

NOVADEL PHARMA INC  
Form 10-K  
March 26, 2007  
**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 10-K**

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

OR

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

For the transition period from August 1, 2006 to December 31, 2006

*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.)

**25 MINNEAKONING ROAD, FLEMINGTON, NEW JERSEY 08822**

(Address of principal executive offices) (Zip Code)

Edgar Filing: NOVADEL PHARMA INC - Form 10-K

(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**

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 June 30, 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 \$62.8 million based upon the closing sale price of \$1.35 for the Registrant's common stock, \$.001 par value, as reported by the American Stock Exchange on that date. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of March 1, 2007, the issuer had 59,395,732 shares of common stock, \$.001 par value, outstanding.

### **DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the definitive proxy statement to be filed pursuant to Regulation 14A within 120 days of the end of the fiscal year (December 31, 2006) are incorporated by reference into Part III of this Transition Report on Form 10-K.

NOVADEL PHARMA INC.

TRANSITION REPORT ON FORM 10-K

FOR THE FIVE MONTHS ENDED DECEMBER 31, 2006

TABLE OF CONTENTS

|          |   |      |
|----------|---|------|
|          | PART I  | PAGE |
| Item 1.  | Business.   | 5    |
| Item 1A. | Risk Factors.   | 23   |
| Item 1B. | Unresolved Staff Comments.  | 43   |
| Item 2.  | Properties.   | 43   |
| Item 3.  | Legal Proceedings.  | 43   |
| Item 4.  | Submission of Matters to a Vote of Security Holders.  | 44   |
|          | PART II   |      |
| Item 5.  | Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities. | 45   |
| Item 6.  | Selected Consolidated Financial Data.   | 47   |
| Item 7.  | Management's Discussion and Analysis of Financial Conditions and Results of Operations.                       | 48   |
| Item 7A. | Quantitative and Qualitative Disclosures About Market Risk.   | 60   |
| Item 8.  | Financial Statements and Supplementary Data.  | 60   |
| Item 9.  | Changes In and Disagreements With Accountants on Accounting and Financial Disclosure.                         | 60   |
| Item 9A. | Controls and Procedures.  | 60   |
| Item 9B. | Other Information.  | 60   |
|          | PART III  |      |
| Item 10. | Directors, Executive Officers and Corporate Governance.   | 61   |
| Item 11. | Executive Compensation.   | 61   |
| Item 12. | Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.               | 61   |
| Item 13. | Certain Relationships and Related Transactions, and Director Independence.                                    | 61   |
| Item 14. | Principal Accountant Fees and Services.   | 62   |
|          | PART IV   |      |
| Item 15. | Exhibits, Financial Statement Schedules.  | 62   |
|          | Signatures  | 67   |



## 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 Transition 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 Transition 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 U.S. 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 Transition 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, referred to herein as we, us and our, is a specialty pharmaceutical company developing oral spray formulations of a broad range of marketed pharmaceuticals. Our oral spray therapeutics are administered by a novel application drug delivery system for presently marketed prescription, over-the-counter, or OTC, and veterinary drugs. This patented and patent-pending delivery system is an oral spray potentially enabling drug absorption through the oral mucosa, potentially increasing the benefits of clinically proven compounds, including more rapid absorption into the bloodstream than presently available oral delivery systems. Our proprietary delivery system potentially enhances and accelerates the onset of the therapeutic benefits within minutes of administration. Our development efforts for our proprietary novel drug delivery system are concentrated on making such system available for drugs that are already available and proven in the marketplace. We believe that our proprietary drug delivery system could offer the following significant advantages: (i) more rapid delivery of drugs to the bloodstream allowing for quicker onset of therapeutic effects compared to conventional oral dosage forms; (ii) increased bioavailability of a drug by avoiding metabolism by the liver; (iii) improved drug safety profile by reducing the required dosage, including possible reduction of side-effects; (iv) improved dosage reliability; (v) allowing medication to be taken without water; (vi) avoiding the need to swallow as is the case with many medications; and (vii) improved patient convenience and compliance. Currently, we have eight patents which have been issued in the U.S. and 54 patents which have been issued outside of the U.S. Additionally, we have over 80 patents pending around the world. We look for drug compounds that are off patent or are coming off patent in the near future, and we reformulate these compounds in conjunction with our proprietary drug delivery method. Once reformulated, we file for new patent applications on these reformulated compounds that comprise our product candidates. Our patent portfolio includes patents and patent applications with claims directed to the pharmaceutical formulations, methods of use and methods of manufacturing of a number of our product candidates.

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 product candidates 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 product candidates 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.

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. As such, we are filing this Transition Report on Form 10-K for the five months ended December 31, 2006.

Highlights for the five months ended December 31, 2006, and additionally through the date of filing of this Transition Report on Form 10-K, include the following product development and business achievements:

Announced positive study results of a pharmacokinetic study in humans of our oral spray formulation of sumatriptan, a study which demonstrated that sumatriptan oral spray achieves a statistically significant faster rate of absorption than Imitrex® (sumatriptan) tablets.

Edgar Filing: NOVADEL PHARMA INC - Form 10-K

Announced positive study results of a pharmacokinetic study in humans of our oral spray formulation of zolpidem, a study which demonstrated that zolpidem oral spray achieves a statistically significant faster rate of absorption than Ambien® (zolpidem) tablets.

Announced the submission of a NDA for Zensana by NovaDel's partner, Hana Biosciences, Inc., or Hana Biosciences, and the subsequent acceptance of such NDA by the U.S. Food and Drug Administration, or FDA.

5

---



## Edgar Filing: NOVADEL PHARMA INC - Form 10-K

Announced that Hana Biosciences has notified us that ongoing scale-up and stability experiments indicate that there is a need to make adjustments to the formulation and/or manufacturing process, and that there will be a delay in the FDA approval and commercial launch of Zensana™.

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.

Issued two additional patents in Canada which 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, and for central nervous system disorders under our oral spray delivery system.

Completed a private placement in December 2006 of our common stock, raising gross proceeds of approximately \$14.2 million.

Appointed Mr. Steven B. Ratoff as Chairman of the Board with Dr. Egberts remaining a member of the Board of Directors.

Appointed David H. Bergstrom, Ph.D. as Chief Operating Officer.

Appointed Deni M. Zodda, Ph.D. as Chief Business Officer.

Appointed Mr. Mark J. Baric as a member of the Board of Directors.

Announced that Mr. Barry C. Cohen will no longer serve as Vice President, Business and New Product Development.

### 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 a New Drug Application, or NDA, which includes complete reports of pre-clinical, clinical and laboratory studies to prove such product's safety and efficacy. 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. 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 NDA submission, 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.



## Edgar Filing: NOVADEL PHARMA INC - Form 10-K

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

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

results of future clinical trials;

the expense of clinical trials for additional indications;

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

the expense and timing of regulatory approvals;

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

the effect of competing technologies and market developments; and

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

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

NitroMist (nitroglycerin lingual aerosol). This product candidate is 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 did not require any additional clinical studies for approval, but 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. On November 3, 2006, we announced that we received an approval letter from the FDA regarding our NDA for NitroMist for which we received a milestone payment from Par. We are currently working with Par to finalize the commercialization strategy for this product. We will receive royalty payments based upon a percentage of net sales.

Zolpidem oral spray. Zolpidem is the active ingredient in Ambien®, the leading sleep-inducing agent marketed by Sanofi-Aventis. A pilot pharmacokinetic, or PK, study in zolpidem oral spray with 10 healthy subjects, completed in the first half of calendar 2005, suggested that our formulation of zolpidem oral spray had a comparable PK profile to the Ambien® tablet but with a more rapid time to detectable drug levels. In October 2006, we announced positive results from a pilot pharmacokinetic study comparing our formulation of Zolpidem Oral Spray to Ambien® tablets. In the study, 10 healthy male volunteers received Zolpidem Oral Spray or Ambien® tablets in 5mg or 10mg doses. For fasting subjects, fifteen minutes after dosing, 80% of subjects using Zolpidem Oral Spray achieved blood concentrations of greater than 20 ng/ml, compared to 33% of subjects in the 5mg Ambien® tablet group and 40% of subjects in the 10mg Ambien® tablet group. The difference between the oral spray groups and tablet groups was statistically significant (p=0.016). Twenty ng/ml is a level generally believed to approximate the lower limit of the therapeutic range for zolpidem. Additionally, drug concentrations were measured at five and ten minutes post-dosing. At these early time points, the oral spray groups achieved drug levels five-to-thirty times greater than subjects in the corresponding tablet groups. These differences were also statistically significant. 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 plasma concentrations of sumatriptan in the therapeutic range. In September 2006 we announced positive results from an additional pilot pharmacokinetic study, with our 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. 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. Additionally, the pharmacokinetics of 20mg oral spray after a meal were evaluated. Sumatriptan oral spray was well tolerated.

While Imitrex® nasal spray was not included in this clinical study, the following represents a discussion of the results of our clinical study as compared to published data for Imitrex® nasal spray. 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.

## Edgar Filing: NOVADEL PHARMA INC - Form 10-K

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 it is estimated that approximately 45% of elderly people have some difficulty in swallowing. Our formulation of ropinirole oral spray may represent a more convenient way for the patient or healthcare provider to deliver ropinirole to patients suffering stiffness and/or tremors. We are currently targeting a NDA submission for our ropinirole product candidate in calendar 2008. If this timeline is met, we may obtain final approval from the FDA in calendar 2009.

We will also support our partners, as necessary, with the following product candidates and opportunities although we do not expect to devote a significant amount of 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. Previously, Hana Biosciences targeted final approval from the FDA and commercial launch in calendar 2007. However, on February 20, 2007, we announced that Hana Biosciences notified us that ongoing scale-up and stability experiments indicate that there is a need to make adjustments to the formulation and/or manufacturing process, and that there is likely to be a delay in the FDA approval and commercial launch of Zensana as a result thereof. On March 23, 2007, Hana Biosciences announced its plan to withdraw, without prejudice, its pending NDA for Zensana with the FDA, and that it plans to re-direct the development plan for Zensana using our patent-protected European formulation of the product. Subject to the successful scale-up and manufacturing tests of our European formulation of ondansetron, Hana Biosciences expects to conduct the appropriate clinical trials and re-file the NDA for Zensana in 2008. Because we rely upon Hana Biosciences to develop and file the NDA for Zensana we can give no assurances as to the amount of delay resulting from Hana Biosciences re-directing the development plan relating to Zensana or that Hana Biosciences will be able to re-file the NDA for Zensana in 2008, if at all, and ultimately receive final FDA approval. 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 development and 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 March 1, 2007, Dr. Rosenwald may be deemed to beneficially own approximately 14% of our outstanding common stock (assuming exercise of certain warrants beneficially owned by Dr. Rosenwald). 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.

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; and

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, a leading 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)**

In June 2004, we announced the granting of an exclusive worldwide 20-year license for our proprietary oral spray technology to Velcera, a veterinary company. We received an equity stake of 529,500 shares of common stock in Velcera, along with an upfront cash technology fee of \$1,500,000 in September 2004. At the time of the signing of the agreement with Velcera it was determined that the Velcera common stock had a de minimus value. Such investment continues to be carried at its cost basis of \$0 as of December 31, 2006. In February 2007, Velcera merged with Denali Sciences, Inc., a publicly reporting Delaware corporation. The common stock of Denali Sciences, Inc. is not traded on any stock exchange. 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.

**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;

## Edgar Filing: NOVADEL PHARMA INC - Form 10-K

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

Increasing focus on products in targeted therapeutic areas (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 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 effect; (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. 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

## Edgar Filing: NOVADEL PHARMA INC - Form 10-K

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.

12

---

## 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**

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.

13

---

## Edgar Filing: NOVADEL PHARMA INC - Form 10-K

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

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 submission of an NDA, 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.

## Edgar Filing: NOVADEL PHARMA INC - Form 10-K

Our determinations regarding the availability of ANDA s 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.



## Edgar Filing: NOVADEL PHARMA INC - Form 10-K

### *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.

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. Previously, Hana Biosciences targeted final approval from the FDA and commercial launch in calendar 2007. However, on February 20, 2007, we announced that Hana Biosciences notified us that ongoing scale-up and stability experiments indicate that there is a need to make adjustments to the formulation and/or manufacturing process, and that there is likely to be a delay in the FDA approval and commercial launch of Zensana as a result thereof. On March 23, 2007, Hana Biosciences announced its plan to withdraw, without prejudice, its pending NDA for Zensana with the FDA, and that it plans to re-direct the development plan for Zensana using our patent-protected European formulation of the product. Subject to the successful scale-up and manufacturing tests of our European formulation of ondansetron, Hana Biosciences expects to conduct the appropriate clinical trials and re-file the NDA for Zensana in 2008. Because we rely upon Hana Biosciences to develop and file the NDA for Zensana we can give no assurances as to the amount of delay resulting from Hana Biosciences re-directing the development plan relating to Zensana or that Hana Biosciences will be able to re-file the NDA for Zensana in 2008, if at all, and ultimately receive final FDA approval. The safety and efficacy of the drug is based on a demonstration of the bioequivalence of Zensana to oral ondansetron, marketed under the tradename Zofran®. This Zofran® formulation is protected by one unexpired patent, which is scheduled to expire in September 2011, and is subject to a period of pediatric exclusivity expiring in March 2012. Additionally, this Zofran® formulation was covered by another patent which, after pediatric exclusivity, expired in December 2006. Hana Biosciences' Section 505(b)(2) NDA contained a paragraph III certification acknowledging that the now expired patent would expire in December 2006, and a paragraph IV certification to the patent which is due to expire in March 2012. 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.

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

Edgar Filing: NOVADEL PHARMA INC - Form 10-K

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.

16

---

*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.

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

Edgar Filing: NOVADEL PHARMA INC - Form 10-K

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.

17

---

## Edgar Filing: NOVADEL PHARMA INC - Form 10-K

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.

We are aware of several companies that are selling or developing oral spray products. Sciele Pharma Inc. (formerly First Horizon Pharmaceutical Corporation), headquartered in Alpharetta, Georgia, currently markets Nitrolingual® Pumpspray, a nitroglycerin oral spray which is an air propelled dispensing system (our nitroglycerin lingual spray is a propellant based dispensing system). Generex Biotechnology Corporation, based in Toronto, Canada, is developing an insulin formulation that is delivered directly into the mouth via its RapidMist device. 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. Generex Biotechnology Corporation is listed as the assignee on 15 U.S. patents. RapidMist is a pending trademark of Generex Biotechnology Corporation. There are several other companies that we are aware of that market oral spray products containing vitamins and homeopathic ingredients. GW Pharmaceuticals plc, based in the UK, has developed a cannabinoid lingual spray called Sativex®. Sativex® was approved by Health Canada in April 2005 for the relief of neuropathic pain in Multiple Sclerosis, or 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, three Canadian patents 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.





## Edgar Filing: NOVADEL PHARMA INC - Form 10-K

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.

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.



## Edgar Filing: NOVADEL PHARMA INC - Form 10-K

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.

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.



## Edgar Filing: NOVADEL PHARMA INC - Form 10-K

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.

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.

**ANTI-HISTAMINE 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 March 1, 2007, we had 23 total employees, 21 of whom were full-time employees.

The names and ages of our Directors and Executive Officers as of the date of filing this Transition Report 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: Dr. Bergstrom, Dr. Egberts, Mr. Spicer and Dr. Zodda.

| NAME                          | AGE | POSITION WITH THE COMPANY                         |
|-------------------------------|-----|---|
| Mark J. Baric                 | 48  | Director  |
| Thomas E. Bonney              | 42  | 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 of Directors   |
| David H. Bergstrom, Ph.D.     | 52  | Senior Vice President and Chief Operating Officer |
| Michael E. Spicer             | 53  | Chief Financial Officer and Corporate Secretary   |
| Deni M. Zodda, Ph.D.          | 54  | Senior Vice President and Chief Business Officer  |

**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](mailto: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.

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 Transition 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.

