NOVADEL PHARMA INC
Form 10-K
March 31, 2010

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

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

For the year ended December 31, 2009

OR

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

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.)

1200 ROUTE 22 EAST, SUITE 2000, BRIDGEWATER, NEW JERSEY 08807
(Address of principal executive offices) (Zip Code)

(908) 203-4640
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 $0.001 per share	OTCBB

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 whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes o No o

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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. x

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

Large accelerated filer o	Accelerated filer o
Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company 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, 2009, the aggregate market value of the voting and non-voting common equity of the issuer held by non-affiliates of the registrant was approximately $17 million based upon the closing sale price of $0.31 for the Registrant's common stock, $0.001 par value, as reported by the NYSE Amex LLC, formerly known as the American Stock Exchange on that date. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of March 24, 2010, the issuer had 89,283,000 shares of common stock, $0.001 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, 2009) are incorporated by reference into Part III of this Annual Report on Form 10-K.

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NOVADEL PHARMA INC.

ANNUAL REPORT ON FORM 10-K
FOR THE YEAR ENDED DECEMBER 31, 2009

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

Examples of the risks and uncertainties include, but are not limited to: the inherent risks and uncertainties in developing products of the type the Company is developing (independently and through collaborative arrangements); the inherent risks and uncertainties in completing the pilot pharmacokinetic feasibility studies being conducted by the Company; possible changes in the Company's financial condition; the progress of the Company's research and development; clinical trials require adequate supplies of drug substance and drug product, which may be difficult or uneconomical to procure or manufacture; timely obtaining sufficient patient enrollment in the Company's clinical trials; the impact of development of competing therapies and/or technologies by other companies; the Company's ability to obtain additional required financing to fund its research programs; the Company's ability to enter into agreements with collaborators and the failure of collaborators to perform under their agreements with the Company; the progress of the 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 Annual Report on Form 10-K and other reports, including this report and other filings filed with the Securities and Exchange Commission from time to time.

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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 for a broad range of marketed pharmaceuticals. Our proprietary technology offers, in comparison to conventional oral dosage forms, the potential for faster absorption of drugs into the bloodstream leading to quicker onset of therapeutic effects and possibly lower doses. Oral sprays eliminate the requirement for water or the need to swallow, potentially improving patient convenience and compliance. Our oral spray technology is focused on addressing unmet medical needs for a broad array of existing and future pharmaceutical products. Our most advanced oral spray candidates target angina, insomnia, erectile dysfunction, migraine headaches, nausea and disorders of the central nervous system. We plan to develop these and other products independently and through collaborative arrangements with pharmaceutical and biotechnology companies. Currently, we have nine patents which have been issued in the U.S. and 69 patents which have been issued outside of the U.S. Additionally, we have over 65 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 formulate these compounds in conjunction with our proprietary drug delivery method. Once formulated, we file for new patent applications on these formulated 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 for our product candidates.

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

- Significant prescription sales already exist;
- Our proprietary novel drug delivery technology enhances the performance of the active ingredient of the target compound, potentially addressing unmet patient needs; 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.

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.

We have a history of recurring losses, giving rise to an accumulated deficit as of December 31, 2009 of $82,766,000, as compared to $74,829,000 as of December 31, 2008. Additionally, we have had negative cash flow from operating activities of $1,578,000 for the year ended December 31, 2009, $5,533,000 for the year ended December 31, 2008, and $15,240,000 for the year ended December 31, 2007. As of December 31, 2009, we had negative working capital of $495,000 as compared to $47,000 as of December 31, 2008, representing a net decrease in working capital of approximately $542,000.

