NOVADEL PHARMA INC
Form 424B3
November 12, 2010

Prospectus Supplement filed under Rule 424(b)(3)
in connection with Registration No. 333-167425

PROSPECTUS SUPPLEMENT NO. 2 DATED NOVEMBER 12, 2010
(To Prospectus Dated June 29, 2010)

NOVADEL PHARMA INC.

This is a supplement ("Prospectus Supplement No. 2") to our prospectus, dated June 29, 2010 (the "Prospectus"), relating to the offer and sale by certain selling securities holders of up to 7,583,335 shares of our common stock, par value $0.001 per share, issuable upon the exercise of five year warrants and six month warrants, each issued pursuant to the March 31, 2010 securities purchase agreement, referred to collectively herein as the Warrants.

This Prospectus Supplement No. 2 is not complete without, and may not be delivered or utilized except in connection with, the Prospectus, including any amendments or supplements thereto.

Quarterly Report on Form 10-Q for Fiscal Quarter Ended September 30, 2010

On November 12, 2010, we filed with the Securities and Exchange Commission a quarterly report on Form 10-Q for the fiscal quarter ended September 30, 2010. The quarterly report, as filed (but without the exhibits filed with the Form 10-Q), is set forth below.

The information contained in this Prospectus Supplement No. 2 supplements and supersedes, in relevant part, the information contained in the Prospectus, as amended and supplemented. This Prospectus Supplement No. 2 is incorporated by reference into, and should be read in conjunction with, the Prospectus, as amended and supplemented, and is not complete without, and may not be delivered or utilized except in connection with, the Prospectus, as amended and supplemented.

The Prospectus, together with Prospectus Supplement No. 2, constitute the prospectus required to be delivered by Section 5(b) of the Securities Act of 1933, as amended, with respect to offers and sales of the common stock as set forth in the Prospectus, as amended and supplemented. All references in the Prospectus to "this prospectus" are amended to read "this prospectus (as supplemented and amended)."

INVESTING IN OUR SECURITIES INVOLVES A HIGH DEGREE OF RISK. YOU SHOULD CONSIDER CAREFULLY THE RISK FACTORS BEGINNING ON PAGE 8 OF THE PROSPECTUS BEFORE PURCHASING ANY OF THE SECURITIES OFFERED.

NEITHER THE SECURITIES AND EXCHANGE COMMISSION NOR ANY STATE SECURITIES COMMISSION HAS APPROVED OR DISAPPROVED OF THESE SECURITIES OR PASSED UPON THE ADEQUACY OR ACCURACY OF THIS PROSPECTUS SUPPLEMENT NO. 2. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.

The date of this Prospectus Supplement No. 2 is dated November 12, 2010

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2010

or

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

For the transition period from _____ to _____ .

COMMISSION FILE NO. 001-32177

NOVADEL PHARMA INC.
(Exact name of registrant as specified in its charter)

| Delaware | 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

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
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 the definitions 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 o (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 Exchange Act). Yes o No x

As of November 1, 2010, the issuer had 98,383,458 shares of common stock, $0.001 par value, outstanding.

NovaDel Pharma Inc.

Form 10-Q
For the Quarterly Period Ended September 30, 2010

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

NovaDel Pharma Inc.
Condensed Balance Sheets

| | September 30, 2010 (unaudited) | December 31, 2009 (Note 1) |
|---|---|---|
| Assets | | |
| Current assets: | | |
| Cash and cash equivalents | $ 1,409,000 | $ 2,663,000 |
| Prepaid expenses and other current assets | 396,000 | 1,430,000 |
| Total current assets | 1,805,000 | 4,093,000 |
| | | |
| Property and equipment, net | 247,000 | 324,000 |
| Other assets | 7,000 | 36,000 |
| | | |
| Total assets | $ 2,059,000 | $ 4,453,000 |
| | | |
| | | |
| Liabilities and stockholders' deficiency | | |
| Current liabilities: | | |
| Accounts payable | $ 201,000 | $ 195,000 |
| Accrued expenses and other current liabilities | 107,000 | 117,000 |
| Derivative liability | 522,000 | — |
| Current portion of deferred revenue | 4,266,000 | 4,266,000 |
| Current portion of capital lease obligations | — | 10,000 |
| Total current liabilities | 5,096,000 | 4,588,000 |
| | | |
| Non-current portion of deferred revenue | 4,003,000 | 4,202,000 |
| Non-current portion of capital lease obligations | — | 4,000 |
| Total liabilities | 9,099,000 | 8,794,000 |
| | | |
| Commitments and contingencies | | |
| | | |
| Stockholders' deficiency: | | |
| Preferred stock, $.001 par value, 1,000,000 shares authorized, none issued and outstanding at September 30, 2010 and December 31, 2009, respectively | — | — |
| Common stock, $0.001 par value, 200,000,000 shares authorized, 98,383,458 and 88,343,457 shares issued and outstanding at September 30, 2010 and December 31, 2009, respectively | 99,000 | 89,000 |
| Additional paid-in capital | 79,363,000 | 78,342,000 |
| Accumulated deficit | (86,496,000) | (82,766,000) |
| Treasury stock, at cost, 3,012 shares | (6,000) | (6,000) |

| | | |
|---|---|---|
| Total stockholders' deficiency | (7,040,000) | (4,341,000) |
| Total liabilities and stockholders' deficiency | $ 2,059,000 | $ 4,453,000 |

See accompanying notes.

NovaDel Pharma Inc.
Condensed Statements of Operations

(Unaudited)

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2010 | 2009 | 2010 | 2009 |
| License and milestone fees earned | $66,000 | $223,000 | $261,000 | $356,000 |
| | | | | |
| Operating expenses | | | | |
| Research and development | 1,011,000 | 530,000 | 2,017,000 | 1,980,000 |
| General and administrative | 578,000 | 973,000 | 2,365,000 | 3,167,000 |
| Total operating expenses | 1,589,000 | 1,503,000 | 4,382,000 | 5,147,000 |
| | | | | |
| Loss from operations | (1,523,000) | (1,280,000) | (4,121,000) | (4,791,000) |
| | | | | |
| Other income (expense): | | | | |
| Derivative liability valuation adjustment | 210,000 | — | 391,000 | 360,000 |
| Loss on sale of fixed assets | — | — | — | (59,000) |
| Interest expense | — | (81,000) | (1,000) | (717,000) |
| Interest income | 1,000 | — | 1,000 | 6,000 |
| Total other income (expense) | 211,000 | (81,000) | 391,000 | (410,000) |
| | | | | |
| Net loss | $(1,312,000) | $(1,361,000) | $(3,730,000) | $(5,201,000) |
| | | | | |
| | | | | |
| Basic and diluted loss per common share | $(0.01) | $(0.02) | $(0.04) | $(0.09) |
| | | | | |
| Weighted average common shares outstanding – basic and diluted | 97,918,458 | 61,385,722 | 94,786,590 | 60,458,548 |
| | | | | |

See accompanying notes.

NovaDel Pharma Inc.
Condensed Statement of Changes in Stockholders' Deficiency

(Unaudited)

| | Common Stock | | Additional Paid-In Capital | Accumulated Deficit | Treasury Stock | Total Stockholders' Deficiency |
|---|---|---|---|---|---|---|
| | Shares | Amount | | | | |
| Balance, December 31, 2009 | 88,343,457 | $89,000 | $78,342,000 | $(82,766,000) | $(6,000) | $ (4,341,000) |
| Share-based compensation expense | — | — | 430,000 | — | — | 430,000 |
| Restricted stock cancelled | (60,000) | — | — | — | — | — |
| Issuance of Common Stock | 10,100,001 | 10,000 | 591,000 | — | — | 601,000 |
| Net loss for the nine month period | — | — | — | (3,730,000) | — | (3,730,000) |
| Balance, September 30, 2010 | 98,383,458 | $99,000 | $79,363,000 | $(86,496,000) | $(6,000) | $ (7,040,000) |

See accompanying notes.