***RISKS RELATED TO OUR BUSINESS***

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

We are a pre-commercialization specialty pharmaceutical company developing oral spray formulations of a broad range of marketed treatments. 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 U.S. Food and Drug Administration, or FDA, approval and achieve market acceptance of our proposed products and respond to competition. The filing of a New Drug Application, or NDA, with the FDA is an important step in the approval process in the U.S. Acceptance for filing by the FDA does not mean that the NDA has been or will be approved, nor does it represent an evaluation of the adequacy of the data submitted. On November 3, 2006, we announced that we received an approval letter from the FDA regarding our NDA for NitroMist . We are currently in the process of working with Par Pharmaceutical, Inc., or Par, to finalize the commercialization strategy for this product. We cannot be certain as to when to anticipate commercializing and marketing any of our product candidates in development, if at all, and do not expect to generate sufficient revenues from proposed product sales to cover our expenses or achieve profitability in the near future.

We had an accumulated deficit as of December 31, 2006 of approximately \$48.3 million. We incurred losses in each of our last ten fiscal years, including net losses of approximately \$3.8 million for the five months ended December 31, 2006, \$10.1 million for the fiscal year ended July 31, 2006, \$9.5 million for the fiscal year ended July 31, 2005, and \$6.3 million for the fiscal year ended July 31, 2004. Additionally, we have reported negative cash flows from operations of approximately \$1.8 million for the five months ended December 31, 2006, \$8.9 million for the fiscal year ended July 31, 2006, \$6.3 million for the fiscal year ended July 31, 2005, and \$6.1 million for the fiscal year ended July 31, 2004. We anticipate that we will incur substantial operating expenses in connection with continued research and development, clinical trials, testing and approval of our proposed products, and expect these expenses will result in continuing and, perhaps, significant operating losses until such time, if ever, that we are able to achieve adequate product sales levels. Our ability to generate revenue and achieve profitability depends upon our ability, alone or with others, to complete the development of our product candidates, obtain the required regulatory approvals and manufacture, market and sell our product candidates.



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

The research, development, testing and approval of our product candidates involve significant expenditures, and, accordingly, we require significant capital to fund such expenditures. Due to our small revenue base, low level of working capital and, until recently, our relative inability to increase the number of development agreements with pharmaceutical companies, we have been unable to pursue aggressively our product development strategy. Until and unless our operations generate significant revenues and cash flow, we will attempt to continue to fund operations from cash on hand and through the sources of capital described below. Our long-term liquidity is contingent upon achieving sales and positive cash flows from operating activities, and/or obtaining additional financing. The most likely sources of financing include private placements of our equity or debt securities or bridge loans to us from third-party lenders, license payments from existing, current and future partners, and royalty payments from sales of approved drugs by partners. We can give no assurances that any additional capital that we are able to obtain will be sufficient to meet our needs. On December 27, 2006, we completed an equity financing in which we received gross proceeds of \$14.2 million and approximate net proceeds of \$13.1 million of which approximately \$11.7 million was received in December 2006 and \$1.4 million was received in January 2007. Given the current and desired pace of development of our product candidates, we estimate that we will have sufficient cash on hand to fund development of our product candidates through December 31, 2007. We may, however, choose to raise additional capital before December 31, 2007 to fund future development activities or to take advantage of other strategic opportunities. This could include the securing of funds through new strategic partnerships and/or the sale of our common stock or other securities. There can be no assurance that such capital will be available to us on favorable terms, or at all. There are a number of risks and uncertainties related to our attempt to complete a financing or strategic partnering arrangement that are outside our control. We may not be able to obtain additional financing on terms acceptable to us, or at all. If we are unsuccessful at obtaining additional financing as needed, we may be required to significantly curtail or cease operations. We will need additional financing thereafter until we achieve profitability, if ever.

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

The additional financings we require may be obtained through one or more transactions which effectively dilute the ownership interests of our existing stockholders. Further, we may not be able to secure such additional financing on terms acceptable to us, if at all. We have the authority to issue additional shares of our common stock, as well as additional classes or series of ownership interests or debt obligations which may be convertible into any one or more classes or series of ownership interests. We are authorized to issue a total of 200,000,000 shares of common stock and 1,000,000 shares of preferred stock. Such securities may be issued without the approval or other consent of our stockholders. See Risk Factors Additional Authorized Shares of our Common Stock and Preferred Stock Available for Issuance May Adversely Affect the Market for a description of certain rights of Paramount BioCapital Inc., or Paramount, that may negatively impact our ability to raise additional capital.

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

Our strategy is to concentrate our product development activities primarily on pharmaceutical products for which there already are significant prescription sales, where the use of our proprietary, novel drug delivery technology could potentially enhance speed of onset of therapeutic effect, could potentially reduce side effects through a reduction of the amount of active drug substance required to produce a given therapeutic effect and improve patient convenience or compliance. Our most recent new product candidates, tizanidine and ropinirole, are focused on the neurology segment, where we believe that the benefits of our proprietary drug delivery technology may apply to a number of different pharmaceutical products.

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

## Edgar Filing: NOVADEL PHARMA INC - Form 10-K

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. Previously, Hana Biosciences targeted final approval from the FDA and commercial launch in calendar 2007. However, on February 20, 2007, we announced that Hana Biosciences notified us that ongoing scale-up and stability experiments indicate that there is a need to make adjustments to the formulation and/or manufacturing process, and that there is likely to be a delay in the FDA approval and commercial launch of Zensana as a result thereof. On March 23, 2007, Hana Biosciences announced its plan to withdraw, without prejudice, its pending NDA for Zensana with the FDA, and that it plans to re-direct the development plan for Zensana using our patent-protected European formulation of the product. Subject to the successful scale-up and manufacturing tests of our European formulation of ondansetron, Hana Biosciences expects to conduct the appropriate clinical trials and re-file the NDA for Zensana in 2008. Because we rely upon Hana Biosciences to develop and file the NDA for Zensana we can give no assurances as to the amount of delay resulting from Hana Biosciences re-directing the development plan relating to Zensana or that Hana Biosciences will be able to re-file the NDA for Zensana in 2008, if at all, and ultimately receive final FDA approval.

We completed pilot pharmacokinetic studies of certain of our product candidates during late calendar year 2004 and early calendar year 2005. These products are oral spray formulations of ondansetron, sumatriptan, propofol and zolpidem. In addition, in September and October 2006, we completed a pharmacokinetic study of our improved oral spray formulation of sumatriptan and zolpidem, respectively. The goal of these pilot pharmacokinetic studies is to determine whether or not a specific oral spray can achieve therapeutic blood levels of an active ingredient via administration through the oral mucosa. If desired therapeutic blood levels are not achieved, it could result in the need to reformulate the oral spray and/or to terminate work on a specific compound which would have a material adverse effect on our operations.

We have also completed pilot pharmacokinetic studies for two antihistamine oral sprays (loratadine and clemastine), an estradiol oral spray, an alprazolam oral spray and a progesterone oral spray. In addition, we completed phase 2 clinical trials for the clemastine oral spray. However, additional development work on these product candidates has been put on hold.

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

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

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

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

**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 March 1, 2007, Dr. Rosenwald beneficially owns approximately 14% of our outstanding common stock (assuming exercise of certain warrants beneficially owned by Dr. Rosenwald). As such, Dr. Rosenwald and Paramount may be deemed to be our affiliates. Dr. Rosenwald has the ability to designate an individual to serve on our Board of Directors, or the Board, and has exercised such ability by designating Mr. J. Jay Lobell to serve on the Board. Although Mr. Lobell is a designee of Dr. Rosenwald, he does not have any voting or dispositive control over the shares held directly or indirectly by Dr. Rosenwald. On December 14, 2005 based upon the recommendation of the Corporate Governance and Nominating Committee, the Board elected Mr. Lobell as a member of the Board. Pursuant to the listing standards of the American Stock Exchange, or AMEX, Mr. Lobell has been deemed to be an independent director by our Board as of September 15, 2006. Dr. Rosenwald and Paramount may also be deemed to be affiliates of Manhattan Pharmaceuticals, Velcera and Hana Biosciences. In addition, Paramount has assisted us in the placement of shares in connection with various private placements. Refer to Note 5 Related Party Transactions of the Financial Statements included in this Transition Report on Form 10-K for the five months ended December 31, 2006 for additional information. Generally, Delaware corporate law requires that any transactions between us and any of our affiliates be on terms that, when taken as a whole, are substantially as favorable to us as those then reasonably obtainable in an arms length transaction from a person who is not an affiliate. Nevertheless, neither Dr. Rosenwald nor Paramount, nor their affiliates, are obligated pursuant to any agreement or understanding with us to make any additional products or technologies available to us, nor can there be any assurance, and we do not expect and our stockholders should not expect, that any biomedical or pharmaceutical product or technology identified by Dr. Rosenwald or Paramount, or their affiliates, in the future will be made available to us. In addition, certain of our current officers and directors or any officers or directors hereafter appointed by us may from time to time serve as officers or directors of other biopharmaceutical or biotechnology companies. Such other companies may have interests in conflict with our interests.

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

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

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

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

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

Our principal efforts are the development of, and obtaining regulatory approvals for, our product candidates. We anticipate that marketing activities for our product candidates, whether by us or one or more of our licensees, if any, will not begin until the second half of calendar 2007 at the earliest. On November 3, 2006, we announced that we received an approval letter from the FDA regarding our NDA for NitroMist . We are currently in the process of working with Par to finalize the commercialization strategy for this product. Accordingly, it is not anticipated that we will generate any revenues from royalties or sales of our product candidates until regulatory approvals are obtained, if ever, and marketing activities begin. Any one or more of our product candidates may not prove to be commercially viable, or if viable, may not reach the marketplace on a basis consistent with our desired timetables. The failure or the delay of any one or more of our proposed product candidates to achieve commercial viability would have a material adverse effect on us.

**WE HAVE NOT COMPLETED PRODUCT DEVELOPMENT.**

We have not completed the development of our product candidates and we will be required to devote considerable effort and expenditures to complete such development. In addition to obtaining adequate financing, satisfactory completion of development, testing, government approval and sufficient production levels of such product candidates must be obtained before the product candidates will become available for commercial sale. We do not anticipate generating material revenue from product sales until perhaps the second half of calendar 2007 at the earliest. On November 3, 2006, we announced that we received an approval letter from the FDA regarding our NDA for NitroMist . We are currently working with Par to finalize the commercialization strategy for this product. Other potential products remain in the conceptual or very early development stage and remain subject to all the risks inherent in the development of pharmaceutical products, including unanticipated development problems and possible lack of funds to undertake or continue development. These factors could result in abandonment or substantial change in the development of a specific formulated product. We may not be able to successfully develop any one or more of our product candidates or develop such product candidates on a timely basis. Further, such product candidates may not be commercially accepted if developed. The inability to successfully complete development, or a determination by us, for financial or other reasons, not to undertake to complete development of any product candidates, particularly in instances in which we have made significant capital expenditures, could have a material adverse effect on our business and operations.

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

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

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

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

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

**WE ARE DEPENDENT ON OUR SUPPLIERS.**

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

We will be required to document and test our internal control procedures in order to satisfy the requirements of Section 404 of the Sarbanes-Oxley Act of 2002, which requires annual management assessments of the effectiveness of our internal controls over financial reporting and reports by our independent registered public accounting firm addressing these assessments and our internal controls. During the course of our testing we may identify deficiencies which we may not be able to remediate in time to meet the deadline imposed by the Sarbanes-Oxley Act of 2002 for compliance with the requirements of Section 404. In addition, if we fail to maintain the adequacy of our internal controls, as such standards are modified, supplemented or amended from time to time, we may not be able to ensure that we can conclude on an ongoing basis that we have effective internal controls over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act of 2002. Failure to achieve and maintain an effective internal control environment could also cause investors to lose confidence in our reported financial information, which could have a material adverse effect on the price of our common stock. As of the date of the filing of this Transition Report, we will have to comply with Section 404 of the Sarbanes-Oxley Act of 2002 as of December 31, 2007.

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

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

**WE FACE INTENSE COMPETITION.**

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

Accordingly, our competitors may succeed in obtaining patent protection, receiving FDA or comparable foreign approval or commercializing products before us. If we commence commercial product sales, we will compete against companies with greater marketing and manufacturing capabilities who may successfully develop and commercialize products that are more effective or less expensive than ours. Our competitors may be more successful in receiving third party reimbursements from government agencies and others for their commercialized products which are similar to our products. If we cannot receive third party reimbursement for our products, we may not be able to commercialize our products. These are areas in which, as yet, we have limited or no experience. In addition, developments by our competitors may render our product candidates obsolete or noncompetitive.

We are aware of several companies that are selling or developing oral spray products. Sciele Pharma Inc. (formerly First Horizon Pharmaceutical Corporation), headquartered in Alpharetta, Georgia, currently markets Nitrolingual<sup>®</sup> Pumpspray, a nitroglycerin oral spray which is an air propelled dispensing system (our nitroglycerin lingual spray is a propellant based dispensing system). Generex Biotechnology Corporation, based in Toronto, Canada, is developing an insulin formulation that is delivered directly into the mouth via its RapidMist<sup>™</sup> device. They also state that they have begun research on four specific target molecules for their RapidMist<sup>™</sup> delivery system: morphine, fentanyl, heparin and flu vaccine. Generex Biotechnology Corporation is listed as the assignee on 15 U.S. patents. RapidMist<sup>™</sup> is a pending trademark of Generex Biotechnology Corporation. There are several other companies that we are aware of that market oral spray products containing vitamins and homeopathic ingredients. GW Pharmaceuticals plc, based in the UK, has developed a cannabinoid lingual spray called Sativex<sup>®</sup>. Sativex<sup>®</sup> was approved by Health Canada in April 2005 for the relief of neuropathic pain in Multiple Sclerosis, or MS, and was launched in Canada in June 2005 by Bayer HealthCare, who will exclusively market Sativex<sup>®</sup> 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 NDA submission, generally takes two to three years under the 505(b)(2) NDA process. Our determinations may prove to be inaccurate or pre-marketing approval relating to our proposed products may not be obtained on a timely basis, if at all. The failure by us to obtain necessary regulatory approvals, whether on a timely basis or at all, would have a material adverse effect on our business. The filing of an NDA with the FDA is an important step in the approval process in the U.S. Acceptance for filing by the FDA does not mean that the NDA has been or will be approved, nor does it represent an evaluation of the adequacy of the data submitted.

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

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

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

**NitroMist** (nitroglycerin lingual aerosol). This product candidate is for acute relief of an attack or acute prophylaxis of angina pectoris due to coronary artery disease. We have partnered with Par, who has exclusive rights to market, sell and distribute NitroMist in the U.S. and Canada. On November 3, 2006, we announced that we received an approval letter from the FDA regarding our NDA for NitroMist. We are currently working with Par to finalize the commercialization strategy for this product. We received a milestone payment from Par for FDA approval. We are currently in the process of working with Par to finalize the commercialization strategy for this product. In addition, we will receive royalty payments based upon a percentage of net sales.

**Zolpidem oral spray.** Zolpidem is the active ingredient in Ambien®, the leading hypnotic marketed by Sanofi-Aventis. In October 2006, we announced positive study results of a pharmacokinetic study of our improved oral spray formulation of zolpidem, a study which demonstrated that zolpidem oral spray achieves a statistically significant faster rate of absorption than Ambien® tablets. We are currently targeting a NDA submission for our zolpidem product candidate in the first half of calendar 2007. If this timeline is met, we may obtain final approval from the FDA in calendar 2008.