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Throughout 2009, our reduced clinical development activities were limited to expenditures required to support our two approved products NitroMist™ and Zolpimist™ and minor expenditures to support formulation development activities for certain other products. We will seek to raise additional capital in 2010 to fund our operations and future development activities through new strategic partnerships or collaborations, the sale of common stock or other equity securities or the issuance of debt. In the event we do not enter into a license agreement or other strategic transaction in which we receive an upfront fee or payment, or we do not undertake a financing of debt or equity securities, we may not have sufficient cash on hand to fund operations. We can give no assurances that we will be able to enter into a strategic transaction or raise any additional capital or, if we do, that such additional capital will be sufficient to meet our needs, or on terms favorable to us. If we are unable to raise additional capital, and we do not use our existing working capital to fund our development plans, we will have sufficient cash on hand to fund operating costs through the fourth quarter 2010. We will need additional financing thereafter until we achieve profitability.

Our audited financial statements for the year ended December 31, 2009 were prepared under the assumption that we will continue our operations as a going concern. We were incorporated in 1982, and have a history of losses. As a result, our independent registered public accounting firm in their audit report has expressed substantial doubt about our ability to continue as a going concern. We believe that the cash inflows that have been generated from our financing transactions and our licensing transactions and any additional potential cash inflows that may be received during 2010 and 2011will improve our ability to continue our operations as a going concern. Continued operations are dependent on our ability to complete equity or debt formation activities or to generate profitable operations. Such capital formation activities may not be available or may not be available on reasonable terms. Our financial statements do not include any adjustments that may result from the outcome of this uncertainty.

As previously disclosed on May 14, 2008, we received notice from the NYSE Amex LLC (formally known as the American Stock Exchange) indicating that we are not in compliance with certain of the NYSE Amex LLC continued listing standards. We submitted a plan of compliance with NYSE Amex LLC, which was accepted, and attempted to regain compliance with such plan during fiscal year 2009. On December 2, 2009, we formally notified NYSE Amex LLC of our intent to voluntarily withdraw our listing and registration due to our failure to regain compliance with the continued listing standards and our plan. On December 14, 2009, we filed a Form 25 voluntarily withdrawing our listing and registration from NYSE Amex LLC. The final day of trading on NYSE Amex LLC was December 23, 2009. On December 24, 2009, our common stock began trading on the Over-the-Counter Bulletin Board, or OTCBB, under its new ticker symbol on OTCBB as NVDL.OB.

Highlights for the year ended December 31, 2009, and additionally through the date of filing of this Annual Report on Form 10-K, include the following product development and business achievements:

Product Pipeline

- After careful review of our portfolio of product opportunities we have selected Sildenafil Citrate (Viagra®) as our next product to develop. Our development plans anticipate that our oral spray formulation, Duromist™, will be available for launch in the first half of 2012.

Intellectual Property

- Announced that we received a Notice of Allowance from the United States Patent and Trademark Office, or USPTO, for claims under U.S. Patent Application No. 10/671,715, entitled “Buccal, Polar and Non-polar Spray Containing Zolpidem,” which covers a method of treating insomnia by administering zolpidem to humans utilizing NovaMist™ Oral Spray technology. Once issued, this patent will expire in 2018.

- Announced that we received an Issue Notification from the USPTO for a new U.S. Patent, No. 7632517, entitled “Buccal, Polar and Non-polar Spray Containing Zolpidem,” which covers a method of treating insomnia by administering zolpidem to humans utilizing NovaDel's oral spray technology.

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Other

- Announced that Michael E. Spicer resigned as Chief Financial Officer and Corporate Secretary, effective April 1, 2009. Our Board of Directors appointed Deni M. Zodda, Ph.D., our Chief Business Officer, to serve as Interim Chief Financial Officer, Principal Financial Officer and Corporate Secretary, effective April 1, 2009. We also hired Joseph M. Warusz as a consultant to serve as Principal Accounting Officer, effective April 1, 2009.

- Announced that Deni M. Zodda, Ph.D., Chief Business Officer, Interim Chief Financial Officer and Corporate Secretary, agreed to leave the Company resulting from a reorganization of the executive team. Mr. Zodda has entered into a Separation, Consulting and General Release Agreement under which he received a one-time fee of $137,500 to provide us with certain consulting services through October 31, 2009. Steven B. Ratoff, our Chairman, President and Chief Executive Officer, has been appointed our Interim Chief Financial Officer.

