333-116665)
10.8	Common Stock and Warrant Purchase Agreement, dated December 12, 2001, by and among the Company and certain purchasers	Incorporated by reference to Exhibit A to the Schedule 13D as filed by Lindsay A. Rosenwald with the SEC on December 21, 2001

Edgar Filing: NOVADEL PHARMA INC - Form 10-K

10.9

Amendment No. 1, dated January 6, 2002, to the Common Stock and Warrant Purchase Agreement dated December 12, 2001 between the Company and certain purchasers

Incorporated by reference to Exhibit 10.25 to the Company's Registration Statement of Form SB-2, as filed with the SEC on April 15, 2002 (File No. 333-86262)

Edgar Filing: NOVADEL PHARMA INC - Form 10-K

10.10	Lease Agreement, dated March 19, 2003, by and between the Company and Macedo Business Park, II, L.L.C.	Incorporated by reference to Exhibit 10.28 to the Company's Quarterly Report on Form 10-QSB for the period ended April 30, 2003, as filed with the SEC on June 19, 2003
10.11	Amendment Number 1 to Lease Agreement dated March 19, 2003 between Macedo Business Park, II, L.L.C. and the Company, dated as of March 19, 2003	Incorporated by reference to Exhibit 10.29 to the Company's Quarterly Report on Form 10-QSB for the period ended April 30, 2003, as filed with the SEC on June 19, 2003
10.12	License and Development Agreement, effective as of April 4, 2003, by and between the Company and Manhattan Pharmaceuticals, Inc.	Incorporated by reference to Exhibit 10.31 to the Amendment No. 1 to the Company's Annual Report on Form 10-KSB, as filed with the SEC on March 11, 2004
10.13	Development, Manufacturing and Supply Agreement, dated July 28, 2004, by and between the Company and Par Pharmaceutical, Inc.	Incorporated by reference to Exhibit 10.13 to the Company's Annual Report on Form 10-KSB, as filed with the SEC on November 15, 2004
10.14	Second Amendment to License and Development Agreement, dated as of June 22, 2004, by and between the Company and the Veterinary Company, Inc.	Incorporated by reference to Exhibit 10.14 to the Company's Annual Report on Form 10-KSB, as filed with the SEC on November 15, 2004
10.15*	Employment Agreement, dated as of May 23, 2003, by and between the Company and Barry Cohen	Incorporated by reference to Exhibit 10.30 to the Company's Quarterly Report on Form 10-QSB for the period ending April 30, 2003, as filed with the SEC on June 19, 2003
10.16*	Disclosure and Release Agreement Related to the Exchange of Non-Plan Options for Stock Options under the NovaDel Pharma Inc. 1998 Stock Option Plan by and between the Company and Thomas E. Bonney	Incorporated by reference to Exhibit 10.3 of the Company's Form 8-K, as filed with the SEC on August 2, 2005
10.17*	Disclosure and Release Agreement Related to the Exchange of Non-Plan Options for Stock Options under the NovaDel Pharma Inc. 1998 Stock Option Plan by and between the Company and William F. Hamilton	Incorporated by reference to Exhibit 10.2 of the Company's Form 8-K, as filed with the SEC on August 2, 2005
10.18*	Disclosure and Release Agreement Related to the Exchange of Non-Plan Options for Stock Options under the NovaDel Pharma Inc. 1998 Stock Option Plan by and between the Company and Charles Nemeroff	Incorporated by reference to Exhibit 10.4 of the Company's Form 8-K, as filed with the SEC on August 2, 2005
10.19*	Employment Agreement, dated as of December 20, 2004, by and between the Company and Michael Spicer	Incorporated by reference to Exhibit 10.35 of the Company's Form 8-K, as filed with the SEC on December 23, 2004
10.20*	Amendment to Employment Agreement dated September 2, 2005, by and between the Company and Michael E.B. Spicer	Incorporated by reference to Exhibit 10.2 of the Company's Form 8-K, as filed with the SEC on September 9, 2005
10.21*	1998 Stock Option Plan Nonqualified Stock Option Agreement dated July 28, 2005, by and between the Company and Thomas E. Bonney	Incorporated by reference to Exhibit 10.25 of the Company's Annual Report on Form 10-KSB for the period ended July 31, 2005, as filed with the SEC on October 31, 2005
10.22*	1998 Stock Option Plan Nonqualified Stock Option Agreement dated July 28, 2005, by and between the Company and William F. Hamilton	Incorporated by reference to Exhibit 10.27 to the Company's Annual Report on Form 10-KSB for the period ended July 31, 2005, as filed with the SEC on October 31, 2005