**Sumatriptan oral spray.** Sumatriptan is the active ingredient in Imitrex® which is the largest selling migraine remedy marketed by GlaxoSmithKline, GSK. In September 2006, we announced positive study results of a pharmacokinetic study of our improved oral spray formulation of sumatriptan, a study which demonstrated that sumatriptan oral spray achieves a statistically significant faster rate of absorption than Imitrex® tablets. We are currently targeting a NDA submission for our sumatriptan product candidate in the second half of calendar 2007. If this timeline is met, we may obtain final approval from the FDA in calendar 2008; however, we will not be able to launch this product candidate until after the expiration of the relevant Imitrex® patents and extensions thereof in February 2009.

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

**Ropinirole oral spray.** Ropinirole is indicated for the treatment of the signs and symptoms of idiopathic Parkinson's disease. Ropinirole oral spray is ideal for the geriatric population who may be suffering from dysphagia (difficulty swallowing); 85% of sufferers of Parkinson's are 65 years of age or older and it is estimated that approximately 45% of elderly people have some 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. Previously, Hana Biosciences targeted final approval from the FDA and commercial launch in calendar 2007. However, on February 20, 2007, we announced that Hana Biosciences notified us that ongoing scale-up and stability experiments indicate that there is a need to make adjustments to the formulation and/or manufacturing process, and that there is likely to be a delay in the FDA approval and commercial launch of Zensana as a result thereof. On March 23, 2007, Hana Biosciences announced its plan to withdraw, without prejudice, its pending NDA for Zensana with the FDA, and that it plans to re-direct the development plan for Zensana using our patent-protected European formulation of the product. Subject to the successful scale-up and manufacturing tests of our European formulation of ondansetron, Hana Biosciences expects to conduct the appropriate clinical trials and re-file the NDA for Zensana in 2008. Because we rely upon Hana Biosciences to develop and file the NDA for Zensana we can give no assurances as to the amount of delay resulting from Hana Biosciences re-directing the development plan relating to Zensana or that Hana Biosciences will be able to re-file the NDA for Zensana in 2008, if at all, and ultimately receive final FDA approval. We will receive a milestone payment from Hana Biosciences upon final approval from the FDA. In addition, we will receive royalty payments based upon a percentage of net sales.

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

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

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

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

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

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

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

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

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

Pursuant to the license and development agreement, as amended, that we entered into with Hana Biosciences, Hana Biosciences submitted an NDA under Section 505(b)(2) for Zensana in June 2006. Previously, Hana Biosciences targeted final approval from the FDA and commercial launch in calendar 2007. However, on February 20, 2007, we announced that Hana Biosciences notified us that ongoing scale-up and stability experiments indicate that there is a need to make adjustments to the formulation and/or manufacturing process, and that there is likely to be a delay in the FDA approval and commercial launch of Zensana as a result thereof. On March 23, 2007, Hana Biosciences announced its plan to withdraw, without prejudice, its pending NDA for Zensana with the FDA, and that it plans to re-direct the development plan for Zensana using our patent-protected European formulation of the product. Subject to the successful scale-up and manufacturing tests of our European formulation of ondansetron, Hana Biosciences expects to conduct the appropriate clinical trials and re-file the NDA for Zensana in 2008. Because we rely upon Hana Biosciences to develop and file the NDA for Zensana we can give no assurances as to the amount of delay resulting from Hana Biosciences re-directing the development plan relating to Zensana or that Hana Biosciences will be able to re-file the NDA for Zensana in 2008, if at all, and ultimately receive final FDA approval.

**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, or USPTO, has not adopted a consistent policy regarding the breadth of claims that the USPTO 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.

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.



## Edgar Filing: NOVADEL PHARMA INC - Form 10-K

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 one unexpired patent, which is scheduled to expire in September 2011, and is subject to a period of pediatric exclusivity expiring in March 2012. Additionally, this Zofran® formulation was covered by another patent which, after pediatric exclusivity, expired in December 2006. Hana Biosciences' Section 505(b)(2) NDA contained a paragraph III certification acknowledging that the now expired patent would expire in December 2006, and a paragraph IV certification to the patent which is due to expire in March 2012. 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 USPTO 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 54 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 USPTO 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 USPTO 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 USPTO keeps U.S. patent applications confidential while the applications are pending. As a result, we cannot determine which inventions third parties claim in pending patent applications that they have filed. We may need to engage in litigation to defend or enforce our patent and license rights or to determine the scope and validity of the proprietary rights of others. It will be expensive and time consuming to defend and enforce patent claims. Thus, even in those instances in which the outcome is favorable to us, the proceedings can result in the diversion of substantial resources from our other activities. An adverse determination may subject us to significant liabilities or require us to seek licenses that third parties may not grant to us or may only grant at rates that diminish or deplete the profitability of the products to us. An adverse determination could also require us to alter our products or processes or cease altogether any related research and development activities or product sales.

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

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



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

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

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

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

they will breach these agreements;

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

**WE ARE DEPENDENT ON EXISTING MANAGEMENT AND BOARD MEMBERS.**

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

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

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

## Edgar Filing: NOVADEL PHARMA INC - Form 10-K

On December 15, 2005, we announced the election of Mr. J. Jay Lobell as a member of our Board effective December 14, 2005. Mr. Lobell was appointed as a result of Dr. Rosenwald's right to designate a director nominee for our Board. Although Mr. Lobell is a designee of Dr. Rosenwald's, he does not have any voting or dispositive control over the shares held directly or indirectly by Dr. Rosenwald. As of September 15, 2006, Mr. Lobell has been deemed independent by our Board of Directors in accordance with the rules of AMEX.

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

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

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

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

On December 4, 2006, our Board appointed David H. Bergstrom, Ph.D. as Senior Vice President and Chief Operating Officer.

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

On February 2, 2007, we announced the election of Mr. Mark J. Baric as a member of our Board, effective February 1, 2007.

On February 22, 2007, our Board appointed Deni M. Zodda, Ph.D. as Senior Vice President and Chief Business Officer.

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

### ***RISKS RELATED TO OUR COMMON STOCK***

#### **WE ARE INFLUENCED BY CURRENT STOCKHOLDERS, OFFICERS AND DIRECTORS.**

Our directors, executive officers and principal stockholders and certain of our affiliates have the ability to influence the election of our directors and most other stockholder actions. As of March 1, 2007, management and our affiliates currently beneficially own, including shares they have the right to acquire, approximately 16% of the common stock on a fully-diluted basis. This determination of affiliate status is not necessarily a conclusive determination for other purposes. Specifically, Dr. Rosenwald has the ability to exert significant influence over the election of the Board and other matters submitted to our stockholders for approval. Dr. Rosenwald has the ability to designate an individual to serve on our Board and has exercised such ability by designating Mr. J. Jay Lobell to serve on the Board. Although Mr. Lobell is a designee of Dr. Rosenwald's, he does not have any voting or dispositive control over the shares held directly or indirectly by Dr. Rosenwald. On December 14, 2005 based upon the recommendation of the Corporate Governance and Nominating Committee, the Board elected Mr. Lobell as a member of the Board. Pursuant to the listing standards of the AMEX, Mr. Lobell has been deemed to be an independent director by our Board on September 15, 2006.

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



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

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

- announcements of the results of clinical trials by us or our competitors;
- adverse reactions to products;
- governmental approvals, delays in expected governmental approvals or withdrawals of any prior governmental approvals or public or regulatory agency concerns regarding the safety or effectiveness of our products;
- changes in the U.S. or foreign regulatory policy during the period of product development;
- developments in patent or other proprietary rights, including any third party challenges of our intellectual property rights;
- announcements of technological innovations by us or our competitors;
- announcements of new products or new contracts by us or our competitors;
- actual or anticipated variations in our operating results due to the level of development expenses and other factors;
- changes in financial estimates by securities analysts and whether our earnings meet or exceed the estimates;
- conditions and trends in the pharmaceutical and other industries;
- new accounting standards; and
- the occurrence of any of the risks set forth in these Risk Factors and other reports, including this Transition Report and other filings filed with the Securities and Exchange Commission from time to time.

Our common stock has been listed for quotation on the AMEX since May 11, 2004 under the symbol **NVD** . Prior to May 11, 2004, our common stock was traded on the OTC Bulletin Board® of the National Association of Securities Dealers, Inc. During the 12-month period ended December 31, 2006, the closing price of our common stock has ranged from \$1.11 to \$1.90. We expect the price of our common stock to remain volatile. The average daily trading volume in our common stock varies significantly. For the 12-month period ended December 31, 2006, the average daily trading volume in our common stock was approximately 115,000 shares. Our relatively low average volume and low average number of transactions per day may affect the ability of our stockholders to sell their shares in the public market at prevailing prices and a more active market may never develop.

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

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

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

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

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

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

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

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

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

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

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

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

We are authorized to issue a total of 200,000,000 shares of common stock and 1,000,000 shares of preferred stock. Such securities may be issued without the approval or other consent of our stockholders. As of March 1, 2007, there were 59,395,732 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 March 1, 2007, we had outstanding stock options and warrants to purchase approximately 38.4 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.

## Edgar Filing: NOVADEL PHARMA INC - Form 10-K

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

| Plan                       | Shares Authorized | Options Outstanding at March 1, 2007 | Remaining Shares Available for Issuance | Comments    |
|----------------------------|-------------------|--------------------------------------|---|-------------|
| 1992 Stock Option Plan     | 500,000           | 80,000                               |   | Plan Closed |
| 1997 Stock Option Plan     | 500,000           | 100,000                              |   | Plan Closed |
| 1998 Stock Option Plan     | 3,400,000         | 3,098,000                            | 7,000                                   |             |
| 2006 Equity Incentive Plan | 6,000,000         | 3,867,000                            | 2,033,000                               |             |
| Non-Plan                   | n/a               | 4,511,000                            |   |             |

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

In addition, in the event that any future financing should be in the form of, be convertible into or exchangeable for, equity securities, and upon the exercise of options and warrants, investors may experience additional dilution.

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

In addition to the above referenced shares of our common stock which may be issued without stockholder approval, we have 1,000,000 shares of authorized preferred stock, the terms of which may be fixed by our Board. We presently have no issued and outstanding shares of preferred stock and while we have no present plans to issue any shares of preferred stock, our Board has the authority, without stockholder approval, to create and issue one or more series of such preferred stock and to determine the voting, dividend and other rights of holders of such preferred stock. The issuance of any of such series of preferred stock may have an adverse effect on the holders of our common stock.

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

From time to time, certain of our stockholders may be eligible to sell all or some of their shares of our common stock by means of ordinary brokerage transactions in the open market pursuant to Rule 144, promulgated under the Securities Act of 1933, as amended, subject to certain limitations. In general, pursuant to Rule 144, a stockholder (or stockholders whose shares are aggregated) who has satisfied a one year holding period may, under certain circumstances, sell within any three month period a number of securities which does not exceed the greater of 1% of the then outstanding shares of common stock or the average weekly trading volume of the class during the four calendar weeks prior to such sale. Rule 144 also permits, under certain circumstances, the sale of securities, without any limitation, by our stockholders that are non-affiliates that have satisfied a two year holding period. Any substantial sale of our common stock pursuant to Rule 144 or pursuant to any resale prospectus may have a material adverse effect on the market price of our common stock.

### **LIMITATION ON DIRECTOR/OFFICER LIABILITY.**

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.**

## Edgar Filing: NOVADEL PHARMA INC - Form 10-K

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.

40

---

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

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

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

On July 20, 2006, we filed a shelf registration statement on Form S-3 registering for sale by us of up to 14,000,000 shares of our common stock. Such shelf registration statement was declared effective by the SEC on August 2, 2006. We may offer and sell such shares from time to time, in one or more offerings in amounts and at prices, and on terms determined at the time of the offering. Such offerings of our common stock may be made through agents we select or through underwriters and dealers we select. If we use agents, underwriters or dealers, we will name them and describe their compensation at the time of the offering. As of the filing date of this Transition Report, such shelf registration statement is no longer effective.

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

In April 2006, we sold securities in a private placement transaction resulting in the issuance of 8,092,796 shares of our common stock, and warrants to purchase 2,896,168 shares of our common stock. The sale of the shares of common stock and warrants resulted in gross proceeds to us of approximately \$11.8 million, prior to offering expenses.

In May 2005, we sold securities in a private placement transaction resulting in the issuance of 6,733,024 shares of our common stock, and certain warrants to purchase 2,693,210 shares of our common stock. The sales of the shares of common stock and warrants resulted in gross proceeds to us of \$7.1 million, prior to offering expenses.

The offering of, and/or resale of our common stock and the exercise of the warrants described immediately above in this risk factor are subject to currently effective registration statements filed by us on Forms S-3. There can be no assurance as to the prices at which our common stock will trade in the future, although they may continue to fluctuate significantly. Prices for our common stock will be determined in the marketplace and may be influenced by many factors, including the following:

- The depth and liquidity of the markets for our common stock;
- Investor perception of us and the industry in which we participate; and
- General economic and market conditions.

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

As of March 1, 2007, we have 59,395,732 shares of common stock issued and outstanding and approximately 38.4 million shares of common stock issuable upon the exercise of outstanding stock options and warrants. In the event we wish to offer and sell shares of our common stock in excess of the 200,000,000 shares of common stock currently authorized by our certificate of incorporation, we will first need to receive stockholder approval. Such stockholder approval has the potential to adversely affect the timing of any potential transactions.



**THE SECURITIES ISSUED IN OUR DECEMBER 2006 PRIVATE PLACEMENT ARE RESTRICTED SECURITIES.**

At the time of the offer and sale of the common stock (and the shares of common stock underlying the warrants) in our December 2006 private placement, the common stock was not registered under the Securities Act or the securities laws of any state. Accordingly, these securities may not be sold or otherwise transferred unless such sale or transfer is subsequently registered under the Securities Act and applicable state securities laws or unless exemptions from such registration are available. The registration statement covering these securities was declared effective by the SEC on January 26, 2007. Notwithstanding our registration obligations regarding these securities, investors may be required to hold these securities for an indefinite period of time. All investors who purchase these securities are required to make representations that it will not sell, transfer, pledge or otherwise dispose of any of the securities in the absence of an effective registration statement covering such transaction under the Securities Act and applicable state securities laws, or the receipt by us of an opinion of counsel to the effect that registration is not required.

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

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

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

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

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

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

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

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

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 January 26, 2007, May 30, 2006 and July 28, 2005 and must continuously remain effective for a specified term. If we fail to continuously maintain such a registration statement as effective throughout the specified term, we may be subject to liability to pay liquidated damages.

**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, known as the New Facility. The New 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 New Facility. Through the lease expiration date of December 31, 2005, we also occupied approximately 4,500 square feet of laboratory and office space at 31 Route 12 West, Flemington, New Jersey, known as the Old Facility, which also formerly housed our executive offices. During the five months ended December 31, 2006, we paid rent for the New Facility of approximately \$184,000. 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 will either contract out manufacturing for our product candidates or we will have to invest additional funds in the New Facility in order to provide internal manufacturing capability. The manufacture of our product candidates is subject to cGMP prescribed by the Food & Drug Administration, or 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.

43

---

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

Our annual meeting of stockholders, or the Annual Meeting, was held on January 16, 2007. A quorum of 40,510,140 shares or 82% of common stock was represented in person or by proxy out of a total of 49,351,749 shares of common stock issued and outstanding and entitled to vote at the Annual Meeting.

The matters that were voted on at the Annual Meeting were:

- (A) A proposal to elect the following persons to our Board of Directors to serve until the next Annual Meeting of Stockholders to be held in June 2007 and until their respective successors have been duly elected and qualified: Thomas E. Bonney; Jan H. Egberts, M.D.; William F. Hamilton, Ph.D.; J. Jay Lobell; Charles Nemeroff, M.D., Ph.D.; and Steven B. Ratoff.
- (B) A proposal to approve an amendment to our Certificate of Incorporation to increase the authorized shares of our common stock from 100,000,000 shares to 200,000,000 shares.
- (C) A proposal to ratify the selection of J.H. Cohn LLP as our independent registered public accounting firm for the transition period ending December 31, 2006.