NovaDel Pharma Inc.
Condensed Statements of Cash Flows

(Unaudited)

| | Nine Months Ended September 30, | |
|---|---|---|
| | 2010 | 2009 |
| Operating activities | | |
| Net loss | $(3,730,000) | $(5,201,000) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Share-based compensation expense | 430,000 | 251,000 |
| Expiration of warrants | — | (360,000) |
| Amortization of debt discount and deferred financing fees | — | 428,000 |
| Depreciation and amortization | 77,000 | 287,000 |
| Change in derivative liability fair value | (391,000) | — |
| Loss on sale of fixed assets | — | 59,000 |
| Changes in operating assets and liabilities: | | |
| Prepaid expenses and other current assets | 1,034,000 | 405,000 |
| Other assets | 12,000 | 227,000 |
| Accounts payable | 6,000 | 270,000 |
| Accrued expenses and other current liabilities | (10,000) | 254,000 |
| Deferred revenue | (199,000) | (199,000) |
| Net cash used in operating activities | (2,771,000) | (3,579,000) |
| | | |
| Investing activities | | |
| Return of lease deposits | 17,000 | — |
| Proceeds from sale of fixed assets | — | 41,000 |
| Net cash provided by investing activities | 17,000 | 41,000 |
| | | |
| Financing activities | | |
| Net proceeds from issuance of common stock and warrants | 1,514,000 | 644,000 |
| Payments of capital lease obligations | (14,000) | — |
| Payments of convertible note obligation | — | (1,000,000) |
| Payments of capital lease obligations | — | (107,000) |
| Net cash provided by (used in) financing activities | 1,500,000 | (463,000) |
| | | |
| Net decrease in cash and cash equivalents | (1,254,000) | (4,001,000) |
| | | |
| Cash and cash equivalents at beginning of period | 2,663,000 | 4,328,000 |
| | | |
| Cash and cash equivalents at end of period | $1,409,000 | $327,000 |
| | | |
| Supplemental disclosure of cash flow information | | |
| Cash paid for interest | $1,000 | — |
| Derivative liability | $913,000 | — |

| | | |
|---|---|---|
| Registration penalty notes issued | — | $159,000 |

See accompanying notes.

NovaDel Pharma Inc.
Notes to Condensed Financial Statements

(Unaudited)

Note 1 – Basis of Presentation

The accompanying unaudited condensed financial statements of NovaDel Pharma Inc. have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") for interim financial information pursuant to the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and disclosures required by GAAP for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring accrual adjustments) considered necessary for a fair presentation have been included. Operating results for the three and nine months ended September 30, 2010 are not necessarily indicative of the results that may be expected for other quarters or the year ending December 31, 2010. The December 31, 2009 condensed balance sheet was derived from audited financial statements but does not include all disclosures required by GAAP and included in the Form 10-K filing. For more complete information, these unaudited condensed financial statements and the notes thereto should be read in conjunction with the audited financial statements for the year ended December 31, 2009 included in the our Form 10-K filed with the Securities and Exchange Commission. References in this report to "NovaDel," "Company," "we," "us," and "our" refer to NovaDel Pharma Inc.

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and the accompanying notes. Actual results could differ from those estimates.

Certain reclassifications have been made to prior period amounts to conform to current period presentation.

Note 2 – The Company

NovaDel Pharma Inc. is a specialty pharmaceutical company developing oral spray formulations for a broad range of marketed pharmaceutical products. Our patented oral spray drug delivery technology seeks to improve the efficacy and safety of existing prescription pharmaceuticals, as well as patient compliance and patient convenience.

Note 3 – Liquidity and Going Concern

As of September 30, 2010, we had cash and cash equivalents of $1.4 million, negative working capital of $3.3 million, and an accumulated deficit of $86.5 million. Based on our operating plan, we expect that our existing cash and cash equivalents, along with the $500,000 milestone payment we received on October 29, 2010, will fund our operations only through December 31, 2010.

These conditions raise substantial doubt about our ability to continue as a going concern. The accompanying financial statements have been prepared assuming that we will continue as a going concern. Our financial statements do not include any adjustments that may result from the outcome of this uncertainty. This basis of accounting contemplates the recovery of our assets and the satisfaction of liabilities in the normal course of business.

Our management plans to address the expected shortfall of working capital by securing additional funding through equity financings, strategic alternatives or similar transactions. There can be no assurance that we will be able to obtain any sources of funding. If we are unsuccessful in securing funding from any of these sources, we will defer, reduce or eliminate certain planned expenditures.

Note 4 – Loss 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 loss per common share is the same as basic loss per common share, since potentially dilutive securities from the assumed exercise of all outstanding options and warrants, and from the conversion of the convertible notes, would have an anti-dilutive effect because the Company incurred a net loss during each period presented. As of September 30, 2010 and 2009, there were 33.3 million and 25.5 million common shares, respectively, issuable upon exercise of options and warrants, the vesting of non-vested restricted common stock, and the conversion of the convertible notes, all of which were excluded from the diluted loss per share computation.

Note 5 – Derivative Liability

Accounting Standard Codification "ASC" 815 – Derivatives and Hedging provides guidance on determining what types of instruments or embedded features in an instrument held by a reporting entity can be considered indexed to its own stock for the purpose of evaluating the first criteria of the scope exception in the pronouncement on accounting for derivatives. These requirements can affect the accounting for warrants and many convertible instruments with provisions that protect holders from a decline in the stock price (or "down-round" provisions). Warrants with such provisions will no longer be recorded in equity. Down-round provisions reduce the exercise price of a warrant or convertible instrument if a company either issues equity shares for a price that is lower than the exercise price of those instruments or issues new warrants or convertible instruments that have a lower exercise price. We evaluated whether warrants to acquire stock of the Company contain provisions that protect holders from declines in the stock price or otherwise could result in modification of the exercise price under the respective warrant agreements. We determined that the Series A and Series B Warrants contained such provisions, thereby concluding they were not indexed to the Company's own stock and were treated as derivative liabilities.

The Company estimated the fair value of the Series A and Series B Warrants as of March 31, 2010 to be $913,000 by recording a corresponding reduction in additional paid-in capital. The Series A Warrants have a term of 5 years and expire on March 31, 2015. The Series B Warrants had a term of 0.5 years and expired on September 30, 2010. The exercise price for the Series A and B Warrants are $0.25 per share. In accordance with this pronouncement, the Company estimated the fair value of the Series A and Series B Warrants at $913,000 and $732,000, as of March 31 and June 30, 2010, respectively. As of September 30, 2010, the fair value of these warrants was $522,000 resulting in a reduction in the derivative liability and a corresponding recognition of $210,000 and $391,000 in other income for the three and nine months ended September 30, 2010, respectively.

The Company utilizes the Black-Scholes option pricing model to estimate the fair value of these derivative instruments. The Company considers them to be Level 2 type instruments in accordance with ASC 820-10 - Fair Value Measurements and Disclosures as the inputs used to estimate their value are observable either directly or indirectly. The risk-free interest rate assumptions were based upon the observed interest rates appropriate for the remaining contractual term of the instruments. The expected volatility assumptions were based upon the historical volatility of the Company's common stock. The expected dividend yield was assumed to be zero as the Company has not paid any dividends since its inception and does not anticipate paying dividends in the foreseeable future. The expected term assumptions were based upon the remaining contractual terms of these instruments.