- Announced the Board of Directors appointed Steven B. Ratoff as President and Chief Executive Officer effective January 1, 2010. Mr. Ratoff will continue to serve as Interim Chief Financial Officer.

- Announced we executed a lease amendment modifying certain terms to the lease for the property in Flemington, New Jersey. The amendment converted the lease term to month to month commencing on July 1, 2009 with a provision that either party may terminate the lease upon thirty days written notice. We have released the lease escrow of $226,000 to the landlord in order to satisfy rent payments through June 30, 2009. This lease was terminated in December 2009.

- Effective February 1, 2010, we entered into a one (1) year lease agreement with Regus Management Group LLC for approximately 5,000 square feet of office space in Bridgewater, New Jersey.

- Announced that we entered into an agreement with Seaside 88, LP, or Seaside. Under the terms of the agreement and subject to the approval of the NYSE Amex LLC, Seaside has committed to purchase up to 13.0 million NovaDel common shares, in a series of closings every two weeks in the amount of 500,000 shares each for a total of up to 26 purchases. We had received approval from NYSE Amex LLC to issue up to 12.0 million shares over twelve (12) months. As of March 24, 2010, we have received $200,140 in gross proceeds for 2010. On March 26, 2010, we mutually agreed to terminate the common stock purchase agreement with Seaside 88, LP.

- Announced we entered into an agreement with Arthur W. Wood Company, Inc., or AWW, pursuant to which AWW agreed to assist us as a non-exclusive financial advisor for the purposes of seeking capital related to the Seaside offering, referred to herein as the Placement. In consideration of AWW's services, we agreed to pay AWW upon closing of a capital-raising transaction, a fee equal to three percent (3%) of the aggregate value of the proceeds paid or payable in the Placement.

- Announced we received a milestone payment of approximately $150,000 from Velcera, Inc., or Velcera, relating to its License and Development Agreement with Velcera, dated June 22, 2004.

- Announced we entered into a license and distribution agreement with privately-held Mist Acquisition, LLC to manufacture and commercialize the NitroMist™ lingual spray version of nitroglycerine, a widely-prescribed and leading short-acting nitrate for the treatment of angina pectoris, in the United States, Canada and Mexico. Under the terms of the agreement, we received a $1,000,000 licensing fee upon execution of the agreement, and will receive milestone payments totaling an additional $1,000,000 over the next twelve months and ongoing performance payments of up to seventeen percent (17%) of net sales, subject to the terms of the agreement.

- Announced we entered into an exclusive license and distribution agreement with ECR Pharmaceuticals Company, Inc. to commercialize and manufacture our ZolpiMist™ product in the United States and Canada. ZolpiMist™ is our oral

spray formulation of zolpidem tartrate, which was approved by the FDA in December of 2008. Under the terms of the agreement, we received $3,000,000 upon the execution of the agreement and ECR will pay us ongoing performance payments of up to 15% of net sales on branded products and a lesser percent of net sales on authorized generic products, subject to the terms of the agreement.

- Announced that we notified NYSE Amex LLC of our intent to voluntarily delist our common stock from the Exchange. We filed Form 25 on December 14, 2009, voluntarily withdrawing our listing and registration from NYSE Amex LLC. The final day of trading on NYSE Amex LLC was December 23, 2009. Our common stock began trading on the OTCBB on December 24, 2009. Our new ticker symbol on OTCBB is NVDL.OB.

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- Announced we entered into an amendment agreement with ProQuest Investments L.P. and its affiliates, referred to herein as ProQuest, to convert the outstanding aggregate principal balance of all convertible notes and all liquidated damages notes, in each case, plus all accrued but unpaid interest, in an aggregate amount equal to $3,657,000 to 23,237,083 shares of our common stock as of December 31, 2009.