The results of the votes of the Annual Meeting were as follows:

|                               | <b>Number of Shares of</b> |                  |
|-------------------------------|----------------------------|------------------|
|                               | <b>Common Stock</b>        |                  |
| <u>Proposal</u>               | For                        | Against/Withheld |
| Thomas E. Bonney              | 40,339,833                 | 170,307          |
| Jan H. Egberts, M.D.          | 40,339,833                 | 170,307          |
| William F. Hamilton, Ph.D.    | 40,292,629                 | 217,511          |
| J. Jay Lobell                 | 39,384,463                 | 1,125,677        |
| Charles Nemeroff, M.D., Ph.D. | 40,318,912                 | 191,228          |
| Steven B. Ratoff              | 40,338,133                 | 172,007          |

|   | <b>Number of Shares of Common Stock</b> |                |                |
|---|---|----------------|----------------|
|   | <b>For</b>                              | <b>Against</b> | <b>Abstain</b> |
| <u>Proposal</u><br>Approve an amendment to our Certificate of Incorporation to increase the authorized shares of our common stock from 100,000,000 shares to 200,000,000 shares | 39,524,986                              | 21,225         | 0              |

|  | <b>Number of Shares of Common Stock</b> |                |                |
|--|---|----------------|----------------|
|  | <b>For</b>                              | <b>Against</b> | <b>Abstain</b> |
| <u>Proposal</u><br>Ratification of the appointment of J.H. Cohn LLP, as our independent registered public accounting firm for the transition period ending December 31, 2006 | 40,444,644                              | 20,057         | 15,445         |

## Edgar Filing: NOVADEL PHARMA INC - Form 10-K

Accordingly, our stockholders elected Thomas E. Bonney, Jan H. Egberts, M.D., William F. Hamilton, Ph.D., J. Jay Lobell, Charles Nemeroff, M.D., Ph.D. and Steven B. Ratoff to serve until our Annual Meeting of Stockholders scheduled to be held in June 2007 and until their respective successors have been duly elected and qualified. Our stockholders also approved the amendment to our Certificate of Incorporation to increase the authorized shares of our common stock from 100,000,000 shares to 200,000,000 shares and ratified the appointment of J.H. Cohn LLP, as our independent registered public accounting firm for the transition period ended December 31, 2006.

**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 since May 11, 2004. The following table sets forth the range of high and low closing sales prices of our common stock as reported by the AMEX during the five months ended December 31, 2006 and for each fiscal quarter for the fiscal years ended July 31, 2006 and 2005.

|  | <u>CLOSING SALE PRICES</u> |            |
|--|----------------------------|------------|
|  | -                          |            |
|  | (\$)                       |            |
|  | <u>HIGH</u>                | <u>LOW</u> |
| <b>FIVE MONTHS ENDED DECEMBER 31, 2006</b>                 |                            |            |
| First Quarter (August 1, 2006 through October 31, 2006)    | 1.35                       | 1.13       |
| Two Months Ended December 31, 2006                         | 1.86                       | 1.24       |
| <b>FISCAL 2006</b>   |                            |            |
| 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       |
| <b>FISCAL 2005</b>   |                            |            |
| 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 of our common stock as reported on the AMEX on March 1, 2007 was \$1.40. As of March 1, 2007, there were approximately 125 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.

**EQUITY COMPENSATION PLANS**

The following table provides information with respect to our compensation plans under which equity compensation is authorized as of December 31, 2006.

Edgar Filing: NOVADEL PHARMA INC - Form 10-K

| Plan Category  | Number of securities to be issued upon exercise of outstanding options, warrants and rights | Weighted-average exercise price of outstanding options, warrants and rights | Number of securities remaining available for future issuance under equity compensation plans |
|--|---|---|--|
| Equity compensation plans approved by security holders     | 4,154,000   | \$ 1.56   | 5,031,000  |
| Equity compensation plans not approved by security holders | 4,621,000   | 1.79  |  |
| Total  | 8,775,000   | \$ 1.68   | 5,031,000  |

**PERFORMANCE GRAPH**

The graph below compares changes in the cumulative total stockholder return (change in stock price plus reinvested dividends) for the period from July 31, 2001 through December 31, 2006 of an initial investment of \$100 invested in (a) NovaDel Pharma Inc.'s common stock, (b) the Total Return Index for the AMEX Composite and (c) the Research Data Group (RDG) Microcap Pharmaceutical Index. Total Return Index values are prepared by the Research Data Group. The stock price performance is not included to forecast or indicate future price performance.

|                             | <b>7/01</b> | <b>7/02</b> | <b>7/03</b> | <b>7/04</b> | <b>7/05</b> | <b>7/06</b> | <b>12/06</b> |
|-----------------------------|-------------|-------------|-------------|-------------|-------------|-------------|--------------|
| NovaDel Pharma Inc.         | \$ 100.00   | \$ 309.09   | \$ 369.09   | \$ 310.91   | \$ 227.27   | \$ 218.18   | \$ 298.18    |
| AMEX Composite              | \$ 100.00   | \$ 101.67   | \$ 114.19   | \$ 149.38   | \$ 199.71   | \$ 242.11   | \$ 260.30    |
| RDG MicroCap Pharmaceutical | \$ 100.00   | \$ 47.22    | \$ 77.64    | \$ 66.77    | \$ 61.73    | \$ 43.56    | \$ 45.94     |

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

On December 29, 2006, we announced that we completed a private placement to certain institutional and accredited investors of an aggregate of 9,823,983 shares of our common stock at a purchase price of \$1.45 per share, and warrants to purchase up to approximately 3,929,593 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 \$1.70 per share pursuant to a certain securities purchase agreement. We received gross proceeds equal to approximately \$14.2 million, of which \$12.8 million was received in December 2006 and \$1.4 million in January 2007. Additionally, the registration statement filed on January 18, 2007 covering the resale of the securities, as required under the securities purchase agreement, was declared effective by the Securities and Exchange Commission on January 26, 2007. We intend to use the proceeds from this private placement to fund our research and development efforts as well as for general working capital.

Oppenheimer & Co. Inc., or Oppenheimer, acted as the lead placement agent for this private placement, with Griffin Securities, Inc., or Griffin, acting as co-placement agent. The placement agents received compensation for acting as placement agents made up of cash compensation equal to 7% of the proceeds from the sale of the common stock, or approximately \$997,000, and warrants to purchase shares of common stock equal to 5% of the shares of common stock purchased, subject to certain exclusions, or warrants to purchase 491,199 shares (such warrants have the same terms as those issued to the investors), plus expenses.

The securities sold in this private placement were exempt from the registration requirements of the Securities Act of 1933, as amended (the Securities Act), pursuant to Section 4(2) thereof and Rule 506 of Regulation D promulgated thereunder, based in part upon our reliance upon the truth and accuracy of each of the representations made by the purchasers in the Securities Purchase Agreement and that (i) all of the purchasers were accredited within the meaning of Rule 501(a); (ii) the transfer of the securities pursuant to the Securities Purchase Agreement were restricted by us in accordance with Rule 502(d); (iii) there were no non-accredited purchasers in the transaction within the meaning of Rule 506(b), after taking into consideration all prior purchasers under Section 4(2) of the Securities Act within the twelve months preceding the transaction; and (iv) none of the offers and sales were effected through any general solicitation or general advertising within the meaning of Rule 502(c).

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 Transition Report on Form 10-K. The data set forth below with respect to our Statements of Operations for the five months ended December 31, 2006 and for the fiscal years ended July 31, 2006, 2005 and 2004 and the Balance Sheet data as of December 31, 2006 and July 31, 2006 are derived from our Financial Statements which are included elsewhere in this Transition Report on Form 10-K 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, 2005, July 31, 2004, 2003 and 2002 are derived from our Financial Statements, which are not included elsewhere in this Transition Report. Our historical results are not necessarily indicative of future results of operations.





Edgar Filing: NOVADEL PHARMA INC - Form 10-K

| STATEMENT OF<br>OPERATIONS DATA:  | Years Ended July 31, |                  |                 |                 |                 |                 |
|---|----------------------|------------------|-----------------|-----------------|-----------------|-----------------|
|   | Five months<br>Ended |                  |                 |                 |                 |                 |
|   | December 31,<br>2006 | 2006             | 2005            | 2004            | 2003            | 2002            |
| Total Revenues  | \$ 2,067,000         | \$ 1,890,000     | \$ 439,000      | \$ 466,000      | \$ 2,000        | \$ 339,000      |
| Total Expenses  | 6,519,000            | 12,454,000       | 10,217,000      | 7,119,000       | 7,091,000       | 6,592,000       |
| Loss from Operations  | (4,452,000 )         | (10,564,000 )    | (9,778,000 )    | (6,653,000 )    | (7,089,000 )    | (6,253,000 )    |
| Interest Income   | 180,000              | 224,000          | 87,000          | 98,000          | 49,000          | 44,000          |
| Income Tax Benefit  | (467,000 )           | (256,000 )       | (241,000 )      | (214,000 )      | (84,000 )       | (88,000 )       |
| Net Loss  | \$ (\$3,805,000 )    | \$ (10,084,000 ) | \$ (9,450,000 ) | \$ (6,341,000 ) | \$ (6,956,000 ) | \$ (6,121,000 ) |
| Basic and Diluted Loss Per<br>Common Share  | \$ (.08 )            | \$ (.23 )        | \$ (.27 )       | \$ (.24 )       | \$ (.45 )       | \$ (.54 )       |
| Weighted Average Number<br>of Shares of Common Stock<br>Used in Computation of<br>Basic and Diluted Loss Per<br>Share | 49,522,000           | 43,000,000       | 34,808,000      | 26,269,000      | 15,419,000      | 11,361,000      |

| BALANCE SHEET<br>DATA:                                | July 31,             |               |               |               |               |               |
|---|----------------------|---------------|---------------|---------------|---------------|---------------|
|   | December 31,<br>2006 | 2006          | 2005          | 2004          | 2003          | 2002          |
| Cash, cash equivalents, and<br>short-term investments | \$ 20,276,000        | \$ 10,138,000 | \$ 8,223,000  | \$ 8,377,000  | \$ 3,086,000  | \$ 3,314,000  |
| Total Assets  | 24,316,000           | 14,822,000    | 13,028,000    | 11,486,000    | 4,327,000     | 3,839,000     |
| Total Current Liabilities                             | 3,146,000            | 2,200,000     | 2,405,000     | 1,086,000     | 457,000       | 316,000       |
| Total Liabilities                                     | 5,718,000            | 4,777,000     | 5,079,000     | 1,463,000     | 457,000       | 316,000       |
| Accumulated deficit                                   | (48,280,000 )        | (44,475,000 ) | (34,391,000 ) | (24,941,000 ) | (18,600,000 ) | (11,644,000 ) |
| Total Stockholders' Equity                            | \$ 18,598,000        | \$ 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 Transition Report on Form 10-K. 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 Transition Report on Form 10-K, our actual results may differ materially from those anticipated in these forward looking statements.

## GENERAL

NovaDel Pharma Inc. is a specialty pharmaceutical company developing oral spray formulations of a broad range of marketed treatments. Our oral spray therapeutics are administered by a novel application drug delivery system for presently marketed prescription, over-the-counter, or OTC, and veterinary drugs. This patented and patent-pending delivery system is an oral spray potentially enabling drug absorption through the oral mucosa, potentially increasing the benefits of clinically proven compounds, including more rapid absorption into the bloodstream than presently available oral delivery systems. Our proprietary delivery system potentially enhances and accelerates the onset of the therapeutic benefits within minutes of administration. Our development efforts for our proprietary novel drug delivery system are concentrated on making such system available for drugs that are already available and proven in the marketplace. We believe that our proprietary drug delivery system could offer the following significant advantages: (i) more rapid delivery of drugs to the bloodstream allowing for quicker onset of therapeutic effects compared to conventional oral dosage forms; (ii) increased bioavailability of a drug by avoiding metabolism by the liver; (iii) improved drug safety profile by reducing the required dosage, including possible reduction of side-effects; (iv) improved dosage reliability; (v) allowing medication to be taken without water; (vi) avoiding the need to swallow as is the case with many medications; and (vii) improved patient convenience and compliance. Currently, we have eight patents which have been issued in the U.S. and 54 patents which have been issued outside of the U.S. Additionally, we have over 80 patents pending around the world. We look for drug compounds that are off patent or are coming off patent in the near future, and we reformulate these compounds in conjunction with our proprietary drug delivery method. Once reformulated, we file for new patent applications on these reformulated compounds that comprise our product candidates. Our patent portfolio includes patents and patent applications with claims directed to the pharmaceutical formulations, methods of use and methods of manufacturing of a number of our product candidates.

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 this Transition Report on Form 10-K for the five months ended December 31, 2006.

Highlights for the five months ended December 31, 2006, and additionally through the date of filing of this Transition Report on Form 10-K, include the following product development and business achievements:

Announced that NitroMist (Nitroglycerin Lingual Aerosol) has been approved by the FDA for acute relief of an attack or acute prophylaxis of angina pectoris due to coronary artery disease. NitroMist is our first product approval utilizing its proprietary oral spray technology.

Announced positive study results of a pharmacokinetic study in humans of our oral spray formulation of sumatriptan, a study which demonstrated that sumatriptan oral spray achieves a statistically significant faster rate of absorption than Imitrex® (sumatriptan) tablets.

Announced positive study results of a pharmacokinetic study in humans of our oral spray formulation of zolpidem, a study which demonstrated that zolpidem oral spray achieves a statistically significant faster rate of absorption than Ambien® (zolpidem) tablets.

Announced the submission of a NDA for Zensana by NovaDel's partner, Hana Biosciences, Inc., or Hana Biosciences, and the subsequent acceptance of such NDA by the FDA.

Announced that Hana Biosciences has notified us that ongoing scale-up and stability experiments indicate that there is a need to make adjustments to the formulation and/or manufacturing process, and that there will be a delay in the FDA approval and commercial launch of Zensana™.

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.

## Edgar Filing: NOVADEL PHARMA INC - Form 10-K

Issued an additional patent in Canada which 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, and for central nervous system disorders under our oral spray delivery system.

Completed a private placement in December 2006 of our common stock, raising gross proceeds of approximately \$14.2 million.

Appointed Mr. Steven B. Ratoff as Chairman of the Board of Directors with Dr. Egberts remaining a member of the Board of Directors.

Appointed David H. Bergstrom, Ph.D. as Senior Vice President and Chief Operating Officer.

Appointed Deni M. Zodda, Ph.D. as Senior Vice President and Chief Business Officer.

Appointed Mr. Mark J. Baric as a member of the Board of Directors.

Announced that Mr. Barry C. Cohen will no longer serve as Vice President, Business and New Product Development.

Drug development in the U.S. and most countries throughout the world is a process that includes several steps defined by the U.S. Food and Drug Administration, or 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 New Drug Application, or NDA, it is necessary to submit an Investigational New Drug, or 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 submission of an NDA, 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;

## Edgar Filing: NOVADEL PHARMA INC - Form 10-K

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. On November 3, 2006, we announced that we received an approval letter from the FDA regarding our NDA for NitroMist for which we received a milestone payment from Par. We are currently working with Par to finalize the commercialization strategy for this product. 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 an 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, 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 an NDA submission for our tizanidine product candidate in calendar 2008. If this timeline is met, we may obtain final approval from the FDA in calendar 2009.