The assumptions used in the September 30, 2010 fair value measurement are as follows:

| | Series A Warrants | Series B Warrants |
|---|---|---|
| Discount Rate | 2.00 % | 2.00% |
| Volatility | 112 % | 112% |
| Expected Term | 4.5 years | 0 years(expired) |
| Dividend Yield | 0 % | 0% |

The assumptions used in the June 30, 2010 fair value measurement are as follows:

| | Series A Warrants | Series B Warrants |
|---|---|---|
| Discount Rate | 2.00 % | 2.00% |
| Volatility | 113 % | 113% |

| | | |
|---|---|---|
| Expected Term | 4.75 years | 0.25 years |
| Dividend Yield | 0 % | 0% |

The assumptions used in the March 31, 2010 fair value measurement are as follows:

| | Series A Warrants | Series B Warrants |
|---|---|---|
| Discount Rate | 2.00 % | 2.00% |
| Volatility | 140 % | 131% |
| Expected Term | 5 years | 0.5 years |
| Dividend Yield | 0 % | 0% |

Note 6 – Deferred Revenue from Licensing Agreements
As of September 30, 2010, the Company has the following deferred revenue from licensing agreements:

| | Total | Current | Non Current |
|---|---|---|---|
| ECR Pharmaceuticals Company, Inc. | $ 3,000,000 | $ 3,000,000 | $ - |
| Mist Acquisition, LLC | 1,000,000 | 1,000,000 | - |
| BioAlliance | 2,635,000 | 154,000 | 2,481,000 |
| Velcera | 1,048,000 | 75,000 | 973,000 |
| Other | 586,000 | 37,000 | 549,000 |
| Total | $ 8,269,000 | $ 4,266,000 | $ 4,003,000 |

ECR Pharmaceuticals Company, Inc. - In November 2009, we entered into an exclusive license and distribution agreement with ECR Pharmaceuticals Company, Inc. to commercialize and manufacture Zolpimist™ in the United States and Canada. Under the terms of the agreement, we received a $3,000,000 licensing fee from ECR upon execution of the agreement. We anticipate the licensing fee will be recognized in full in the current calendar year.

Mist Acquisition, LLC – In October 2009, we entered into a license and distribution agreement with Mist Acquisition, LLC to manufacture and commercialize NitroMist®, our lingual spray version of nitroglycerine, in the United States, Canada and Mexico. Under terms of the agreement, Mist paid us a $1,000,000 licensing fee upon execution of the agreement. We anticipate the licensing fee will be recognized in full in the current calendar year.

BioAlliance - In May 2008, the Company and BioAlliance Pharma SA entered into an agreement where BioAlliance acquired the European rights for Zensana™. Under the terms of the agreement, BioAlliance paid NovaDel a license fee of $3,000,000 upon closing and this fee is being recognized in income over the nineteen and one half-years term of the agreement.

Velcera - 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 propriety 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 is being recognized in income over the 20-year term of the agreement.

Note 7 – Commitments and Contingencies
Our major outstanding contractual obligations relate to our operating leases, employment agreements, consulting agreements, and license agreements with our strategic partners. Our Board of Directors appointed Steven B. Ratoff as President and Chief Executive Officer effective January 1, 2010 and Mr. Ratoff also served as Interim Chief Financial Officer until June 2010, when we appointed Mr. Craig Johnson as Senior Vice President, Chief Financial Officer and Secretary. In connection with Mr. Johnson's appointment, we entered into an Employment Agreement to compensate Mr. Johnson. Additionally, beginning February 1, 2010, we entered into a one (1) year lease agreement with Regus Management Group LLC for approximately 1,000 square feet of office space in Bridgewater, New Jersey.

Note 8 – Stockholders' Deficiency
Common Stock
On July 17, 2009, the Company entered into a common stock purchase agreement with Seaside 88, LP, whereby Seaside 88, LP would purchase 500,000 shares of common stock in a series of closings occurring every two weeks for a total of up to 26 closings, provided that the 3-day volume weighed average price prior to the scheduled closing was

greater than or equal to the stated floor price of $0.25 per share. The Company received net proceeds of $1,183,000 through March 31, 2010 of which $191,000 was received for 1,000,000 shares during the three months ended March 31, 2010. On March 26, 2010, we mutually agreed to terminate the common stock purchase agreement with Seaside 88, LP.

On March 31, 2010, the Company announced it would receive approximately $1.5 million in gross proceeds from its registered direct offering (the "Offering") of 9,100,001 shares of common stock, par value $0.001 per share (the "Common Shares"), at a price of $0.165 per share. The investors received five-year warrants (the "Series A Warrants") to purchase 4,550,001 shares of common stock with an exercise price of $0.25 per share and six-month warrants (the "Series B Warrants," together with the Common Shares and the Series A Warrants, the "Securities") to purchase 3,033,334 shares of common stock at an exercise price of $0.25 per share. The exercise price of the Series A and Series B Warrants are subject to adjustment as provided by such warrants (See Note 5). The Offering closed on March 31, 2010 and the Company sold the Securities pursuant to an effective registration statement. As of September 30, 2010, the Company recorded net proceeds of $1,323,000 relating to the Offering.

Stock Based Compensation

The Company recorded share-based compensation expense of $107,000 and $430,000 for the three and nine months ended September 30, 2010 and $98,000 and $251,000 for the three and nine months ended September 30, 2009, respectively. We will continue to incur share-based compensation charges in future periods. As of September 30, 2010, unamortized share-based compensation expense of $489,000 remains to be recognized, which is comprised of $299,000 related to non-performance based stock options to be recognized over a weighted average period of 1.25 years, $24,000 related to restricted stock to be recognized over a weighted average period of 0.3 years, and $166,000 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. No options were exercised during the three and nine months ended September 30, 2010 or September 30, 2009.

During the nine months ended September 30, 2010 and 2009, employees and non-employee directors of the Company were granted stock options under our 1998 and 2006 Stock Option Plans per the table below:

| Period Ended | Grants Issued | Weighted Average Exercise Price | Weighted Average Fair Value |
|---|---|---|---|
| September 30, 2010 | 900,000 | $ 0.19 | $ 0.13 |
| September 30, 2009 | 5,102,500 | $ 0.24 | $ 0.14 |

Note 9 – Related Party Transactions

In September 2006, the 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 was on a month-to-month basis, and ended in December 2009. Mr. Ratoff was compensated at a rate of between $10,000 and $17,500 per month depending upon the amount of his involvement at the Company. In January 2010, our Board of Directors appointed Steven B. Ratoff as President and Chief Executive Officer effective January 1, 2010, and the Company and Mr. Ratoff entered into an employment agreement in connection therewith.

Mr. Ratoff has served as a venture partner with ProQuest Investments, or ProQuest, since December 2004. Mr. Ratoff has no authority for investment decisions made by ProQuest. ProQuest owns approximately 35% of our common stock. In March 2010, ProQuest participated in the Offering. As of September 30, 2010, ProQuest owns 34.4 million shares of our common stock, which includes 4.8 million shares acquired in the Offering.