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 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 submission of an NDA, will require significantly less time and 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. We anticipate generating revenues in 2010 from our existing licensed products, Zolpimist™ and NitroMist™. 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 or changes in the regulatory approval process;
- 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.

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We expect to spend significant amounts on the development of certain of our product candidates and we expect our costs to increase if we restart certain programs to develop and ultimately commercialize our product candidates. The following table summarizes our product candidates:

	Active Ingredient or Class of Molecule	Indications	Stage of Development	Partner
Approved Products				
NitroMist™	nitroglycerin	Angina Pectoris	FDA Approved	Mist Acquisition, LLC
Zolpimist™	zolpidem	Insomnia	FDA Approved	ECR Pharmaceuticals Company
Product Candidates				
Duromist™	sildenafil	Erectile Dysfunction	Preclinical development	-
Zensana™	ondansetron	Nausea/Vomiting	Clinical development	Hana Biosciences/Par Pharmaceutical, Inc./BioAlliance Pharma S.A.
NVD-201	sumatriptan	Migraines	Pilot Efficacy study complete	-
NVD-301	midazolam	Pre-Procedure Anxiety	Preclinical development	-

NitroMist™ (nitroglycerin lingual aerosol). This product is indicated for acute relief of an attack or acute prophylaxis of angina pectoris due to coronary artery disease, and was approved by the FDA in November 2006. Previously, this product was partnered with Par Pharmaceutical, Inc., or Par; however, on August 1, 2007, we announced that Par returned the rights to NitroMist™ to us as part of Par's strategy to concentrate its resources on supportive care in AIDS and oncology markets. Our former contract manufacturer for NitroMist™, INyX Pharma, filed for protection under the Chapter 11 bankruptcy laws in 2007, and ceased operations at its facility in Puerto Rico where our product was to be manufactured during 2008. As a result, we selected an alternative contract manufacturer, DPT Laboratories. On October 27, 2009, we entered into a licensing and distribution agreement with privately-held Mist Acquisition, LLC, or Mist, to manufacture and commercialize the NitroMist™ in the United States, Canada and Mexico. Under the terms of the agreement, Mist paid us a $1,000,000 licensing fee upon execution of the agreement, and will pay us milestone payments totaling an additional $1,000,000 over the next twelve months if certain milestones are met and ongoing performance payments of up to seventeen percent (17%) of net sales. In addition, Mist will assume the activities and costs necessary for the completion of the product transfer to DPT Laboratories.

Zolpimist™ (zolpidem oral spray). Zolpidem is the active ingredient in Ambien®, the leading hypnotic for insomnia marketed by Sanofi-Aventis. Our oral spray formulation of zolpidem was approved for the short-term treatment of insomnia by the FDA in December 2008. In October 2009, we received a Notice of Allowance from the United States

Patent and Trademark Office, or USPTO for claims which cover a method of treating insomnia by administering zolpidem to humans utilizing NovaMist™ Oral Spray technology. On November 13, 2009, we entered into an exclusive license and distribution agreement with ECR Pharmaceuticals Company, Inc. to commercialize and manufacture our ZolpiMist™ in the United States and Canada. Under the terms of the agreement, we received a $3,000,000 licensing fee and will receive ongoing performance payments of up to 15% of net sales on branded products and a lesser percent of net sales on authorized generic products.

Duromist™ (Sildenafil oral spray). Duromist™ contains sildenafil, the leading PDE-5 inhibitor for the treatment of erectile dysfunction marketed under the brand name Viagra®. We believe that an oral spray of sildenafil has the potential of a faster onset of action and a lower dose compared to tablets.

Erectile dysfunction occurs in approximately 18% of the male population with prevalence of over 50% in men over 65 years of age. PDE-5 inhibitors are effective in approximately 75% of the erectile dysfunction population. Sildenafil is the most popular molecule with over 50% market share in a erectile dysfunction market of over $3 billion.