**Ropinirole oral spray.** Ropinirole is indicated for the treatment of the signs and symptoms of idiopathic Parkinson's disease. Ropinirole oral spray is ideal for the geriatric population who may be suffering from dysphagia (difficulty swallowing); 85% of sufferers of Parkinson's are 65 years of age or older and it is estimated that 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 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 and such NDA was accepted for review by the FDA in August 2006. Previously, Hana Biosciences targeted final approval from the FDA and commercial launch in calendar 2007. However, on February 20, 2007, we announced that Hana Biosciences notified us that ongoing scale-up and stability experiments indicate that there is a need to make adjustments to the formulation and/or manufacturing process, and that there is likely to be a delay in the FDA approval and commercial launch of Zensana as a result thereof. On March 23, 2007, Hana Biosciences announced its plan to withdraw, without prejudice, its pending NDA for Zensana with the FDA, and that it plans to re-direct the development plan for Zensana using our patent-protected European formulation of the product. Subject to the successful scale-up and manufacturing tests of our European formulation of ondansetron, Hana Biosciences expects to conduct the appropriate clinical trials and re-file the NDA for Zensana in 2008. Because we rely upon Hana Biosciences to develop and file the NDA for Zensana we can give no assurances as to the amount of delay resulting from Hana Biosciences re-directing the development plan relating to Zensana or that Hana Biosciences will be able to re-file the NDA for Zensana in 2008, if at all, and ultimately receive final FDA approval. 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.

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.

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

### **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 superseded 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.

We have adopted the provisions of Statement of Financial Accounting Standards, or SFAS, No. 123 (revised 2004), Share-Based Payment, or SFAS 123R, effective August 1, 2005 and have selected the Black-Scholes method of valuation for share-based compensation. SFAS 123R 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 and for all options granted after the date of adoption. 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. For the five months ended December 31, 2006 and 2005, we recorded share-based compensation of approximately \$498,000 or \$0.01 per share and \$520,000 or \$0.01 per share, respectively. For the fiscal year ended July 31, 2006, we recorded share-based compensation expense of approximately \$1.2 million or \$0.03 per share. We will continue to incur share-based compensation charges in future periods. As of December 31, 2006, unamortized stock-based compensation expense of \$2.7 million remains to be recognized, which is comprised of \$1.9 million to be recognized over a weighted average period of 1.8 years, \$0.2 million related to restricted stock to be recognized over a weighted average period of 3.0 years, and \$0.6 million related to performance-based stock options which vest upon reaching certain milestones. Expenses related to the performance-based stock options will be recognized if and when the Company determines that it is probable that the milestone will be reached.

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:

|  | <b>Fiscal Year Ended July 31,</b> |                |
|--|-----------------------------------|----------------|
|  | <b>2005</b>                       | <b>2004</b>    |
| 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****FIVE MONTHS ENDED DECEMBER 31, 2006 AND 2005**

License fees and milestone fees earned from related parties for the five months ended December 31, 2006 were \$2,067,000, as compared to \$568,000 for the five months ended December 31, 2005. The increase is primarily due to milestone payments received in connection with our license and development agreements for Zensana with Hana Biosciences and NitroMist with Par Pharmaceuticals.

Consulting revenues from related parties for the five months ended December 31, 2006 were \$0 as compared to \$109,000 for the five months ended December 31, 2005. The decrease is primarily attributable to lower levels of revenue from Velcera related to veterinary products.

Research and development expenses for the five months ended December 31, 2006 were \$3,396,000, as compared to \$2,082,000 for the five months ended December 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 five months ended December 31, 2006 and 2005.

|   | <b>2006</b>  | <b>2005</b>  |
|---|--------------|--------------|
| NitroMist                               | \$ 602,000   | \$ 355,000   |
| Zolpidem                                | 1,216,000    | 380,000      |
| Sumatriptan                             | 109,000      | 118,000      |
| Zensana                                 |              | 221,000      |
| Propofol                                |              |              |
| Alprazolam                              |              |              |
| Tizanidine                              | 161,000      |              |
| Ropinirole                              | 43,000       |              |
| Other research and development costs    | 467,000      | 283,000      |
| Internal costs                          | 798,000      | 725,000      |
| Total research and development expenses | \$ 3,396,000 | \$ 2,082,000 |

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.

## Edgar Filing: NOVADEL PHARMA INC - Form 10-K

Research and development expenses in the five months ended December 31, 2006 increased primarily as a result of the following items:

\$247,000 increase related to the establishment of a reserve for certain raw materials and process validation batches for our NitroMist product candidate;

\$836,000 increase primarily related to product development and clinical trial costs for our zolpidem product candidate;

\$161,000 increase primarily related to product development costs for our tizanidine product candidate; and

\$221,000 decrease related to clinical trial material costs for Zensana incurred during the five months ended December 31, 2005. Such costs did not recur during the five months ended December 31, 2006.

Consulting, selling, general and administrative expenses for the five months ended December 31, 2006 were \$3,123,000 as compared to \$3,347,000 for the five months ended December 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 decrease in consulting, selling, general and administrative costs is primarily related to lower payroll and other personnel related costs during the period, partially offset by higher costs associated with external consultants.

Total costs and expenses for the five months ended December 31, 2006 were \$6,519,000 as compared to \$5,429,000 for the five months ended December 31, 2005 primarily due to the increase in research and development expenses, partially offset by the decrease in selling general and administrative expenses noted above.

Interest income for the five months ended December 31, 2006 was \$180,000 as compared to \$67,000 for the five months ended December 31, 2005 due to higher average cash and short-term investment balances and a general increase in interest rates.

Income tax benefit for the five months ended December 31, 2006 was \$467,000 as compared to \$256,000 for the five months ended December 31, 2005. These increased income tax benefits resulted from the sale of our New Jersey Net Operating Losses.

The resulting net loss for the five months ended December 31, 2006 was \$3,805,000 as compared to \$4,429,000 for the five months ended December 31, 2005.

### **FISCAL YEARS ENDED JULY 31, 2006 AND 2005**

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.

## Edgar Filing: NOVADEL PHARMA INC - Form 10-K

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.

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.

55

---

Edgar Filing: NOVADEL PHARMA INC - Form 10-K

|   | 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;

\$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:

## Edgar Filing: NOVADEL PHARMA INC - Form 10-K

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 research and development-related personnel in the fiscal year ended July 31, 2005; and

Approximate \$185,000 decrease in research and development-related consultants expense.

## Edgar Filing: NOVADEL PHARMA INC - Form 10-K

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;

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 our 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 as of December 31, 2006 of \$48,280,000 as compared to \$44,475,000 as of July 31, 2006. We have had negative cash flow from operating activities of \$1,782,000 for the five-months ended December 31, 2006, \$8,855,000 for the fiscal year ended July 31, 2006, \$6,258,000 for the fiscal year ended July 31, 2005, and \$6,120,000 for the fiscal year ended July 31, 2004. As of December 31, 2006, we had working capital of approximately \$18,200,000, as compared to working capital of \$9,574,000 as of July 31, 2006, representing a net increase in working capital of approximately \$8,626,000. As explained further below, such increase is primarily attributable to a net increase in cash and short-term investments. In December 2006, we closed a private placement of our common stock and warrants to purchase shares of our common stock involving the sale of 9,823,983 shares of common stock and warrants to purchase 3,929,593 shares of common stock. We received proceeds, net of offering costs, of \$13,144,000 of which \$11,749,000 was received in December 2006 and \$1,395,000 million in January 2007.



## Edgar Filing: NOVADEL PHARMA INC - Form 10-K

Net cash used in operating activities was approximately \$1,782,000 for the five months ended December 31, 2006, as compared to \$3,873,000 for the five months ended December 31, 2005. The \$2,091,000 decrease in net cash used in operating activities in the five months ended December 31, 2006 compared with 2005 is due to the following:

\$624,000 decrease in net loss in the five months ended December 31, 2006 primarily due to an increase in revenues and an increase in income tax benefit, partially offset by higher research and development expenses;

\$553,000 decrease in inventory in the five months ended December 31, 2006 primarily related to the establishment of reserve for certain raw materials and process validation batches for NitroMist ; and

\$721,000 decrease in accounts payable in the five months ended December 31, 2005 primarily due to the payment of invoices included in accounts payable at July 31, 2005 related to the manufacturing and process development of NitroMist .

In the five months ended December 31, 2006 and 2005, \$760,000 and \$2,432,000, respectively, was provided by investing activities, principally due to maturities of short-term investments, net of purchases of short-term investments.

Cash provided by financing activities was approximately \$11,921,000 in the five months ended December 31, 2006, as compared to \$0 in the five months ended December 31, 2005. This increase is primarily due to \$11,749,000 in net proceeds received in December 2006 relating to our December 2006 private placement.

Until and unless our operations generate significant revenues and cash flow, we will attempt to continue to fund operations from cash on hand and through the sources of capital described below. Our long-term liquidity is contingent upon achieving sales and positive cash flows from operating activities, and/or obtaining additional financing. The most likely sources of financing include private placements of our equity or debt securities or bridge loans to us from third-party lenders, license payments from existing, current and future partners, and royalty payments from sales of approved drugs by partners. We can give no assurances that any additional capital that we are able to obtain will be sufficient to meet our needs. On December 27, 2006, we completed a private placement of our common stock and warrants to purchase shares of common stock in which we received gross proceeds of \$14.2 million and approximate net proceeds of \$13.1 million, of which \$11.7 million was received in December 2006 and \$1.4 million was received in January 2007. Given the current and desired pace of development of our product candidates, we estimate that we will have sufficient cash on hand to fund development of our product candidates through December 31, 2007. We may, however, choose to raise additional capital before December 31, 2007 to fund future development activities or to take advantage of other strategic opportunities. This could include the securing of funds through new strategic partnerships and/or the sale of our common stock or other securities. There can be no assurance that such capital will be available to us on favorable terms, or at all. There are a number of risks and uncertainties related to our attempt to complete a financing or strategic partnering arrangement that are outside our control. We may not be able to 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 December 31, 2006.

|                                    | <b>Total</b> | <b>&lt;1 year</b> | <b>Payments Due<br/>By Period</b> |                  |                  |
|------------------------------------|--------------|-------------------|-----------------------------------|------------------|------------------|
|                                    |              |                   | <b>2-3 years</b>                  | <b>4-5 years</b> | <b>5 years +</b> |
| Capital leases                     | \$ 253,000   | \$ 125,000        | \$ 128,000                        | \$               | \$               |
| Operating leases                   | 2,382,000    | 332,000           | 709,000                           | 732,000          | 609,000          |
| Employment agreements              | 1,463,000    | 885,000           | 578,000                           |                  |                  |
| Total contractual cash obligations | \$ 4,098,000 | \$ 1,342,000      | \$ 1,415,000                      | \$ 732,000       | \$ 609,000       |

## Edgar Filing: NOVADEL PHARMA INC - Form 10-K

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 Item 1A. 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, or SEC, 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 December 31, 2006. Based on this evaluation, our Chief Executive Officer and our Chief Financial Officer concluded that as of December 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

During the period covered by this Transition Report on Form 10-K, 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.**

On March 23, 2007, we announced that our licensee for ondansetron oral spray, Hana Biosciences Inc., or Hana Biosciences, has notified us that it intends to re-direct the development plan for Zensana by using our patent-protected European formulation of the product. Zensana is an oral spray formulation of ondansetron targeted for the prevention of chemotherapy-, radiotherapy-induced and post-operative nausea and vomiting. Hana Biosciences announced its plan to withdraw, without prejudice, its pending New Drug Application, or NDA, for Zensana with the Food and Drug Administration. Subject to the successful scale-up and manufacturing tests of our European formulation of ondansetron, Hana Biosciences expects to conduct the appropriate clinical trials and re-file the NDA for Zensana in 2008.

**PART III**

**ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.**

Certain of the information required to be disclosed by this Item with respect to our executive officers is set forth under the caption Executive Officers and Directors contained in Part I, Item 1 of this Transition Report on Form 10-K.

Certain information required to be disclosed by this Item about our board of directors is incorporated in this Transition Report on Form 10-K by reference from the section entitled Election of Directors, and Board of Directors and Committees contained in our definitive proxy statement for our annual meeting of stockholders scheduled to be held in June 2007, which we intend to file within 120 days of the end of our transition period (December 31, 2006).

Information required to be disclosed by this Item about the Section 16(a) compliance of our directors and executive officers is incorporated in this Transition Report on Form 10-K by reference from the section entitled Section 16(a) Beneficial Ownership Reporting Compliance contained in our definitive proxy statement for our annual meeting of stockholders scheduled to be held in June 2007, which we intend to file within 120 days of the end of our transition period (December 31, 2006).

Information required to be disclosed by this Item about our board of directors, the audit committee of our board of directors, our audit committee financial expert, our Business Conduct Policy, and other corporate governance matters is incorporated in this Transition Report on Form 10-K by reference from the section entitled Meetings and Committees of our Board contained in our definitive proxy statement related to our annual meeting of stockholders scheduled to be held in June 2007, which we intend to file within 120 days of the end of our transition period (December 31, 2006).

The text of our Business Conduct Policy, which applies to all of our directors, officers and employees is posted in the Corporate Governance section of our website, [www.novadel.com](http://www.novadel.com). A copy of the Business Conduct Policy can be obtained free of charge on our website or 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. We intend to disclose on our website any amendments to, or waivers from, our Business Conduct Policy that are required to be disclosed pursuant to the rules of the Securities and Exchange Commission and American Stock Exchange.

**ITEM 11. EXECUTIVE COMPENSATION.**

Incorporated by reference to Compensation Discussion and Analysis, Compensation Committee Report, Summary Compensation Table, Grants of Plan-Based Awards, Outstanding Equity Awards, Option Exercises and Stock Vested, Potential Payments Upon Termination and Directors Compensation and Compensation Committee Interlocks and Insider Participants contained in our definitive proxy statement related to our annual meeting of stockholders scheduled to be held in June 2007, which we intend to file within 120 days of the end of our transition period (December 31, 2006).

**ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS.**

Incorporated by reference to *Stock Ownership of Directors, Management and Certain Beneficial Owners* contained in our definitive proxy statement related to our annual meeting of stockholders scheduled to be held in June 2007, which we intend to file within 120 days of the end of our transition period (December 31, 2006).

**ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE.**

Incorporated by reference to *Certain Relationships and Related Transactions* and *Independence of Directors* contained in our definitive proxy statement related to our annual meeting of stockholders scheduled to be held in June 2007, which we intend to file within 120 days of the end of our transition period (December 31, 2006).

**ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES.**

Incorporated by reference to Independent Registered Public Accounting Firm's Fee Summary contained in our definitive proxy statement related to our annual meeting of stockholders scheduled to be held in June 2007, which we intend to file within 120 days of the end of our transition period (December 31, 2006).