Note 10 – Recent Accounting Pronouncement

In April 2010, an accounting standard update was issued to provide guidance on defining a milestone and determining when it is appropriate to apply the milestone method of revenue recognition for research and development transactions. Vendors can recognize consideration that is contingent upon achievement of a milestone in its entirety as revenue in the period the milestone is achieved if the milestone meets all the criteria stated in the guidance to be considered substantive and must be considered substantive in its entirety. The amendments in this update were adopted by the Company during the three months ended June 30, 2010. The adoption did not have a significant impact on the Company's financial statements or disclosures.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion of our financial condition and results of operations should be read in conjunction with the financial statements and the notes to those statements included elsewhere in this Quarterly Report on Form 10-Q. The discussion includes forward-looking statements that involve risks and uncertainties. As a result of many factors, such as those set forth in Part II; Item 1A "Risk Factors" of this Quarterly Report on Form 10-Q, our actual results may differ materially from those anticipated in these forward looking statements.

Overview

Recent Developments

In July 2010, we initiated a non-IND pilot pharmacokinetic, or PK, clinical trial comparing Duromist™ to Viagra®. Duromist is our oral spray formulation of sildenafil. Viagra is the tablet formulation of sildenafil, developed and marketed by Pfizer. On October 15, 2010, we announced positive data from this trial. We intend to review the results from the trial with the U.S. Food and Drug Administration, or FDA, to obtain guidance on defining definitive clinical trial requirements as a pathway to new drug application, or NDA, approval. We plan to complete the clinical trial and to file a NDA in 2011.

On October 29, 2010, we received a $500,000 milestone payment under our license and distribution agreement with Mist Acquisition, LLC, or Mist. Mist is a subsidiary of Akrimax Pharmaceuticals, LLC.

On November 3, 2010, we announced that we have been awarded a $244,479 grant under the IRS' Qualifying Therapeutic Discovery Project program. We expect the grant to be fully funded in January 2011.

Company Overview

NovaDel Pharma Inc. is a specialty pharmaceutical company developing oral spray formulations for a broad range of marketed pharmaceutical products. Our patented oral spray drug delivery technology seeks to improve the efficacy and safety of existing prescription pharmaceuticals, as well as patient compliance and patient convenience. The following table summarizes our approved products and product candidates:

| | Active Ingredient or Class of Molecule | Indications | Stage of Development | Partner |
|---|---|---|---|---|
| Approved Products | | | | |
| NitroMist® | Nitroglycerin | Angina Pectoris | FDA Approved | Mist Acquisition |
| Zolpimist™ | Zolpidem | Insomnia | FDA Approved | ECR Pharmaceuticals |
| Product Candidates | | | | |
| Duromist™ | Sildenafil | Erectile Dysfunction | Clinical development | - |

| | | | | |
|---|---|---|---|---|
| Zensana™ | Ondansetron | Nausea/Vomiting | Clinical development | Hana Biosciences<br>Par Pharmaceutical<br>BioAlliance Pharma |
| NVD-201 | Sumatriptan | Migraine headache | Clinical development | - |
| NVD-301 | Midazolam | Pre-Procedure Anxiety | Preclinical development | - |

NitroMist®

NitroMist, our oral spray formulation of nitroglycerin, has been approved by the FDA for acute relief of an attack of angina pectoris, or acute prophylaxis of angina pectoris, due to coronary artery disease. In October 2009, we entered into a license and distribution agreement with Mist Acquisition, LLC, or Mist, to manufacture and commercialize NitroMist in North America. Mist is a subsidiary of Akrimax Pharmaceuticals, LLC. Under the terms of the agreement, we received an upfront payment of $1,000,000. We also received a milestone payment of $500,000 on October 29, 2010, and we expect to receive an additional milestone payment of $500,000 before December 31, 2010. We are also eligible to receive royalty payments of up to 17% of net sales. Mist is expected to begin marketing NitroMist in January 2011.

Zolpimist™

Zolpimist, our oral spray formulation of zolpidem, has been approved by the FDA for short-term treatment of insomnia. Zolpidem is the active ingredient in Ambien®, a leading prescription medication for the treatment of insomnia, marketed by Sanofi-Aventis. In November 2009, we entered into an exclusive license and distribution agreement with ECR Pharmaceuticals Company, Inc., or ECR, to manufacture and commercialize Zolpimist in the U.S. and Canada. ECR is a subsidiary of Hi-Tech Pharmacal Co., Inc. Under the terms of the agreement, we received an upfront payment of $3,000,000. We are also eligible to receive royalty payments of up to 15% of net sales on branded products. ECR is expected to begin marketing Zolpimist in late 2010.

Duromist™

Duromist, our oral spray formulation of sildenafil, is being developed for the treatment of erectile dysfunction. Sildenafil is the active ingredient in Viagra, a leading prescription medication for the treatment of erectile dysfunction, marketed by Pfizer. The patent for Viagra is expected to expire in the second quarter of 2012. We believe that an oral spray of sildenafil may afford faster onset of therapeutic action, and may allow for a lower dose compared to tablets.

The preclinical work has been completed, and a prototype formulation with satisfactory stability has been developed. In July 2010, we initiated a non-IND pilot PK clinical trial comparing Duromist to Viagra. On October 15, 2010, we announced positive data from this trial. We intend to review the results from the trial with the FDA to obtain guidance on defining definitive clinical trial requirements as a pathway to NDA approval. We plan to complete the clinical trial and to file a NDA in 2011.

The non-IND pilot PK clinical trial was designed to assess the relative bioavailability and safety of one, two and three doses of 10 mg/0.12ml of Duromist, compared to that of the 25 mg Viagra tablet. The trial was a single-center, open-label, single-dose, randomized, four-period, four-treatment crossover study under fasting conditions. The total number of healthy adult male subjects enrolled in the study was 24. All subjects were required to stay at the clinical site for at least 24 hours after each treatment period.

The preliminary data from the trial demonstrated that the 20 mg dose (two sprays) of Duromist is bioequivalent to the 25 mg Viagra tablet with respect to systemic exposure (AUC0-inf). The mean AUC0-inf for the 10 mg dose (one spray) was approximately 40% of the 25 mg Viagra tablet, as expected. The mean AUC0-inf for the 30 mg dose (three sprays) was approximately 40% higher than the 25 mg Viagra tablet which is about 20% higher than expected. The increased systemic exposure observed with the 20 and 30 mg oral spray doses compared to the Viagra tablet is suggestive of absorption of sildenafil via the oral transmucosal route.

A slightly lower maximum measured plasma concentration (Cmax) than that of the 25 mg Viagra tablet was observed with the 20 mg oral spray dose. The Tmax (or time point at Cmax) for the 20 mg oral spray dose was essentially the same as the 25 mg Viagra tablet (1.10 and 1.04 hours, respectively). Duromist demonstrated an excellent safety profile and was well tolerated in the pilot PK study.

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Zensana™

Zensana is our oral spray formulation of ondansetron. Ondansetron is the active ingredient in Zofran®, a leading prescription medication for the treatment of chemotherapy-induced nausea and vomiting, marketed by GlaxoSmithKline, or GSK. In October 2004, we entered into an exclusive license and development agreement with Hana Biosciences, Inc., or Hana Biosciences, to develop and market Zensana in the U.S. and Canada. In July 2007, we entered into a product development and commercialization sublicense agreement with Hana Biosciences and Par Pharmaceutical, Inc., or Par, pursuant to which Hana Biosciences granted a sublicense to Par to develop and commercialize Zensana. Also at that time, we entered into an amended and restated license and development agreement with Hana Biosciences. Par is responsible for all development, regulatory, manufacturing and commercialization activities of Zensana in the United States and Canada. 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, and had ceased development of the product.

