NOVADEL PHARMA INC
Form 10-K
March 26, 2007

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

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

OR

x 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	22-2407152
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

25 MINNEAKONING ROAD, FLEMINGTON, NEW JERSEY 08822

(Address of principal executive offices) (Zip Code)

(908) 782-3431

Registrant s telephone number, including area code

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

Title of each class	Name of each exchange on which registered
COMMON STOCK, PAR VALUE $.001 PER SHARE	**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-know seasoned issuer, as defined in Rule 405 of the Securities Act. Yes o No x

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 o No x

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 x No o

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. o

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 o Accelerated filer o Non-accelerated filer x

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

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

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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.

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.

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.

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

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

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

- NitroMist (nitroglycerin lingual aerosol). This product candidate is 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.

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.

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 NDA s 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 Zensana , 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).

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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 deminimus 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;

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

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.

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.

Under the Federal Food, Drug and Cosmetic Act, or FFDCA, as amended (21 U.S.C. 301 et. seq.), a new drug may not be commercialized or otherwise distributed in the U.S. without the prior approval of the FDA or pursuant to an applicable exemption from the FFDCA.

The FDA approval process relating to a new drug differs, depending on the nature of the particular drug for which approva