**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 Transition Report on Form 10-K. 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         | Certificate of Amendment to the Certificate of Incorporation of the Company    | Filed herewith   |
| 3.3         | 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  |
| 4.3         | Form of Warrant issued to certain accredited investors and the placement agent | Incorporated by reference to Exhibit 4.1 of the Company's Current Report on Form 8-K filed with the SEC on January 4, 2007                                   |
| 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)   |

Edgar Filing: NOVADEL PHARMA INC - Form 10-K

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

63

---

## 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)            |
| 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 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   |





## Edgar Filing: NOVADEL PHARMA INC - Form 10-K

|        |   |  |
|--------|---|--|
| 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 |
| 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* | 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   |
| 10.28* | 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                                      |
| 10.29* | 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                                      |
| 10.30* | 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                                      |
| 10.31* | 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                                      |
| 10.32* | 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                                      |
| 10.33  | 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   |
| 10.34  | 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   |
| 10.35  | 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

|        |   |   |
|--------|---|---|
| 10.36* | Employment Agreement dated December 4, 2006 by and between the Company and David H. Bergstrom, Ph.D.  | Incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K, as filed with the SEC on December 8, 2006  |
| 10.37* | Incentive Stock Option Award between the Company and David H. Bergstrom dated December 4, 2006  | Incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K, as filed with the SEC on December 8, 2006  |
| 10.38* | Nonqualified Stock Option Award between the Company and David H. Bergstrom, dated December 4, 2006  | Incorporated by reference to Exhibit 10.3 of the Company's Current Report on Form 8-K, as filed with the SEC on December 8, 2006  |
| 10.39  | 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 Current Report on Form 8-K, as filed with the SEC on January 4, 2007   |
| 10.40  | Placement Agent Agreement, dated as of November 21, 2006, by and between the Company and Oppenheimer & Co., Inc.                                | Incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K, as filed with the SEC on January 4, 2007   |
| 10.41* | Employment Agreement dated February 22, 2007 by and between the Company and Deni M. Zodda, Ph.D.  | Incorporated by reference to Exhibit 10.1 of the Company's Current Report on form 8-K, as filed with the SEC on February 28, 2007 |
| 10.42* | Incentive Stock Option Award between the Company and Deni M. Zodda dated February 22, 2007  | Incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K, as filed with the SEC on February 28, 2007 |
| 10.43* | Nonqualified Stock Option Award between the Company and Deni M. Zodda dated February 22, 2007   | Incorporated by reference to Exhibit 10.3 of the Company's Current Report on Form 8-K, as filed with the SEC on February 28, 2007 |
| 10.44* | Amendment No. 2 to Employment Agreement dated March 12, 2007 by and between the Company and Michael E. Spicer                                   | Filed herewith  |
| 10.45* | Amendment 2007-1 to the NovaDel Pharma Inc. 1998 Stock Option Plan dated March 2, 2007  | Filed herewith  |
| 10.46* | Amendment 2007-1 to the NovaDel Pharma Inc. 2006 Equity Incentive Plan dated March 2, 2007  | Filed herewith  |
| 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  |
| 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.

66

---

**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: March 26, 2007

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<br>Jan H. Egberts, M.D.            | Director, President and Chief Executive Officer<br><br>(Principal Executive Officer) | March 26, 2007 |
| /S/ MICHAEL E. SPICER<br>Michael E. Spicer            | Chief Financial Officer<br><br>(Principal Financial and Accounting Officer)          | March 26, 2007 |
| /S/ MARK J. BARIC<br>Mark J. Baric                    | Director   | March 26, 2007 |
| /S/ THOMAS E. BONNEY<br>Thomas E. Bonney              | Director   | March 26, 2007 |
| /S/ WILLIAM F. HAMILTON<br>William F. Hamilton, Ph.D. | Director   | March 26, 2007 |
| /S/ J. JAY LOBELL<br>J. Jay Lobell                    | Director   | March 26, 2007 |
| /S/ CHARLES NEMEROFF<br>Charles Nemeroff              | Director   | March 26, 2007 |
| /S/ STEVEN B. RATOFF<br>Steven B. Ratoff              | Director and Chairman of the Board   | March 26, 2007 |



**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 December 31, 2006, July 31, 2006 and July 31, 2005 and the related statements of operations, changes in stockholders' equity and cash flows for the five months ended December 31, 2006 and 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 December 31, 2006, July 31, 2006 and July 31, 2005, and its results of operations and cash flows for the five months ended December 31, 2006 and 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 the fiscal year ended July 31, 2006.

/s/ J.H. COHN LLP

Roseland, New Jersey

February 13, 2007



## NOVADEL PHARMA INC.

## BALANCE SHEETS

AS OF DECEMBER 31, 2006, JULY 31, 2006 AND JULY 31, 2005

| ASSETS   | December<br>31, 2006 | July 31,<br>2006     | 2005                 |
|--|----------------------|----------------------|----------------------|
| Current Assets:  |                      |                      |                      |
| Cash and cash equivalents  | \$ 16,586,000        | \$ 5,687,000         | \$ 4,680,000         |
| Short-term investments   | 3,690,000            | 4,451,000            | 3,543,000            |
| Accounts receivable from related parties, net of allowances:   |                      |                      |                      |
| \$54,000   |                      |                      | 108,000              |
| Inventories  | 32,000               | 585,000              | 549,000              |
| Investment in marketable equity security available for sale  | 466,000              | 560,000              |                      |
| Prepaid expenses and other current assets  | 572,000              | 491,000              | 306,000              |
| Total Current Assets   | 21,346,000           | 11,774,000           | 9,186,000            |
| Property and equipment, net  | 2,611,000            | 2,704,000            | 2,991,000            |
| Other assets   | 359,000              | 344,000              | 351,000              |
| Investment in non-marketable equity security, at cost  |                      |                      | 500,000              |
| <b>TOTAL ASSETS</b>  | <b>\$ 24,316,000</b> | <b>\$ 14,822,000</b> | <b>\$ 13,028,000</b> |
| <b>LIABILITIES AND STOCKHOLDERS EQUITY</b>   |                      |                      |                      |
| Current Liabilities:   |                      |                      |                      |
| Accounts payable   | 798,000              | 845,000              | 1,179,000            |
| Accrued expenses and other current liabilities   | 2,061,000            | 1,111,000            | 1,064,000            |
| Current portion of deferred revenue  | 162,000              | 162,000              | 162,000              |
| Current portion of capitalized lease obligation  | 125,000              | 82,000               |                      |
| Total Current Liabilities  | 3,146,000            | 2,200,000            | 2,405,000            |
| Non-current portion of deferred revenue  | 2,444,000            | 2,512,000            | 2,674,000            |
| Non-current portion of capitalized lease obligation  | 128,000              | 65,000               |                      |
| Total Liabilities  | 5,718,000            | 4,777,000            | 5,079,000            |
| <b>COMMITMENTS AND CONTINGENCIES</b>   |                      |                      |                      |
| <b>STOCKHOLDERS EQUITY</b>   |                      |                      |                      |
| Preferred stock, \$.001 par value:   |                      |                      |                      |
| Authorized 1,000,000 shares, none issued   |                      |                      |                      |
| Common stock, \$.001 par value:  |                      |                      |                      |
| Authorized 100,000,000 shares, Issued 58,358,818, 49,123,869 and 40,597,318 at December 31, 2006, July 31, 2006, and July 31, 2005, respectively | 58,000               | 49,000               | 41,000               |
| Additional paid-in capital   | 66,860,000           | 54,417,000           | 42,305,000           |
| Accumulated deficit  | (48,280,000 )        | (44,475,000 )        | (34,391,000 )        |
| Accumulated other comprehensive income (loss)  | (34,000 )            | 60,000               |                      |
| Less: Treasury stock, at cost, 3,012 shares  | (6,000 )             | (6,000 )             | (6,000 )             |
| Total Stockholders Equity  | 18,598,000           | 10,045,000           | 7,949,000            |
| <b>TOTAL LIABILITIES AND STOCKHOLDERS EQUITY</b>   | <b>\$ 24,316,000</b> | <b>\$ 14,822,000</b> | <b>\$ 13,028,000</b> |

See accompanying notes to financial statements.

F-2

---

## NOVADEL PHARMA INC.

## STATEMENTS OF OPERATIONS

FOR THE FIVE MONTHS ENDED DECEMBER 31, 2006 AND 2005

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

|  | Five Months Ended<br>December 31, |                     | Year Ended July 31, |                 |                 |
|--|-----------------------------------|---------------------|---------------------|-----------------|-----------------|
|  | 2006                              | 2005<br>(Unaudited) | 2006                | 2005            | 2004            |
| License Fees and Milestone Payments Earned from Related Parties                                  | \$ 2,067,000                      | \$ 568,000          | \$ 1,662,000        | \$ 141,000      | \$ 13,000       |
| Consulting Revenues from Related Parties   |                                   | 109,000             | 228,000             | 298,000         | 453,000         |
| Total Revenues   | 2,067,000                         | 677,000             | 1,890,000           | 439,000         | 466,000         |
| Research and Development Expenses  | 3,396,000                         | 2,082,000           | 5,275,000           | 3,826,000       | 2,492,000       |
| Consulting, Selling, General and Administrative Expenses   | 3,123,000                         | 3,347,000           | 7,179,000           | 6,391,000       | 4,627,000       |
| Total Expenses   | 6,519,000                         | 5,429,000           | 12,454,000          | 10,217,000      | 7,119,000       |
| Loss From Operations   | (4,452,000 )                      | (4,752,000 )        | (10,564,000 )       | (9,778,000 )    | (6,653,000 )    |
| Interest Income  | 180,000                           | 67,000              | 224,000             | 87,000          | 98,000          |
| Loss Before Income Tax Benefit   | (4,272,000 )                      | (4,685,000 )        | (10,340,000 )       | (9,691,000 )    | (6,555,000 )    |
| Income Tax Benefit   | (467,000 )                        | (256,000 )          | (256,000 )          | (241,000 )      | (214,000 )      |
| Net Loss   | \$ (3,805,000 )                   | \$ (4,429,000 )     | \$ (10,084,000 )    | \$ (9,450,000 ) | \$ (6,341,000 ) |
| Basic and Diluted Loss Per Common Share  | \$ (.08 )                         | \$ (.11 )           | \$ (.23 )           | \$ (.27 )       | \$ (.24 )       |
| Weighted Average Number of Common Shares Used in Computation of Basic and Diluted Loss Per Share | 49,522,000                        | 40,619,000          | 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 FIVE MONTHS ENDED DECEMBER 31, 2006

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

|   | Common Stock |           | Additional<br>Paid-In<br>Capital | Accumulated<br>Deficit | Accumulated<br>Other<br>Comprehensive<br>Income | Treasury<br>Stock | Total<br>Stockholders<br>Equity |
|---|--------------|-----------|----------------------------------|------------------------|---|-------------------|---------------------------------|
|   | Shares       | Amount    |                                  |                        |   |                   |                                 |
| 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                      |
| Share-based compensation expense  | 100,000      |           | 498,000                          |                        |   |                   | 498,000                         |
| Stock issued in connection with private placement, net of costs           | 8,862,069    | 9,000     | 11,740,000                       |                        |   |                   | 11,749,000                      |
| Stock issued for options and warrants exercised                           | 272,880      |           | 205,000                          |                        |   |                   | 205,000                         |
| Comprehensive income (loss):  |              |           |                                  |                        |   |                   |                                 |
| Unrealized loss on investment in marketable equity security               |              |           |                                  |                        | (94,000 )                                       |                   | (94,000 )                       |
| Net loss  |              |           |                                  | (3,805,000 )           |   |                   | (3,805,000 )                    |
| Total comprehensive loss  |              |           |                                  |                        |   |                   | (3,899,000 )                    |
| BALANCE, December 31, 2006  | 58,358,818   | \$ 58,000 | \$ 66,860,000                    | \$ (48,280,000 )       | \$ (34,000 )                                    | \$ (6,000 )       | \$ 18,598,000                   |

See accompanying notes to financial statements.





## NOVADEL PHARMA INC.

## STATEMENTS OF CASH FLOWS

FOR THE FIVE MONTHS ENDED DECEMBER 31, 2006 AND 2005

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

|   | Five Months Ended<br>December 31, |                     | Year Ended July 31, |                     |                     |
|---|-----------------------------------|---------------------|---------------------|---------------------|---------------------|
|   | 2006                              | 2005<br>(Unaudited) | 2006                | 2005                | 2004                |
| <b>CASH FLOWS FROM OPERATING ACTIVITIES</b>   |                                   |                     |                     |                     |                     |
| Net loss  | \$ (3,805,000 )                   | \$ (4,429,000 )     | \$ (10,084,000 )    | \$ (9,450,000 )     | \$ (6,341,000 )     |
| Adjustments to reconcile net loss to net cash used in operating activities:                     |                                   |                     |                     |                     |                     |
| Stock and warrants issued for services  |                                   |                     |                     | 318,000             |                     |
| Amortization of discount on short-term investments  | (53,000 )                         |                     |                     |                     |                     |
| Share-based compensation expense  | 498,000                           | 520,000             | 1,201,000           |                     |                     |
| Impact of variable plan accounting  |                                   |                     |                     | (106,000 )          | (736,000 )          |
| Inventory reserve   | 551,000                           |                     | 55,000              |                     |                     |
| Depreciation and amortization   | 286,000                           | 202,000             | 583,000             | 380,000             | 222,000             |
| Changes in operating assets and liabilities:  |                                   |                     |                     |                     |                     |
| Accounts receivable from related parties  |                                   | 32,000              | 108,000             | 22,000              | (128,000 )          |
| Inventories   | 2,000                             | 6,000               | (91,000 )           | (549,000 )          |                     |
| Prepaid expenses and other current liabilities  | (81,000 )                         | (200,000 )          | (185,000 )          | (51,000 )           | (87,000 )           |
| Other assets  | (15,000 )                         |                     | 7,000               |                     | 6,000               |
| Accounts payable  | (47,000 )                         | (721,000 )          | (334,000 )          | 938,000             | 102,000             |
| Accrued expenses and other current liabilities  | 950,000                           | 785,000             | 47,000              | 266,000             | 480,000             |
| Deferred revenue  | (68,000 )                         | (68,000 )           | (162,000 )          | 1,974,000           | 362,000             |
| Net cash used in operating activities   | (1,782,000 )                      | (3,873,000 )        | (8,855,000 )        | (6,258,000 )        | (6,120,000 )        |
| <b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>  |                                   |                     |                     |                     |                     |
| Purchases of property and equipment   | (54,000 )                         | (116,000 )          | (130,000 )          | (2,305,000 )        | (487,000 )          |
| Purchases of short-term and long-term investments   | (1,310,000 )                      | (1,300,000 )        | (5,751,000 )        | (5,180,000 )        | (9,560,000 )        |
| Maturities of short-term and long-term investments  | 2,124,000                         | 3,848,000           | 4,843,000           | 9,155,000           | 2,042,000           |
| Net cash provided by (used in) investing activities   | 760,000                           | 2,432,000           | (1,038,000 )        | 1,670,000           | (8,005,000 )        |
| <b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>  |                                   |                     |                     |                     |                     |
| Proceeds from issuance of common stock through private placements                               | 11,749,000                        |                     | 10,593,000          | 6,309,000           | 12,785,000          |
| Proceeds from options and warrants exercised  | 205,000                           |                     | 326,000             | 219,000             | 445,000             |
| Proceeds from shares of common stock issued to Hana Biosciences, Inc.                           |                                   |                     |                     | 636,000             |                     |
| Payments of capitalized lease obligations   | (33,000 )                         |                     | (19,000 )           | (62,000 )           | (25,000 )           |
| Net cash provided by financing activities   | 11,921,000                        |                     | 10,900,000          | 7,102,000           | 13,205,000          |
| <b>NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS</b>                                     | <b>10,899,000</b>                 | <b>(1,441,000 )</b> | <b>1,007,000</b>    | <b>2,514,000</b>    | <b>(920,000 )</b>   |
| <b>CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD</b>   | <b>5,687,000</b>                  | <b>4,680,000</b>    | <b>4,680,000</b>    | <b>2,166,000</b>    | <b>3,086,000</b>    |
| <b>CASH AND CASH EQUIVALENTS, END OF PERIOD</b>   | <b>\$ 16,586,000</b>              | <b>\$ 3,239,000</b> | <b>\$ 5,687,000</b> | <b>\$ 4,680,000</b> | <b>\$ 2,166,000</b> |
| <b>SUPPLEMENTAL DISCLOSURE OF NONCASH INVESTING AND FINANCING ACTIVITIES:</b>                   |                                   |                     |                     |                     |                     |
| Investment in Hana Biosciences, Inc. common stock received in connection with license agreement | \$                                | \$                  | \$                  | \$ 500,000          | \$                  |
| Equipment acquired under capitalized lease obligation   | \$ 139,000                        | \$                  | \$ 166,000          | \$                  | \$ 87,000           |
| Treasury stock acquired   | \$                                | \$                  | \$                  | \$                  | \$ 6,000            |

See accompanying notes to financial statements.