In May 2008, we entered into an agreement with BioAlliance Pharma S.A., whereby BioAlliance acquired the European rights for Zensana. Under the terms of the agreement, we received an upfront payment of $3,000,000. We are eligible to receive milestone payments totaling approximately $24 million, as well as royalty payments on net sales. Product development in Europe is subject to the completion of product development in the U.S.

NVD-201

NVD-201 is our oral spray formulation of sumatriptan. Sumatriptan is the active ingredient in Imitrex®, a leading prescription medication for the treatment of migraine headache, marketed by GSK. We have completed a series of pilot pharmacokinetic clinical trials evaluating multiple doses of NVD-201 given to healthy adults. The results from these trials demonstrated that NVD-201 was well tolerated, achieved plasma concentrations in the therapeutic range, achieved a statistically significant increase in absorption rate when compared with Imitrex® tablets, and achieved up to a 50% increase in relative bioavailability in comparison with Imitrex® tablets. In September 2008, we announced the results from a pilot efficacy study for NVD-201. As previously announced, we believe this trial demonstrates that treatment with NVD-201 is safe and effective in relieving migraine headaches at a dose lower than that for sumatriptan tablets. In order to pursue further clinical development, we will need to secure project financing, equity financing or a development partner.

NVD-301

NVD-301 is our oral spray formulation of midazolam. Midazolam is a 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. In order to pursue further clinical development, we will need to secure project financing, equity financing or a development partner.

Other Product Candidates

Our veterinary initiatives are being carried out by our partner, Velcera, Inc., or Velcera. In June 2004, we entered into a license and development agreement with Velcera. In June 2009, Velcera announced that it had entered into a global licensing agreement with a multinational animal health company. In August 2009, we announced that we received a milestone payment of $156,250 from Velcera. In March 2010, we received another milestone payment of $62,500. These milestone payments resulted from Velcera's global licensing agreement for the first canine pain management product delivered in a transmucosal mist form.

We also have a license and development agreement with Manhattan Pharmaceuticals, Inc., or Manhattan, for the development of propofol oral spray. Propofol is the active ingredient in Diprivan®, a leading intravenous anesthetic

marketed by AstraZeneca. We entered into this agreement in April 2003. In July 2007, Manhattan announced its intention to pursue appropriate sub-licensing opportunities for this product candidate.

Since inception, substantially all of our revenue has been derived from license fees and milestone payments in connection with our partnership agreements, and from consulting fees in connection with our product development activities for various pharmaceutical companies. 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.

Going Concern and Management's Plan

Our independent registered public accounting firm included an explanatory paragraph in their report on our 2009 financial statements related to the uncertainty and substantial doubt of our ability to continue as a going concern.

We have incurred net losses since inception, and as of September 30, 2010 we have cash and cash equivalents of $1.4 million, negative working capital of $3.3 million, and accumulated deficit of $86.5 million. Based on our operating plan, we expect that our existing cash and cash equivalents, along with the $500,000 milestone payment we received on October 29, 2010, will fund our operations only through December 31, 2010.

These conditions raise substantial doubt about our ability to continue as a going concern. The accompanying financial statements have been prepared assuming that we will continue as a going concern. This basis of accounting contemplates the recovery of our assets and the satisfaction of liabilities in the normal course of business.

Our management plans to address the expected shortfall of working capital by securing additional funding through equity financings, strategic alternatives or similar transactions. There can be no assurance that we will be able to obtain any sources of funding. If we are unsuccessful in securing funding from any of these sources, we will defer, reduce or eliminate certain planned expenditures.

Results of Operations

Fluctuations in Operating Results

Our results of operations have fluctuated significantly from period to period in the past and are likely to continue to do so in the future. We anticipate that our quarterly and annual results of operations will be affected for the foreseeable future by several factors, including the timing and amount of payments received pursuant to any current or future strategic alliance agreements, as well as the progress and timing of expenditures related to our development efforts. Due to these fluctuations, we believe that the period-to-period comparisons of our operating results are not indicative of our future performance.

Nine Months Ended September 30, 2010 and 2009

License fees and milestone fees earned for the nine months ended September 30, 2010 were $261,000 as compared to $356,000 for the nine months ended September 30, 2009. The decrease was due to $62,000 and $157,000 in earned and received milestones from Velcera in 2010 and 2009, respectively.

Total operating expenses for the first nine months decreased by $765,000 or 15% from $5,147,000 in 2009 to $4,382,000 in 2010.

Research and development expenses increased by $37,000 or 2% from $1,980,000 for the nine months ended September 30, 2009 to $2,017,000 for the same period in 2010. This increase is related to our sole focus on the development of Duromist in 2010 and a greater allocation of resources to research and development in 2010. The Duromist expenditures include clinical trial material costs and other costs related to initiating the pilot PK study.

General and administrative expenses decreased by $802,000 or 25% from $3,167,000 for the nine months ended September 30, 2009 to $2,365,000 for the same period in 2010. General and administrative expenses consist primarily of salaries and related expenses for executive, finance and other administrative personnel, professional fees and other corporate expenses. The decrease in general and administrative expenses is primarily attributable to our employee-related costs due to decrease in headcount and to occupancy costs due to the relocation of facilities.

Other income from the derivative liability valuation adjustment for the nine months ended September 30, 2010 of $391,000 reflects the gain resulting from the decline in the derivative liability fair value determination at September 30, 2010 related to the warrants issued in conjunction with the March 31, 2010 common stock offering. The decline in the derivative liability fair value calculation was primarily due to the decline in the common stock price and the September 30, 2010 expiration of the Series B Warrants. Other income from a derivative liability valuation adjustment for the nine months ended September 30, 2009 of $360,000 was recorded upon the expiration of warrants that were deemed to be derivative instruments that were issued in conjunction with convertible notes.

Interest expense decreased by $716,000 or 99% from $717,000 for the nine months ended September 30, 2009 to $1,000 for the same period in 2010. The interest was incurred on our convertible notes. This decrease in interest expense reflects the conversion of the convertible notes to common stock in 2009.

The resulting net loss for the nine months ended September 30, 2010 was $3,730,000 as compared to $5,201,000 for the nine months ended September 30, 2009.

Three Months Ended September 30, 2010 and 2009

License fees and milestone fees earned for the three months ended September 30, 2010 were $66,000 as compared to $223,000 for the three months ended September 30, 2009. The decline in license fees and milestone fees results from an earned and received Velcera milestone of $157,000 received in 2009.

Total operating expenses for the three months ended September 30, 2010 increased by $86,000 or 6% from $1,503,000 in 2009 to $1,589,000 in 2010.

Research and development expenses increased by $481,000 or 91% from $530,000 for the three months ended September 30, 2009 to $1,011,000 for the same period in 2010. This increase is related to our sole focus on the development of Duromist and initiating the related pilot PK study. The Duromist expenditures include clinical trial material costs and other costs related to the pilot PK study.

General and administrative expenses decreased by $395,000 or 41% from $973,000 for the three months ended September 30, 2009 to $578,000 for the same period in 2010. General and administrative expenses consist primarily of salaries and related expenses for executive, finance and other administrative personnel, professional fees and other corporate expenses. The decrease in general and administrative expenses is primarily attributable to our employee-related costs due to decrease in headcount and to occupancy costs due to the relocation of facilities.