Development is in progress for a formulation to be used in future clinical trials to begin in 2010, with a development plan that would deliver a FDA approved product available for launch in the second quarter of 2012.

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Zensana™ (ondansetron oral spray). Ondansetron is the active ingredient in Zofran®, the leading anti-emetic marketed by GlaxoSmithKline, or GSK. Through July 31, 2007, this product candidate was licensed to Hana Biosciences, who was overseeing all clinical development and regulatory approval activities for this product in the U.S. and Canada. On July 31, 2007, we entered into a Product Development and Commercialization Sublicense Agreement with Hana Biosciences and Par, pursuant to which Hana Biosciences granted a sublicense to Par to develop and commercialize Zensana™. Par is responsible for all development, regulatory, manufacturing and commercialization activities of Zensana™ in the United States and Canada, including the development and re-filing of the NDA in the United States. In addition, we entered into an Amended and Restated License Agreement with Hana Biosciences, pursuant to which Hana Biosciences relinquished its right to pay reduced royalty rates to us until such time as Hana Biosciences had recovered one-half of its costs and expenses incurred in developing Zensana™ from sales of Zensana™ and we agreed to surrender for cancellation all 73,121 shares of the Hana Biosciences common stock we acquired in connection with execution of the original license agreement with Hana Biosciences. Par had previously announced that it expected to complete clinical development on the revised formulation of Zensana™ during 2008, and expected to submit a new NDA for Zensana™ by the end of 2008. However, in November 2008, Par announced that it had completed bioequivalency studies on Zensana™ with mixed results, with bioequivalence to reference drug (Zofran® tablets) achieved in some of the studies and not achieved in others. We have notified Hana and Par that under the terms of our agreement, they are required to return the product to us.

On May 19, 2008, we entered into an agreement with BioAlliance Pharma S.A., whereby BioAlliance acquired the European rights for our ondansetron oral spray. Under the terms of the agreement, BioAlliance paid us a license fee of $3,000,000 upon closing. We are eligible for additional milestone payments totaling approximately $24 million (an approval milestone of $5,000,000 and sales-related milestone payments of approximately $19 million) as well as a royalty on net sales. We anticipate that their development activities will not be initiated until development is completed in the United States.

Sumatriptan oral spray (NVD-201). Sumatriptan is the active ingredient in Imitrex® which is the largest selling migraine remedy marketed by GSK. A pilot PK study of NVD-201 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 NVD-201 which demonstrated that NVD-201 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. NVD-201 was evaluated in a four-arm, crossover pharmacokinetic study comparing 50mg Imitrex® tablets to 20mg and 30mg of the NVD-201 in 10 healthy male volunteers under fasting conditions. At least 90% of subjects receiving NVD-201 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 NVD-201 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 NVD-201 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 NVD-201 in comparison to the Imitrex® tablet. Additionally, the pharmacokinetics of 20mg NVD-201 after a meal were evaluated. NVD-201 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 NVD-201 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 NVD-201 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 NVD-201 appears to be greater than published estimates for the same dose of the Imitrex® nasal spray.

In September 2008, we announced the results from a pilot efficacy study for NVD-201. This was a multi-center, active control, open-label, dose-ranging, efficacy and safety study. Subjects received up to 5 treatments, comprising single doses of the following: Imigran® 50-mg tablets, Imigran® 100-mg tablets, NVD-201 20-mg, NVD-201 30-mg, and NVD-201 40-mg. Their response to Imigran® 50-mg tablets determined whether they were eligible to receive the other four treatments. Patients recorded the severity of each migraine attack on the same 4-point scale immediately before dosing and at 15, 30, 60, 90, 120, and 240 minutes, and at 24 hours post-dosing. Associated symptoms (nausea, vomiting, photophobia, and phonophobia) were also recorded immediately before dosing and at 30, 60, 90 and 120 minutes post-dosing. All dosing was done on an outpatient basis and patients returned to the clinic between migraine attacks.