Edgar Filing: NOVADEL PHARMA INC - Form 10-K

10.23*	1998 Stock Option Plan Nonqualified Stock Option Agreement dated July 28, 2005, by and between the Company and Charles Nemeroff	Incorporated by reference to Exhibit 10.29 of the Company's Annual Report on Form 10-KSB for the period ended July 31, 2005, as filed with the SEC on October 31, 2005
10.24	Amendment No. 1 to License and Development Agreement dated as of August 8, 2005, by and between the Company and Hana Biosciences Inc.	Incorporated by reference to Exhibit 99.1 of the Company's Form 8-K, as filed with the SEC on August 12, 2005
10.25*	Employment Agreement, dated as of September 26, 2005, by and between the Company and Jan H. Egberts, M.D.	Incorporated by reference to Exhibit 10.1 of the Company's Form 8-K, as filed with the SEC on September 28, 2005
10.26*	Nonqualified Stock Option Agreement dated September 26, 2005, by and between the Company and Jan H. Egberts, M.D.	Incorporated by reference to Exhibit 10.2 of the Company's Form 8-K, as filed with the SEC on September 28, 2005
10.27	Confidential Separation Agreement and General Release dated November 29, 2005, by and between the Company and Gary Shangold, M.D.	Incorporated by reference to Exhibit 10.1 of the Company's Form 8-K, as filed with the SEC on December 2, 2005
10.28	Consulting Agreement dated November 29, 2005, by and between the Company and Gary Shangold, M.D.	Incorporated by reference to Exhibit 10.2 of the Company's Form 8-K, as filed with the SEC on December 2, 2005
10.29*	NovaDel Pharma Inc. 2006 Equity Incentive Plan	Incorporated by reference to Exhibit 10.1 of the Company's Form 8-K, as filed with the SEC on January 23, 2006
10.30*	1998 Stock Option Plan Nonqualified Stock Option Agreement dated January 17, 2006, by and between the Company and Thomas Bonney	Incorporated by reference to Exhibit 10.2 of the Company's Quarterly Report on Form 10-Q, as filed with the SEC on March 15, 2006
10.31*	1998 Stock Option Plan Nonqualified Stock Option Agreement dated January 17, 2006, by and between the Company and William Hamilton	Incorporated by reference to Exhibit 10.3 of the Company's Quarterly Report on Form 10-Q, as filed with the SEC on March 15, 2006
10.32*	1998 Stock Option Plan Nonqualified Stock Option Agreement dated December 14, 2005, by and between the Company and J. Jay Lobell	Incorporated by reference to Exhibit 10.4 of the Company's Quarterly Report on Form 10-Q, as filed with the SEC on March 15, 2006
10.33*	1998 Stock Option Plan Nonqualified Stock Option Agreement dated January 17, 2006, by and between the Company and Charles Nemeroff	Incorporated by reference to Exhibit 10.5 of the Company's Quarterly Report on Form 10-Q, as filed with the SEC on March 15, 2006
10.34*	1998 Stock Option Plan Nonqualified Stock Option Agreement dated January 17, 2006, by and between the Company and Steven Ratoff	Incorporated by reference to Exhibit 10.6 of the Company's Quarterly Report on Form 10-Q, as filed with the SEC on March 15, 2006
10.35	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 April 17, 2006
10.36	Registration Rights Agreement by and between the Company and certain accredited investors (with attached schedule of parties and terms thereto)	Incorporated by reference to Exhibit 10.2 of the Company's Form 8-K, as filed with the SEC on April 17, 2006
10.37	Placement Agent Agreement, dated March 15, 2006, by and between the Company, Griffin Securities, Inc. and Paramount BioCapital, Inc.	Incorporated by reference to Exhibit 10.1 of the Company's Form 8-K, as filed with the SEC on April 20, 2006

Edgar Filing: NOVADEL PHARMA INC - Form 10-K

21.1	Subsidiaries of the Registrant	The registrant has no subsidiaries
23.1	Consent of J.H. Cohn LLP	Filed herewith
31.1	Certification of Chief Executive Officer under Rule 13a-14(a)	Filed herewith

Edgar Filing: NOVADEL PHARMA INC - Form 10-K

31.2	Certification of Principal Financial Officer under Rules 13a-14(a)	Filed herewith
32.1	Certifications of the Chief Executive Officer and Chief Financial Officer under 18 USC 1350	Filed herewith