Other income from the derivative liability valuation adjustment for the three months ended September 30, 2010 of $210,000 reflects the gain resulting from the decline in the derivative liability fair value determination at September 30, 2010 related to the warrants issued in conjunction with the March 31, 2010 common stock offering. The decline in the derivative liability fair value calculation was primarily due to the decline in the common stock price and the September 30, 2010 expiration of the Series B Warrants.

Interest expense decreased by $81,000 or 100% from $81,000 for the three months ended September 30, 2009 to $0 for the same period in 2010. The interest was incurred on our convertible notes. This decrease in interest expense reflects the conversion of the convertible notes to common stock in 2009.

The resulting net loss for the three months ended September 30, 2010 was $1,312,000 as compared to $1,361,000 for the three months ended September 30, 2009.

Liquidity and Capital Resources

From our inception, our principal sources of capital have been revenue from our partnership agreements, 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 September 30, 2010 of $86,496,000, as compared to $82,766,000 as of December 31, 2009. As of September 30, 2010, we had working capital deficiency of $3,291,000, which includes a derivative liability of $522,000, as compared to working capital deficiency of $495,000 as of December 31, 2009, representing a net decrease in working capital of approximately $2,796,000.

Our cash used in operating activities was $2,771,000 and $3,579,000 for the nine months ended September 30, 2010 and 2009, respectively. The decrease in cash used was primarily due to the $1,057,000 received in first quarter 2010 from the sale of net operating losses in the prior year quarter and an overall reduction in expenses. Net cash flows provided by financing and investing activities were $1,517,000 for the nine months ended September 30, 2010, primarily due to net proceeds received relating to issuance of common stock during the first quarter 2010.

Based on our operating plan, we expect that our existing cash and cash equivalents, along with the $500,000 milestone payment we received on October 29, 2010, will fund our operations only through December 31, 2010.

These conditions raise substantial doubt about our ability to continue as a going concern. The accompanying financial statements have been prepared assuming that we will continue as a going concern. This basis of accounting contemplates the recovery of our assets and the satisfaction of liabilities in the normal course of business.

Our management plans to address the expected shortfall of working capital by securing additional funding through equity financings, strategic alternatives or similar transactions. There can be no assurance that we will be able to obtain any sources of funding. If we are unsuccessful in securing funding from any of these sources, we will defer, reduce or eliminate certain planned expenditures.

Critical Accounting Policies and Estimates

The discussion and analysis of our financial condition and results of operations are based on our unaudited condensed financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States, or GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues, expenses, and related disclosure of contingent assets and liabilities. We evaluate our estimates on an ongoing basis. We base our estimates on historical experience and on other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for

making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We believe the following accounting policies and estimates are most critical to aid you in understanding and evaluating our reported financial results.

Cash and Cash Equivalents
Cash equivalents consist of money market instruments with original maturities of three months or less when purchased. We maintain our cash and cash equivalents with two financial institutions. Deposits held with banks may exceed the amount of insurance provided on such deposits. Generally, these deposits may be redeemed on demand and are maintained with high-quality financial institutions, therefore reducing credit risk.

Revenue Recognition
We receive revenue from license agreements. Upfront license agreement payments are recognized as earned or deferred and subsequently amortized into revenue over the contractual period. Milestone payments related to license agreements are recognized as revenue when earned.

Warrants Issued with Financing
The value of warrants and the intrinsic value of beneficial conversion rights arising from the issuance of convertible notes are determined by allocating an appropriate portion of the proceeds received from the debt instruments to the debt and warrants based on their relative fair value, which was determined using the Black-Scholes model. We adopted Accounting Standards Codification, or ASC, 815-40-15 on January 1, 2009. ASC 815-40-15 provides guidance in assessing whether an equity-linked financial instrument (or embedded feature) is indexed to an entity's own stock.

Valuation of Long-Lived Assets
We assess the impairment of long-lived assets whenever events or changes in circumstances indicate that the carrying value may not be recoverable. Our long-lived assets as of September 30, 2010 were represented by property and equipment, as we have no intangible assets on our balance sheets. Factors we consider important which could trigger an impairment review include the following:

- significant underperformance relative to expected historical or projected future operating results;
- significant changes in the manner of our use of the acquired assets or the strategy for our overall business;
- significant negative industry or economic trends; and
- significant decrease in the market value of the assets.

The impairment test is based upon a comparison of the estimated undiscounted cash flows to the carrying value of the long-lived assets. If we determine that the carrying value of long-lived assets may not be recoverable based upon the existence of one or more of the above indicators of impairment, we measure any impairment based on projected discounted cash flows. The cash flow estimates used to determine the impairment, if any, contain management's best estimate using appropriate assumptions and projections at that time.

Stock-Based Compensation
We calculate the fair value of stock-based compensation using the Black-Scholes method. Stock based compensation costs are recorded as earned for all unvested stock options outstanding. 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.

Recent Accounting Pronouncement

See Note 10 to the unaudited condensed financial statements included in Item 1 of this Quarterly Report on Form 10-Q.

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.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

We invest primarily in short-term, highly-rated investments, including U.S. government securities and certificates of deposit guaranteed by banks. Our market risk exposure consists principally of exposure to changes in interest rates. Because of the short-term maturities of our investments, however, we do not believe that a decrease in interest rates would have a significant negative impact on the value of our investment portfolio.

Item 4. 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, 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 principal executive officer and principal financial officer, 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 September 30, 2010. Based on this evaluation, our principal executive officer and principal financial officer concluded that as of September 30, 2010, 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

During the quarter ended September 30, 2010, there were no changes in our internal control over financial reporting (as defined in Rule 13a-15(f) 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.

PART II. OTHER INFORMATION

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

Our auditors have expressed substantial doubt about our ability to continue as a going concern.

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 on our 2009 Financial Statements has expressed substantial doubt about our ability to continue as a going concern. Continued operations are dependent on our ability to complete equity or debt formation activities or to generate profitable operations. Given the recent downturn in the economy, 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. If we cannot continue as a viable entity, our stockholders may lose some or all of their investment in us.

We will require significant additional capital to fund our operations.

Our operations to date have required significant cash expenditures. Our future capital requirements will depend on the results of our research and development activities, and preclinical studies.

We have significantly reduced clinical development activities on our product candidate pipeline since the fourth quarter 2007 and continuing throughout the second quarter of 2010, limiting our expenditures primarily to NitroMist and Zolpimist, and recently on Duromist. During the third quarter 2010, we have initiated a pilot PK study of Duromist, an oral spray of sildenafil citrate, for the treatment of erectile dysfunction. We will need to obtain more funding in the future through collaborations or other arrangements with research institutions and corporate partners or public and private offerings of our securities, including debt or equity financing, to complete the development of this product and other products in our product development pipeline.

On October 27, 2009, we entered into a license and distribution agreement with privately-held Mist Acquisition, LLC to manufacture and commercialize NitroMist, our lingual spray version of nitroglycerine, a widely-prescribed and leading short-acting nitrate for the treatment of angina pectoris. Under the terms of the agreement, we received an upfront payment of $1,000,000. We also received a milestone payment of $500,000 on October 29, 2010, and we expect to receive an additional milestone payment of $500,000 before December 31, 2010. We are also eligible to receive royalty payments of up to 17% of net sales.

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.

In addition, on December 31, 2009, 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.

We have entered into a common stock purchase agreement with Seaside 88, LP, whereby Seaside 88, LP will purchase 500,000 shares of common stock in a series of closings occurring every two weeks for a total of up to 26 closings, provided that the 3 day volume weighed average price prior to the scheduled closing is greater than or equal to the stated floor price of $0.25 per share. We have received $1,055,000 in gross proceeds for the closings that have occurred through December 31, 2009. Through March 26, 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 as of such date.