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In the primary analysis of efficacy, the percentage of patients responding to treatment at or before 60 minutes post-dosing, there was a statistically significant greater percentage of subjects receiving the 30- and 40-mg doses of NVD-201 with a reduction in headache pain compared to those receiving the 50-mg s Imigran® tablet (42% and 46%, respectively, vs 12%; P<0.011), and was comparable to the percentage who responded to the higher (100 mg) dose of the tablet formulation (42%). Significantly more patients had responded to all three doses of NVD-201 than to 50-mg Imigran® tablet by 90 minutes post-dosing (57% to 70.0% vs 32%; P<0.028) and all three oral spray doses were comparable to the 100-mg tablet. There were no treatment differences by 2 hours after dosing, when 68% to 77% of patients had responded irrespective of treatment.

Compared to 50-mg Imigran® tablet, at least one dose of NVD-201 also significantly increased percentage of patients who were pain free by 1 to 2 hours post-dosing, with the response ratio indicating significantly faster complete pain relief for the 40-mg dose, and significantly more patients had complete pain relief without use of rescue medication after receiving any dose of NVD-201. In addition, after one or more doses of NVD-201, the percentage of patients who were asymptomatic was significantly increased, and the percentages who experienced nausea, photophobia, or phonophobia were significantly decreased. NVD-201 was comparable to the 100-mg tablet on all the above measures.

We believe NVD-201 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, we believe NVD-201 may be attractive to patients who have trouble taking oral medications due to nausea and vomiting caused by the migraine attack. Previously, we were targeting an NDA submission for our sumatriptan product candidate in the first half of calendar 2008; however, due to funding constraints and other higher priorities associated with our current product pipeline, we have not progressed our development efforts.

We will continue to evaluate this program when sufficient additional funding becomes available.

Midazolam oral spray (NVD-301). NVD-301 contains midazolam which is the leading benzodiazepine used for sedation during diagnostic, therapeutic and endoscopic procedures. We believe that NVD-301 has the potential to be an easy-to use, rapid onset product useful to relieve the pre-procedure anxiety suffered by many patients prior to undergoing a wide variety of procedures performed in hospitals, imaging centers, ambulatory surgery centers and dental offices.

Annually, there are approximately 40 million invasive procedures performed in the ambulatory surgical setting, > 25 million MRI/CT scans and over 90 million pediatric dental procedures performed. Pre- procedure anxiety occurs in approximately 60% of children undergoing surgery and is associated with an increase in post-surgical complications including delirium, pain and sleep disorders, as well as higher levels of use of post-surgical medications. Anxiety interferes with approximately 30% of MRI scans with 5-10% of scans not completed due to anxiety. Pre-procedure anxiety is the number one reason for the use of sedation in dental procedures.

As of the current date, we have not yet secured sufficient financing to resume our clinical development activity. There can be no assurances that we will be able to secure additional capital, and as a result, there can be no assurances as to whether, and when, we will be able to resume our clinical development activities.

Propofol oral spray. Propofol is the active ingredient in Diprivan®, a leading intravenous anesthetic marketed by AstraZeneca. On July 10, 2007, Manhattan Pharmaceuticals, our licensee, announced its intention to pursue appropriate sub-licensing opportunities for this product candidate.

Veterinary. Our veterinary initiatives are being carried out largely by our partner, Velcera, Inc., or Velcera. In June 2007, Velcera announced that it had entered into a global license and development agreement with Novartis Animal Health. The agreement calls for Novartis Animal Health to develop, register and commercialize a novel canine

product utilizing Velcera's Promist™ platform, which is based on our patented oral spray technology. On March 5, 2008, Velcera announced that it had received notice from Novartis that it was terminating the agreement without cause. On August 24, 2009, we issued a press release to announce that we received a milestone payment of approximately $150,000 from Velcera, Inc. relating to our License and Development agreement dated June 22, 2004. This milestone payment resulted from Velcera's recently announced global licensing agreement for the first canine pain management product delivered in a transmucosal mist form.

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