F-5

---

**NOVADEL PHARMA INC.**

**NOTES TO FINANCIAL STATEMENTS**

**NOTE 1 - NATURE OF THE BUSINESS**

NovaDel Pharma Inc. (the Company) is a specialty pharmaceutical company developing oral spray formulations of a broad range of marketed treatments. The Company's oral spray therapeutics are administered by a novel application drug delivery system for presently marketed prescription, over-the-counter, or 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 December 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.

All financial information as of December 31, 2005 and for the five months ended December 31, 2005 included in the notes to the financial statements is unaudited.

**NOTE 2 - LIQUIDITY AND BASIS OF PRESENTATION**

The Company has reported a net loss of \$3,805,000, \$10,084,000, \$9,450,000 and \$6,341,000 and negative cash flows from operating activities of \$1,782,000, \$8,855,000, \$6,258,000, and \$6,120,000 for the five months ended December 31, 2006 and for the fiscal years ended July 31, 2006, 2005, and 2004, respectively. As of December 31, 2006, the Company had working capital of \$18,200,000, cash and cash equivalents of \$16,586,000 and short-term investments of \$3,690,000. Until and unless the Company's 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. The Company's 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 the Company's equity or debt securities or bridge loans to the Company from third-party lenders, license payments from existing, 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 it is able to obtain will be sufficient to meet its needs. On December 27, 2006, the Company completed an equity financing in which it received proceeds, net of offering costs, of \$13,144,000 of which \$11,749,000 was received in December 2006 and \$1,395,000 was received in January 2007. Given the current and desired pace of development of its product candidates, the Company estimates that it will have sufficient cash on hand to fund development of its product candidates through December 31, 2007. The Company may, however, choose to raise additional capital before December 31, 2007 to fund future development activities or to take advantage of other strategic opportunities. This could include the securing of funds through new strategic partnerships and/or the sale of common stock or other securities. There can be no assurance that such capital will be available to the Company on favorable terms, or at all.

## Edgar Filing: NOVADEL PHARMA INC - Form 10-K

There are a number of risks and uncertainties related to the Company's attempt to complete a financing or strategic partnering arrangement that are outside its control. The Company may not be able to obtain additional financing on terms acceptable to it, or at all. If the Company is unsuccessful at obtaining additional financing as needed, it may be required to significantly curtail or cease operations. The Company will need additional financing thereafter until it achieves profitability, if ever.

F-6

---

**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.

**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 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 maturities when purchased greater than three months and less than one year.

**FINANCIAL INSTRUMENTS** - Financial instruments include cash and cash equivalents, short-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 five months ended December 31, 2006 and 2005 and the years ended July 31, 2006, 2005 and 2004, the Company contributed approximately \$34,000, \$39,000, \$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.

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

## 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.

F-7

---

## Edgar Filing: NOVADEL PHARMA INC - Form 10-K

**LOSS PER SHARE** Loss per common share is computed pursuant to SFAS No. 128, Earnings Per Share. Basic loss per common 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 December 31, 2006, July 31, 2006, 2005 and 2004, there were 38.4 million, 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 common share computation. Subsequent to December 31, 2006, in accordance with its remuneration practices, the Company issued an additional 3.1 million stock options, including (i) 1.8 million to existing executive officers and directors; (ii) 0.8 million to new executive officers and directors; and (iii) 0.5 million to existing and new employees.

**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 revised Accounting for Stock-Based Compensation, ( SFAS 123 ) and superseded 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 requires 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. The Company recorded share-based compensation of approximately \$498,000, or \$0.01 per share, and \$520,000 or \$0.01 per share for the five months ended December 31, 2006 and 2005, respectively, and \$1,201,000, or \$0.03 per share, for the fiscal year ended July 31, 2006. The Company will continue to incur share-based compensation charges in future periods. As of December 31, 2006, unamortized stock-based compensation expense of \$2.7 million remains to be recognized, which is comprised of \$1.9 million to be recognized over a weighted average period of 1.8 years, \$0.2 million related to restricted stock to be recognized over a weighted average period of 3.0 years, and \$0.6 million related to performance-based stock options which vest upon reaching certain milestones. Expenses related to the performance-based stock options will be recognized if and when the Company determines that it is probable that the milestone will be reached.

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 the Company's 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:

|  | <b>Fiscal Year Ended July 31,</b> |                     |
|--|-----------------------------------|---------------------|
|  | <b>2005</b>                       | <b>2004</b>         |
| 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 )          |
| <br>Pro forma net loss   | <br>\$ (10,410,000 )              | <br>\$ (7,872,000 ) |
| <br>Basic and diluted net loss per common share:   |                                   |                     |
| As reported  | \$ (0.27 )                        | \$ (0.24 )          |
| <br>Pro forma net loss   | <br>(0.30 )                       | <br>(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:

|  | <b>December 31,</b> | <b>July 31,</b> | <b>July 31,</b> |
|--|---------------------|-----------------|-----------------|
|  | <b>2006</b>         | <b>2006</b>     | <b>2005</b>     |
| Equipment  | \$ 2,407,000        | \$ 2,215,000    | \$ 1,912,000    |
| Furniture and fixtures                                 | 455,000             | 455,000         | 455,000         |
| Leasehold improvements                                 | 1,432,000           | 1,472,000       | 1,479,000       |
|  | 4,294,000           | 4,142,000       | 3,846,000       |
| <br>Less: Accumulated depreciation<br>and amortization | <br>1,683,000       | <br>1,438,000   | <br>855,000     |
|  | \$ 2,611,000        | \$ 2,704,000    | \$ 2,991,000    |

The Company had total fixed assets of \$570,000 and inventories of \$32,000 at the facilities of INyX as of December 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 December 31, 2006, the Company had total gross fixed assets of \$351,000, with an accumulated depreciation of \$22,000, 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 for the five months ended December 31, 2006 and 2005; and \$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 for the five months ended December 31, 2006 and 2005; and \$0, \$1,000 and \$186,000 for the years ended July 31, 2006, 2005 and 2004, respectively, pursuant to its consulting agreement with Mr. Klein (including finder fees relating to the Company's licensing agreements).

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. In December 2005, pursuant to the Separation Agreement, the Company paid Dr. Shangold a separation payment of \$150,000. Pursuant to the Consulting Agreement, the Company paid Dr. Shangold \$125,000 and \$0 for the five months ended December 31, 2006 and 2005, respectively, and \$175,000 for the fiscal year ended July 31, 2006.

In September 2006, the Company's Board of Directors appointed Steven B. Ratoff as Chairman of the Board. In connection with Mr. Ratoff's appointment as Chairman of the Board, the Board entered into a consulting arrangement to compensate Mr. Ratoff for his efforts. This arrangement is on a month-to-month basis and compensates Mr. Ratoff at a rate of \$17,500 per month. Pursuant to this consulting arrangement, the Company paid Mr. Ratoff approximately \$61,000 for the five months ended December 31, 2006. In March 2007, Mr. Ratoff's monthly compensation was reduced to \$10,000 to reflect his decreased day-to-day time involvement at the Company.

**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 Biosciences 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**

**PRIVATE PLACEMENTS** In December 2006, the Company completed a private placement of 9,823,983 shares of common stock, at a purchase price of \$1.45 per share and warrants to purchase up to approximately 3,929,593 shares of common stock at an exercise price of \$1.70 per share. The Company received proceeds, net of offering costs, of \$13,144,000 of which \$11,749,000 was received in December 2006 and \$1,395,000 was received in January 2007. As such, the Company issued 8,862,069 shares in December 2006 and 961,914 shares in January 2007 for this private placement.

F-10

---

## Edgar Filing: NOVADEL PHARMA INC - Form 10-K

Oppenheimer & Co. Inc. acted as the lead placement agent for this private placement, with Griffin Securities, Inc. acting as co-placement agent. The placement agents received compensation for acting as placement agents made up of cash compensation equal to 7% of the proceeds from the sale of the common stock, or \$997,000, and warrants to purchase shares of common stock equal to 5% of the shares of common stock purchased, subject to certain exclusions, or warrants to purchase 491,199 shares (such warrants have the same terms as those issued to the investors), plus expenses. On the date of grant, the warrants had an approximate fair value of \$0.89 per warrant. 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.

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. On the date of grant, the warrants had an approximate fair value of \$0.92 per warrant. 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.

In May 2005, the Company closed a private placement of 6,733,024 shares of common stock and 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. 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). On the date of grant, the warrants had an approximate fair value of \$0.66 per warrant. 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. On the date of grant, the warrants had an approximate fair value of \$0.88 per warrant. 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 December 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.

F-11

---

**NOTE 7 - COMMITMENTS AND CONTINGENCIES**

**EMPLOYMENT AGREEMENTS** - At December 31, 2006, the Company had employment agreements with four officers of the Company providing for an aggregate salary of \$885,000, \$300,000, and \$278,000 in the years ending December 31, 2007, 2008 and 2009, respectively, 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, Dr. Bergstrom's agreement in December 2009, 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. As of January 4, 2007, Mr. Cohen ceased to be an officer of the Company. On March 16, 2007, the Company and Mr. Cohen entered into a Separation Agreement and General Release (the Settlement/Release Agreement) pursuant to which the Employment Agreement between the Company and Mr. Cohen was terminated. The Settlement/Release Agreement will provide Mr. Cohen with payments of approximately \$114,000 over a six-month period. In addition, Mr. Cohen will receive a bonus payment in the amount of \$34,200 and a grant of 10,000 options for certain licensing agreements closed during 2006. Mr. Cohen is also entitled to a continuation of health benefits for a period of six months. Mr. Cohen released the Company from any further obligations related to his departure.

On February 22, 2007, the Company entered into an employment agreement with Dr. Deni Zodda which will expire on February 21, 2010. Dr. Zodda will be paid an annual base salary of \$275,000. See Note 12.

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.

**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 five months ended December 31, 2006 and 2005 and for the years ended July 31, 2006, 2005 and 2004, the Company invoiced Manhattan Pharmaceuticals approximately \$0, \$0, \$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 five months ended December 31, 2006 and 2005 and for the years ended July 31, 2006, 2005 and 2004, the Company invoiced Velcera approximately \$0, \$109,000, \$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

Edgar Filing: NOVADEL PHARMA INC - Form 10-K

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.

F-12

---

## Edgar Filing: NOVADEL PHARMA INC - Form 10-K

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 five months ended December 31, 2006 and the fiscal year ended July 31, 2006, the Company received \$1,000,000 and \$1,500,000, respectively, in milestone payments from Hana Biosciences. During the five months ended December 31, 2006 and 2005 and for the years ended July 31, 2006, 2005, and 2004, the Company invoiced Hana Biosciences approximately \$0, \$0, \$13,000, \$84,000, and \$0, respectively, for pass-through expenses incurred by the Company on behalf of 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 December 31, 2006, the Company has aggregate capital lease obligations of \$253,000 of which \$125,000, \$75,000, and \$53,000 are scheduled to be paid in the years ending December 31, 2007, 2008, and 2009, 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 area charges. 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 five months ended December 31, 2006 and 2005 and for the fiscal years ended July 31, 2006, 2005 and 2004, the Company paid rent of approximately \$184,000, \$223,000, \$495,000, \$521,000, and \$477,000, respectively.

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

Years Ending December 31,

|            |             |
|------------|-------------|
| 2007       | \$332,000   |
| 2008       | \$343,000   |
| 2009       | \$366,000   |
| 2010       | \$366,000   |
| 2011       | \$366,000   |
| Thereafter | \$609,000   |
|            | \$2,382,000 |

### **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



## Edgar Filing: NOVADEL PHARMA INC - Form 10-K

account for those shares using the cost method through October 2005 and thereafter as marketable equity securities. At December 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 \$466,000 at December 31, 2006 and, accordingly, the Company has included its \$34,000 unrealized loss in accumulated comprehensive loss, a separate component of stockholders' equity, as of December 31, 2006. At December 31, 2006, the Company believes the decrease in the fair value of these shares to be temporary and no charge for impairment in the statement of operations is required.

F-13

---

**NOTE 9 ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES**

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

|                            | December 31, 2006 | July 31, 2006 | July 31, 2005 |
|----------------------------|-------------------|---------------|---------------|
| Accrued compensation       | \$ 503,000        | \$ 396,000    | \$ 383,000    |
| Professional fees          | 229,000           | 70,000        | 244,000       |
| Accrued milestone payments | 312,000           | 312,000       | 312,000       |
| Product development costs  | 782,000           | 112,000       |               |
| Insurance premiums         | 178,000           | 127,000       |               |
| Property and Equipment     |                   |               | 70,000        |
| Other                      | 57,000            | 94,000        | 55,000        |
|                            | \$ 2,061,000      | \$ 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:

|                                  | December 31, 2006 | July 31, 2006 | July 31, 2005 |
|----------------------------------|-------------------|---------------|---------------|
| Stock-based compensation         | \$ 560,000        | \$ 397,000    | \$            |
| Net operating loss carryforwards | 14,828,000        | 14,511,000    | 10,671,000    |
| Deferred revenue                 | 1,043,000         | 1,070,000     | 1,196,000     |
| Inventory reserve                | 242,000           |               |               |
| Property and equipment           | (157,000)         | (157,000)     | (36,000)      |
| Other                            | 182,000           | 49,000        | 21,000        |
| Total gross deferred tax assets  | 16,698,000        | 15,870,000    | 11,852,000    |
| Valuation allowance              | (16,698,000)      | (15,870,000)  | (11,852,000)  |
| Net deferred tax assets          | \$                | \$            | \$            |

At December 31, 2006, the Company had federal and state net operating loss carryforwards for financial reporting and income tax purposes of approximately \$39.9 million and \$21.0 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 the five months ended December 31, 2006 and for fiscal years ended July 31, 2006, 2005 and 2004 were \$0.8 million, \$4.0 million, \$3.8 million and \$2.7 million, respectively.

The tax benefits expected based on the Company's pre-tax loss, utilizing the applicable statutory rates, have been reduced to an actual benefit of \$467,000 and \$256,000 in the five months ended December 31, 2006 and 2005, respectively; and \$256,000, \$241,000 and \$214,000 in the fiscal years ended July 31, 2006, 2005 and 2004, 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.

F-14

---

## Edgar Filing: NOVADEL PHARMA INC - Form 10-K

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

|                                 | <b>Five Months Ended</b> |                    | <b>Year Ended July 31,</b> |             |             |
|---------------------------------|--------------------------|--------------------|----------------------------|-------------|-------------|
|                                 | <b>December 31,</b>      | <b>2005</b>        | <b>2006</b>                | <b>2005</b> | <b>2004</b> |
|                                 | <b>2006</b>              | <b>(Unaudited)</b> |                            |             |             |
| Federal tax at statutory rate   | (34.0% )                 | (34.0% )           | (34.0% )                   | (34.0% )    | (34.0% )    |
| State income tax                | (6.0% )                  | (6.0% )            | (6.0% )                    | (6.0% )     | (6.0% )     |
| Other                           | (0.3% )                  |                    |                            | 0.3%        | (4.5% )     |
| Sale of net operating losses    | (10.9% )                 | (5.5% )            | (2.5% )                    | (2.5% )     | (3.3% )     |
| Increase in valuation allowance | 40.3%                    | 40.0%              | 40.0%                      | 39.7%       | 44.5%       |
|                                 | (10.9% )                 | (5.5% )            | (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 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.

**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 \$467,000 and \$256,000 for the five months ended December 31, 2006 and 2005, respectively; and \$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 \$21.5 million as of December 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, or at all.