On March 31, 2010, we received approximately $1.5 million in gross proceeds from our registered direct offering, referred to herein as the Offering, of 9,100,001 shares of common stock, par value $0.001 per share, at a price of $0.165 per share. The investors received five-year warrants, or the Series A Warrants, to purchase 4,550,001 shares of common stock with an exercise price of $0.25 per share and six-month warrants, or the Series B Warrants, to purchase 3,033,334 shares of common stock at an exercise price of $0.25 per share. As of June 30, 2010, we recorded net proceeds of $1,323,000 from the Offering. The exercise price of the Series A and Series B Warrants are subject to adjustment as provided by such warrants. The Offering closed on March 31, 2010 and we sold the securities pursuant to an effective registration statement. The Series B Warrants expired on September 30, 2010.

We may not be able to obtain adequate funds for our operations from these sources when needed or on acceptable terms. Future collaborations or similar arrangements may require us to license valuable intellectual property to, or to share substantial economic benefits with, our collaborators. If we raise additional capital by issuing additional equity or securities convertible into equity, our stockholders may experience dilution and our share price may decline. Any debt financing may result in restrictions on our spending.

If we are unable to raise additional funds, we will need to do one or more of the following:

- further delay, scale-back or eliminate some or all of our research and product development programs;
- license third parties to develop and commercialize products or technologies that we would otherwise seek to develop and commercialize ourselves;
- attempt to sell our company;
- cease operations; or
- declare bankruptcy.

We are seeking to raise additional capital in 2010 to fund our operations and future development. A capital raise could include the securing of funds 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.

Based on our operating plan, we expect that our existing cash and cash equivalents, along with the $500,000 milestone payment we received on October 29, 2010, will fund our operations only through December 31, 2010.

We will require significant capital for product development and commercialization in the near term.

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, negative 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, license agreements and sale of equity securities. 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 current and future partners, and royalty payments from sales of approved product candidates by

partners. We can give no assurances that any additional capital that we are able to obtain will be sufficient to meet our needs, or on terms favorable to us.

Although we have significantly reduced clinical development activities on our product candidate pipeline since the fourth quarter 2007 and continuing through the second quarter of 2010, we have limited our expenditures primarily to NitroMist, Zolpimist and recently on Duromist. During the third quarter 2010, we have initiated a pilot PK study of Duromist, an oral spray of sildenafil citrate, for the treatment of erectile dysfunction. We will need to obtain more funding in the future through collaborations or other arrangements with research institutions and corporate partners or public and private offerings of our securities, including debt or equity financing, to complete the development of this product and other products in our product development pipeline. 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.

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, however our licensees for NitroMist and Zolpimist are expected to commercially launch these products in late 2010 or January 2011. 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. 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 September 30, 2010 of approximately $86,496,000. We incurred losses in each of our last ten fiscal years, including net losses of approximately $3,730,000 for the nine months ended September 30, 2010, $7,577,000 for the year ended December 31, 2009, $9,586,000 for the year ended December 31, 2008, and $16,963,000 for the year ended December 31, 2007. Additionally, we have reported negative cash flows from operations of approximately $2,771,000 for the nine months ended September 30, 2010, and negative cash flows from operations 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. We anticipate that, even with our limited research and development activities, we could incur substantial operating expenses in connection with continued research and development, clinical trials, testing and approval of our proposed products, administrative costs associated with operating as a SEC registrant, 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.

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. Given the recent downturn in the economy, 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.

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.

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.

In May 2008, we entered into definitive agreements for the private placement with ProQuest Investments II, L.P., ProQuest Investments II Advisors Fund, L.P., and ProQuest Investments III, L.P., collectively referred to herein as ProQuest, for an aggregate of up to $4,000,000 in gross proceeds, in the form of secured convertible promissory notes with an interest rate of 10%, and warrants to purchase shares of our common stock, referred to herein as the 2008 Financing. In May 2008, we sold securities in the initial closing of the 2008 Financing, resulting in the issuance of notes convertible into 5,000,000 shares of our common stock, and warrants to purchase 3,000,000 shares of our common stock. The sale of the notes and warrants resulted in gross proceeds to us of $1,475,000, before deducting certain fees and expenses. In October 2008, we sold securities in the subsequent closing of the 2008 Financing, resulting in the issuance of notes convertible into 10,744,681 shares of our common stock, and warrants to purchase 6,446,809 shares of our common stock. The sale of the notes and warrants resulted in gross proceeds to us of $2,525,000, before deducting certain fees and expenses.

In December 2009, we entered into an amendment agreement with ProQuest, whereby ProQuest agreed to convert the outstanding aggregate principal amount of all of their convertible notes and liquidated damages notes, in each case, plus accrued interest thereon, in an amount equal to $3,657,517 into 23,237,083 shares of our common stock, $0.001 par value per shares. Immediately following such transaction, ProQuest's equity ownership consisted of (i) 29,504,653 shares of our common stock and (ii) warrants to purchase 11,433,345 shares of our common stock at an exercise price of $0.1888 per share.

In March 2010, ProQuest participated in the Offering, whereby ProQuest received 4,848,485 shares of our common stock and warrants to purchase 4,040,405 shares of our common stock.

As of September 30, 2010, ProQuest, directly and indirectly, of us, beneficially owns approximately 43% of our outstanding common stock (assuming full exercise of the warrants held by ProQuest). As such, ProQuest may be deemed to be our affiliate. Mr. Steven B. Ratoff, our Chairman, President, and Chief Executive Officer, has served as

a venture partner with ProQuest since December 2004, although he has no authority for investment decisions by ProQuest.

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.

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, such as our Duromist product candidate, 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 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 commercially available products.

Our principal efforts are to obtain regulatory approvals for our product candidates and to license our product candidates. We anticipate that marketing activities by our licensees for our two approved products will begin in late 2010 or January 2011.

There can be no assurances that our licensees will successfully market our two approved product candidates, or that such product candidates will become commercially available.

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 Mist, ECR, BioAlliance, 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 current 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.

On December 28, 2009, DPT Laboratories became our contract manufacturer for Duromist, sildenafil citrate oral spray.

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 DPT Laboratories, or Rechon Life Sciences 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 are 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. 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.

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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 NYSE Amex, or NYSE 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 recent 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 requires the commitment of 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 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 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 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 FFDCA. 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.

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 and Zolpimist, 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 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.

Legislative or regulatory reform of the healthcare system may affect our ability to sell our current and future products profitably.

In the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the healthcare system in ways that could impact our ability to sell our current and future products profitably. On March 23, 2010, President Obama signed into law the Patient Protection and Affordable Care Act or PPACA, which includes a number of health care reform provisions and requires most U.S. citizens to have health insurance. Effective January 1, 2010, the new law increases the minimum Medicaid drug rebates for pharmaceutical companies, expands the 340B drug discount program, and makes changes to affect the Medicare Part D coverage gap, or “donut hole.” The law also revises the definition of “average manufacturer price” for reporting purposes (effective October 1, 2011), which could increase the amount of our Medicaid drug rebates to states, once the provision is effective. The new law also imposes a significant annual fee on companies that manufacture or import branded prescription drug products (beginning in 2010). Substantial new provisions affecting compliance also have been added, which may require modification of business practices with health care practitioners.

The reforms imposed by the new law will significantly impact the pharmaceutical industry; however, the full effects of PPACA cannot be known until these provisions are implemented and the Centers for Medicare & Medicaid

Services and other federal and state agencies issue applicable regulations or guidance. Moreover, in the coming years, additional change could be made to governmental healthcare programs that could significantly impact the success of our current and future products, and we could be adversely affected by current and future health care reforms.

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 agreement, 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.

Through September 30, 2010, we entered into strategic license agreements with: (i) Hana Biosciences, for the development and marketing rights in the U.S. and Canada which was subsequently sublicensed to Par for our ondansetron oral spray Zensana, (ii) Manhattan Pharmaceuticals, in connection with propofol, (iii) Velcera, in connection with veterinary applications for currently marketed veterinary drugs, (iv) BioAlliance Pharma SA, for the European rights for ondansetron oral spray Zensana, (v) Mist Acquisition, LLC, for the manufacturing and commercialization rights in the United States, Canada and Mexico for our lingual spray version of nitroglycerine, NitroMist, and (vi) ECR Pharmaceuticals Company, for the manufacturing and commercialization rights in the United States and Canada for our oral spray formulation of zolpidem tartrate, Zolpimist.

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. For example, in November 2008, Par announced that it had completed bioequivalence studies on Zensana with mixed results and, as a result, it had ceased development of the product. Since such time, we have had numerous meetings and discussions with both Par and Hana regarding the development of Zensana. We cannot assure you that Par or Hana will perform under our license agreements.

We may, in the future, grant to collaboration partners, rights to license and commercialize pharmaceutical products developed under collaboration agreements. Under these arrangements, our collaboration partners may control key decisions relating to the development of the products. The rights of our collaboration partners could limit our flexibility in considering alternatives for the commercialization of such product candidates. If we fail to successfully develop these relationships or if our collaboration partners fail to successfully develop or commercialize such product candidates, it may delay or prevent us from developing or commercializing our proposed products in a competitive and timely manner and would have a material adverse effect on our business.

If we cannot protect our intellectual property, other companies could use our technology in competitive products. If we infringe the intellectual property rights of others, other companies could prevent us from developing or marketing our products.

We seek patent protection for our technology so as to prevent others from commercializing equivalent products in substantially less time and at substantially lower expense. The pharmaceutical industry places considerable importance on obtaining patent and trade secret protection for new technologies, products and processes. Our success will depend in part on our ability and that of parties from whom we license technology to:

- defend our patents and otherwise prevent others from infringing on our proprietary rights;
- protect our trade secrets; and
- operate without infringing upon the proprietary rights of others, both in the U.S. and in other countries.

The patent position of firms relying upon biotechnology is highly uncertain and involves complex legal and factual questions for which important legal principles are unresolved. To date, the U.S. Patent and Trademark Office, 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 FFDCA 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.

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. 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.

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.

Risk Related To Our Common Stock

Because our common stock is listed on the Over-the-Counter Bulletin Board, the liquidity of our common stock may be impaired.

On December 24, 2009, we announced that our common stock was accepted for quotation on the Over-the-Counter Bulletin Board, or OTCBB. Our new ticker symbol on OTCBB is NVDL.OB. We filed a 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.

Because our common stock is quoted on the OTCBB, the liquidity of the common stock is impaired, not only in the number of shares that are bought and sold, but also through delays in the timing of transactions, and limited coverage by security analysts and the news media. As a result, prices for shares of our common stock may be lower than might otherwise prevail if our common stock was listed on NYSE Amex LLC or another national securities exchange.

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 September 30, 2010, management and our affiliates currently beneficially own, including shares they have the right to acquire, approximately 44% of the common stock on a fully-diluted basis. This determination of affiliate status is not necessarily a conclusive determination for other purposes. Specifically, ProQuest has the ability to exert significant influence over matters submitted to our stockholders for approval. 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 prospectus and other filings filed with the Securities and Exchange Commission from time to time.

Our common stock is currently quoted on the OTCBB under the symbol “NVDL.OB” and was previously listed on the NYSE Amex LLC from May 11, 2004 to December 23, 2009. During the nine-month period ended September 30, 2010, the closing price of our common stock has ranged from $0.15 to $0.29. We expect the price of our common stock to remain volatile. The average daily trading volume in our common stock varies significantly. Our relatively low volume and low 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 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 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 September 30, 2010, there were 98,383,458 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 September 30, 2010, we had outstanding stock options and warrants to purchase approximately 32.8 million shares of common stock, the exercise prices of which range between $0.17 per share and $3.18 per share, and we have reserved shares of our common stock for issuance in connection with the potential exercise thereof. As a result, as of September 30, 2010, 370,000 and 10,121,000 shares remain available for issuance under the 1998 Stock Option Plan and the 2006 Equity Incentive Plan, respectively.

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 six-month 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 one-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 and officer liability.

As permitted by Delaware law, our certificate of incorporation limits the liability of our directors for monetary damages for breach of a director's fiduciary duty except for liability in certain instances. As a result of our charter provision and Delaware law, stockholders may have limited rights to recover against directors for breach of fiduciary duty. In addition, our certificate of incorporation provides that we shall indemnify our directors and officers to the fullest extent permitted by law.

We have no history of paying dividends on our common stock.

We have never paid any cash dividends on our common stock and do not anticipate paying any cash dividends on our common stock in the foreseeable future. We plan to retain any future earnings to finance growth. If we decide to pay dividends to the holders of our common stock, such dividends may not be paid on a timely basis.

Provisions of our certificate of incorporation and Delaware law could deter a change of our management which could discourage or delay offers to acquire us.

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

Sales of large quantities of our common stock by our stockholders, including those shares issued in connection with private placement transactions, could reduce the price of our common stock.

Since May 2005, we have entered into private placements and registered direct offerings whereby we sell large quantities of our common stock to investors. For example, on March 31, 2010, we sold 9,100,001 shares of our common stock at a price of $0.165 per share to certain investors in a registered direct offering. The investors also received warrants to purchase 7,583,335 shares of common stock with an exercise price of $0.25 per share.

These holders of the shares may sell such shares, if such shares are registered or pursuant to an exemption from registration, at any price and at any time, as determined by such holders in their sole discretion without limitation. Any sales of large quantities of our common stock could reduce the price of our common stock. 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.

We cannot assure you of the prices at which our common stock will trade in the future, and such prices 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.

As of September 30, 2010, we have 98,383,458 shares of common stock issued and outstanding and approximately 32.8 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.

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 have a material adverse effect on 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. In addition, 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 5. Other Information

Simultaneously with the appointment of Mr. Johnson as Chief Financial Officer on June 16, 2010, Mr. Warusz resigned from the position of Principal Accounting Officer. There was no disagreement between us and Mr. Warusz on any matter relating to our operations, policies or practices. Mr. Warusz continued in his capacity as a consultant to the Company until July 31, 2010.

Item 6. Exhibits

INDEX TO EXHIBITS

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

| Exhibit No. | Description | Method of Filing |
|---|---|---|
| 31.1 | Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. | Filed herewith. |
| 31.2 | Certification of Principal Financial and Accounting Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. | Filed herewith. |
| 32.1 | Certification of the Principal Executive Officer and Principal Financial and Accounting Officer under 18 USC 1350, Section 1330 as adopted, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. | Furnished. |

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

NovaDel Pharma Inc.

Date: November 12, 2010 By: /s/ Steven B. Ratoff

Steven B. Ratoff
President and Chief Executive Officer
(principal executive officer)

Date: November 12, 2010 By: /s/ Craig A. Johnson

Craig A. Johnson
Chief Financial Officer
(principal financial and accounting officer)