### **NOTE 11 - STOCK OPTIONS AND WARRANTS**

At December 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 number 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 December 31, 2006, there were approximately 5.0 million shares available for issuance under the Plans. Subsequent to December 31, 2006, in accordance with its remuneration practices, the Company issued an additional 3.1 million stock options, including (i) 1.8 million to existing executive officers and directors; (ii) 0.8 million to new executive officers and directors; and (iii) 0.5 million to existing and new employees.

Edgar Filing: NOVADEL PHARMA INC - Form 10-K

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

F-15

---

Edgar Filing: NOVADEL PHARMA INC - Form 10-K

| <b>Options</b>                   | <b>Shares (000)</b> | <b>Weighted-Average Exercise Price</b> | <b>Weighted-Average Remaining Contractual Terms (Years)</b> | <b>Aggregate Intrinsic Value (\$000)</b> |
|----------------------------------|---------------------|--|---|--|
| 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                                   |
| Outstanding at August 1, 2006    | 8,177               | \$ 1.64                                |   |  |
| Grants                           | 900                 | 1.71                                   |   |  |
| Exercises                        | (242 )              | \$ .75                                 |   |  |
| Cancellations                    | (60 )               | 1.56                                   |   |  |
| Outstanding at December 31, 2006 | 8,775               | \$ 1.68                                | 4.5   | \$ 1,203                                 |
| Exercisable at December 31, 2006 | 5,313               | \$ 1.73                                | 3.1   | \$ 973                                   |

The Company recorded share-based compensation for options using the fair value method required by SFAS 123R of approximately \$498,000 or \$0.01 per share, and \$520,000 or \$0.01 per share for the five months ended December 31, 2006 and 2005, respectively, and \$1,201,000 or \$0.03 per share, for the fiscal year ended July 31, 2006, which amounts are included in the Company's net loss for each period.

During the five months ended December 31, 2006, the Company did not grant any additional stock options other than the December 2006 grant of 900,000 performance-based stock options which vest upon reaching certain milestones. Previously, the Company had not granted performance-based stock options. In addition, during the five months ended December 31, 2006, the Company granted 100,000 shares of restricted stock to an executive of the Company with a grant price equal to the fair market value on the date of grant, or \$1.71 per share. The restricted stock vests ratably over a three-year period ending on the third anniversary of the grant, or December 4, 2009. Such performance-based stock options and restricted stock had a de minimus impact on the Company's net loss for the five months ended December 31, 2006. As of December 31, 2006, unamortized stock-based compensation expense of \$2.7 million remains to be recognized, which is comprised of \$1.9 million to be recognized over a weighted average period of 1.8 years, \$0.2 million related to restricted stock to be recognized over a weighted average period of 3.0 years, and \$0.6 million related to performance-based stock options which vest upon reaching certain milestones. Expenses related to the performance-based stock options will be recognized if and when the Company determines that it is probable that the milestone will be reached.

The Company used the following weighted average assumptions in determining fair value under the Black-Scholes model for grants in the respective periods:

|                                      | <b>Five Months Ended</b> |                         | <b>Year Ended</b>    |
|--------------------------------------|--------------------------|-------------------------|----------------------|
|                                      | <b>December 31, 2006</b> | <b>2005 (Unaudited)</b> | <b>July 31, 2006</b> |
| Expected volatility                  | 60%                      | 64%                     | 64%                  |
| Dividend yield                       | 0%                       | 0%                      | 0%                   |
| Expected term until exercise (years) | 2.5                      | 4.3                     | 4.5                  |
| Risk-free interest rate              | 4.4%                     | 4.1%                    | 4.3%                 |



## Edgar Filing: NOVADEL PHARMA INC - Form 10-K

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, the effects of such resulting adjustment will be recorded in the period estimates are revised. The weighted average grant date fair value of options granted was \$0.63 and \$0.86 during the five months ended December 31, 2006 and 2005, respectively, and \$0.86 during the fiscal year ended July 31, 2006. The total intrinsic value of options exercised was \$137,000 and \$0 during the five months ended December 31, 2006 and 2005, respectively, and \$261,000 for the fiscal year ended July 31, 2006.

At December 31, 2006, there were approximately 4.7 million non-plan options reserved for issuance.

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

| Price Range   | Number of Warrants Outstanding and Exercisable 000's | Remaining Contractual Life (Years) |
|---------------|--|------------------------------------|
| \$0.01 - 0.99 | 10,078   | 2.1                                |
| \$1.00 - 1.99 | 15,775   | 3.5                                |
| \$2.00        | 900  | 1.2                                |
| Totals        | 26,753   |                                    |

### NOTE 12 SUBSEQUENT EVENTS

On February 26, 2007, the Board of Directors (the "Board") of the Company announced its appointment of Dr. Deni M. Zodda as the Company's Chief Business Officer. There was no arrangement or understanding between Dr. Zodda and any other persons pursuant to which Dr. Zodda was appointed Chief Business Officer.

The Company and Dr. Zodda entered into an Employment Agreement, dated as of February 22, 2007 (the "Employment Agreement"). The term of the Employment Agreement commenced on February 22, 2007 and expires on February 21, 2010. The material terms of the Employment Agreement are set forth below. In addition, the Company and Dr. Zodda entered into an Incentive Stock Option Agreement and a Nonqualified Stock Option Agreement, both dated as of February 22, 2007 (the "Option Agreements"), pursuant to which the Company granted to Dr. Zodda incentive stock options to purchase 68,027 shares of common stock of the Company and non-qualified stock options to purchase 598,973 shares of common stock of the Company. The material terms of the Option Agreements are also set forth below.

**Base salary:** Pursuant to the Employment Agreement, the Company will pay Dr. Zodda a base salary of \$275,000 per annum, payable in equal semi-monthly installments (the "Base Salary").

**Bonuses:** The Company shall pay Dr. Zodda a cash bonus of up to 30% of his Base Salary, provided, however, that such bonus shall be payable only upon the successful achievement of certain performance milestones related to Dr. Zodda's role in the Company, which milestones shall be defined and enumerated by mutual agreement between Dr. Zodda and the President and Chief Executive Officer of the Company within the first month of Dr. Zodda's employment with the Company, and again at the same time in each succeeding year during the term of the Employment Agreement. The amount of bonus paid to Dr. Zodda shall be increased or decreased from time to time at the discretion of the Compensation Committee of the Board.



Stock Options: Pursuant to the Employment Agreement, the Company granted Dr. Zodda incentive stock options to purchase 68,027 shares of common stock of the Company and non-qualified stock options to purchase 598,973 shares of common stock of the Company. Such option grants will have a term of ten (10) years. The stock options shall vest upon achievement of performance milestones; so that 22,676 incentive stock options and 200,324 non-qualified stock options will vest on the signing of a Board approved third party agreement for U.S. or worldwide rights of sumatriptan; 22,676 incentive stock options and 199,324 non-qualified stock options will vest on the signing of a Board approved third party agreement for U.S. or worldwide rights of zolpidem; and 22,675 incentive stock options and 199,325 non-qualified stock options will vest upon approval by the Board of any third party agreement whereby the Company obtains the right to

F-17

---

Edgar Filing: NOVADEL PHARMA INC - Form 10-K

develop a product incorporating an active pharmaceutical ingredient that is the subject of a then valid U.S. Patent (or in-process U.S. Patent Application) and already approved for sale by the U.S. Food and Drug Administration with sales in the U.S. of at least \$100 million. Such options will expire on February 21, 2017. The exercise price of each option is \$1.47 (the closing price of the Company's common stock on February 22, 2007, as listed on the American Stock Exchange).

Severance: If Dr. Zodda's employment is terminated by the Company prior to the expiration of the term of the Employment Agreement or if terminated by Dr. Zodda for Good Reason (as defined in the Employment Agreement). Dr. Zodda will receive certain severance payments and benefits, which vary depending upon the reason for the termination of the Employment Agreement, and which are fully described in the Employment Agreement attached hereto. In addition, upon termination, certain options will vest and certain options will be terminated either at the date of termination of the Employment Agreement or at a later date, varying in both cases, depending upon the reason for the termination, all as fully described in the Employment Agreement and the Option Agreements. If Dr. Zodda's Employment Agreement were to not be renewed at the expiration of the term thereof by the Company, Dr. Zodda will receive certain severance payments and benefits, as fully described in the Employment Agreement, and all of his outstanding options will be deemed to be vested and will expire 90 days after the date of nonrenewal.

At the Company's Annual Meeting of stockholders in January 2007, the Company's stockholders approved an amendment to the Company's Certificate of Incorporation to increase the number of authorized shares of the Company's common stock from 100,000,000 to 200,000,000.

**NOTE 13 VALUATION AND QUALIFYING ACCOUNTS**

| Accounts                                   | Balance<br>Beginning<br>of Year | Additions<br>Charged<br>to Cost<br>and<br>Expense | Charged<br>to Other<br>Accounts | Deductions | Balance End<br>of Year |
|--|---------------------------------|---|---------------------------------|------------|------------------------|
| <b>Five months ended December 31, 2006</b> |                                 |   |                                 |            |                        |
| Allowance for doubtful accounts            | \$ 54,000                       | \$  | \$                              | \$         | \$ 54,000              |
| Deferred tax valuation allowance           | 15,870,000                      | 828,000   |                                 |            | 16,698,000             |
| Allowance for inventory obsolescence       | 55,000                          | 551,000   |                                 |            | 606,000                |
| <b>Year ended July 31, 2006</b>            |                                 |   |                                 |            |                        |
| 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                 |
| <b>Year ended July 31, 2005</b>            |                                 |   |                                 |            |                        |
| Allowance for doubtful accounts            | \$                              | \$ 54,000   | \$                              | \$         | \$ 54,000              |
| Deferred tax valuation allowance           | 8,001,000                       | 3,851,000   |                                 |            | 11,852,000             |
| <b>Year ended July 31, 2004</b>            |                                 |   |                                 |            |                        |
| Deferred tax valuation allowance           | \$ 5,300,000                    | \$ 2,701,000                                      | \$                              | \$         | \$ 8,001,000           |

Edgar Filing: NOVADEL PHARMA INC - Form 10-K

**NOTE 14 QUARTERLY RESULTS OF OPERATIONS (UNAUDITED)**

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

|  | Three Months<br>Ended<br>October<br><br>31, 2006 | Two Months<br>Ended<br>December<br><br>31, 2006 | Five<br>Months Ended<br>December<br><br>31, 2006 |
|--|--|---|--|
| Total Revenues   | \$ 1,041,000                                     | 1,026,000                                       | \$ 2,067,000                                     |
| Total Expenses   | 3,656,000  | 2,863,000                                       | 6,519,000  |
| Loss from Operations   | (2,615,000 )                                     | (1,837,000 )                                    | (4,452,000 )                                     |
| Interest Income  | 106,000  | 74,000  | 180,000  |
| Income Tax Benefit   |  | (467,000 )                                      | (467,000 )                                       |
| Net Loss   | \$ (2,509,000 )                                  | \$ (1,296,000 )                                 | \$ (3,805,000 )                                  |
| Basic and Diluted Loss Per<br>Common Share   | \$ (.05 )  | \$ (.03 )                                       | \$ (.08 )  |
| Weighted Average Number of<br>Shares of Common Stock Used<br>in Computation of Basic and<br>Diluted Loss Per Share | 49,213,000                                       | 49,987,000                                      | 49,522,000                                       |

|  | <b>Three Months Ended</b> |                     |                 |                 | Fiscal Year<br>Ended July 31,<br>2006 |
|--|---------------------------|---------------------|-----------------|-----------------|---------------------------------------|
|  | October 31,<br>2005       | January 31,<br>2006 | April 30, 2006  | 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<br>Common Share   | \$ (0.06 )                | \$ (0.07 )          | \$ (0.05 )      | \$ (0.05 )      | \$ (0.23 )                            |
| Weighted Average Number of<br>Shares of Common Stock Used in<br>Computation of Basic and Diluted<br>Loss Per Share | 40,606,000                | 40,648,000          | 41,715,000      | 48,991,000      | 43,000,000                            |

F-19

---

Edgar Filing: NOVADEL PHARMA INC - Form 10-K

**Three Months Ended**

|  | October 31,<br>2004 | January 31,<br>2005 | April 30, 2005  | July 31, 2005   | Fiscal Year<br>Ended July 31,<br>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<br>Common Share   | \$ (0.07 )          | \$(0.08 )           | \$ (0.08 )      | \$ (0.05 )      | \$(0.27 )                             |
| Weighted Average Number of<br>Shares of Common Stock Used in<br>Computation of Basic and Diluted<br>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 Transition Report on Form 10-K. 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         | Certificate of Amendment to Certificate of Incorporation of the Company         | Filed herewith   |
| 3.3         | 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  |
| 4.3         | Form of Warrant issued to certain accredited investors and the placement agents | Incorporated by reference to Exhibit 4.1 of the Company's Current Report on Form 8-K filed with the SEC on January 4, 2007                                   |
| 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)   |

Edgar Filing: NOVADEL PHARMA INC - Form 10-K

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)            |
| 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 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   |





## Edgar Filing: NOVADEL PHARMA INC - Form 10-K

|        |   |  |
|--------|---|--|
| 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 |
| 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* | 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   |
| 10.28* | 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                                      |
| 10.29* | 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                                      |
| 10.30* | 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                                      |
| 10.31* | 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                                      |
| 10.32* | 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                                      |
| 10.33  | 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   |
| 10.34  | 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   |
| 10.35  | 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

|        |   |   |
|--------|---|---|
| 10.36* | Employment Agreement dated December 4, 2006 by and between the Company and David H. Bergstrom, Ph.D.  | Incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K, as filed with the SEC on December 8, 2006  |
| 10.37* | Incentive Stock Option Award between the Company and David H. Bergstrom dated December 4, 2006  | Incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K, as filed with the SEC on December 8, 2006  |
| 10.38* | Nonqualified Stock Option Award between the Company and David H. Bergstrom, dated December 4, 2006  | Incorporated by reference to Exhibit 10.3 of the Company's Current Report on Form 8-K, as filed with the SEC on December 8, 2006  |
| 10.39  | 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 Current Report on Form 8-K, as filed with the SEC on January 4, 2007   |
| 10.40  | Placement Agent Agreement, dated as of November 21, 2006, by and between the Company and Oppenheimer & Co., Inc.                                | Incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K, as filed with the SEC on January 4, 2007   |
| 10.41* | Employment Agreement dated February 22, 2007 by and between the Company and Deni M. Zodda, Ph.D.  | Incorporated by reference to Exhibit 10.1 of the Company's Current Report on form 8-K, as filed with the SEC on February 28, 2007 |
| 10.42* | Incentive Stock Option Award between the Company and Deni M. Zodda dated February 22, 2007  | Incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K, as filed with the SEC on February 28, 2007 |
| 10.43* | Nonqualified Stock Option Award between the Company and Deni M. Zodda dated February 22, 2007   | Incorporated by reference to Exhibit 10.3 of the Company's Current Report on Form 8-K, as filed with the SEC on February 28, 2007 |
| 10.44* | Amendment No. 2 to Employment Agreement dated March 12, 2007 by and between the Company and Michael E. Spicer                                   | Filed herewith  |
| 10.45* | Amendment 2007-1 to the NovaDel Pharma Inc. 1998 Stock Option Plan dated March 2, 2007  | Filed herewith  |
| 10.46* | Amendment 2007-1 to the NovaDel Pharma Inc. 2006 Equity Incentive Plan dated March 2, 2007  | Filed herewith  |
| 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  |
| 31.2   | Certification of Principal Financial Officer under Rule 13a-14(a)   | Filed herewith  |
| 32.1   | Certifications of the Chief Executive Officer and Chief Financial Officer under 18 USC 1350   | Filed herewith  |