NOVADEL PHARMA INC
Form S-1
October 21, 2010

As filed with the Securities and Exchange Commission on October 21, 2010

Registration Statement No. 333-

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

FORM S-1

REGISTRATION STATEMENT
UNDER THE SECURITIES ACT OF 1933

NovaDel Pharma Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware	2834	22-2407152
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code)	(I.R.S. Employer Identification No.)

1200 Route 22 East, Suite 2000
Bridgewater, New Jersey 08807
(908) 203-4640
(Address, including zip code, and telephone number, including area code, of registrant s principal executive offices)

Steven B. Ratoff
Chairman, President and Chief Executive Officer

Novadel Pharma, Inc.
1200 Route 22 East, Suite 2000
Bridgewater, New Jersey 08807
(908) 203-4640
(Name, address, including zip code, and telephone number including area code, of agent for service)

Copies to:
Emilio Ragosa, Esq.
Morgan, Lewis & Bockius, LLP, 502 Carnegie Center, Princeton, New Jersey 08540 (609) 919-6600

Approximate date of commencement of proposed sale to public: As soon as practicable after the effective date hereof.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. x

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. 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 definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act.

Large accelerated filer o	Accelerated filer o
Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company x

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	Proposed maximum aggregate offering price	Amount of registration fee(1)
Units, each unit consisting of ___ share of Common Stock, $0.001 par value, and warrants to purchase ___ share of Common Stock	$ 10,000,000	$ 713.00
Common Stock included in the Units	$	$
Warrants included in the Units	$	(3)
Common Stock issuable upon exercise of the warrants included in the Units (2)	$	(3)
Total	**$ 10,000,000**	**$ 713.00**

(1) Calculated pursuant to Rule 457(o) on the basis of the maximum aggregate offering price of all of the securities to be registered.

(2) Pursuant to Rule 416, the securities being registered hereunder include such indeterminate number of additional shares of common stock as may be issuable upon exercise of warrants registered hereunder as a result of stock splits, stock dividends, or similar transactions. The common stock underlying the warrants is being offered pursuant to Rule 415 provided the warrants are not exercised on a cashless basis.

(3) No fee required pursuant to Rule 457(g).

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

The information contained in this prospectus is not complete and may be changed. We may not sell these securities until the Registration Statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and we are not soliciting offers to buy these securities in any state or jurisdiction where the offer or sale is not permitted.

Subject to Completion, dated October 21, 2010

PROSPECTUS

_____ UNITS, EACH CONSISTING OF
_____ SHARES OF COMMON STOCK AND
WARRANTS TO PURCHASE _____ SHARES OF COMMON STOCK

We are offering up to [_____] units, each unit consisting of [____] share of our common stock and warrants to purchase [____] share of our common stock. Each warrant entitles its holder to purchase one share of our common stock at an exercise price of $[___] per share. The units will separate immediately and the common stock and warrants will be issued separately and the common stock will trade separately. We are not required to sell any specific dollar amount or number of units, but will use our best efforts to sell all of the units being offered. We and the placement agent may, upon request of any investor in this offering, sell units to such investors that exclude the warrants, provided that the sale of units that exclude such warrants shall be at the same offering price per unit as all other investors.

Our common stock is presently listed on the Over-the-counter Bulletin Board under the symbol NVDL.OB We do not intend to apply for listing of the warrants on any securities exchange. On October 14, 2010, the last reported sale price of our common stock on the Over-the-counter Bulletin Board was $0.18 per share.

INVESTING IN THE OFFERED SECURITIES INVOLVES RISKS, INCLUDING THOSE SET FORTH IN THE RISK FACTORS SECTION OF THIS PROSPECTUS BEGINNING ON PAGE 6.

	Per Unit	Total
Offering Price per Unit	$ [__]	$ 10,000,000
Placement Agent s Fees	$ [__]	$ [__]
Offering Proceeds before expenses	$ [__]	$ [__]

[_____] has agreed to act as our placement agent in connection with this offering. In addition, we may engage one or more sub placement agents or selected dealers. The placement agent is not purchasing the securities offered by us, and is not required to sell any specific number or dollar amount of units, but will assist us in this offering on a best efforts basis. We have agreed to pay the placement agent a cash fee equal to [__]% of the gross proceeds of the offering of units by us. We estimate the total expenses of this offering, excluding the placement agent fees, will be approximately $[____]. Because there is no minimum offering amount required as a condition to closing in this offering, the actual public offering amount, placement agent fees, and proceeds to us, if any, are not presently determinable and may be substantially less than the total maximum offering amounts set forth above. See Plan of Distribution beginning on page 91 of this prospectus for more information on this offering and the placement agent arrangements. All costs associated with the registration will be borne by us.

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. Any representation to the contrary is a criminal offense.

The shares of Common Stock may be sold directly by us to investors, through our placement agent or to or through underwriters or dealers. See Plan of Distribution . If any underwriters are involved in the sale of any shares of Common Stock in respect of which this prospectus is being delivered, the names of such underwriters and any applicable commissions or discounts will be set forth in a prospectus supplement. The net proceeds we expect to receive from such sale also will be set forth in a prospectus supplement.

Brokers or dealers effecting transactions in these shares should confirm that the shares are registered under the applicable state law or that an exemption from registration is available.

The date of this prospectus is _____, 2010.

TABLE OF CONTENTS

You should rely only on the information contained in this prospectus. We have not authorized anyone to provide you with information different from the information contained in this prospectus. We are not making an offer to sell securities in any state where offers and sales are not permitted. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of when this prospectus is delivered or when any sale of our common stock occurs.

FOR INVESTORS OUTSIDE THE UNITED STATES: We have not done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. You are required to inform yourselves about, and to observe any restrictions relating to, this offering and the distribution of this prospectus.

PROSPECTUS SUMMARY

This summary does not contain all of the information you should consider before buying our securities. You should read the entire prospectus carefully, especially the Risk Factors section and our consolidated financial statements and the related notes appearing at the end of this prospectus, before deciding to invest in our securities.

Overview

Unless otherwise stated, all references to us, our, we, NovaDel, the Company and similar designations refer to NovaDel Pharma Inc.

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	Hana Biosciences Par Pharmaceutical BioAlliance Pharma
Zensana	Ondansetron	Nausea/Vomiting	Clinical development	
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 United States Food and Drug Administration, or 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 licensing 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, and we expect to receive milestone payments totaling $1,000,000 by the end of 2010. We are also eligible to receive royalty payments of up to 17% of net sales. Mist is expected to begin marketing NitroMist in late 2010.

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 pharmacokinetic, or 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 new drug application, or NDA, approval. We plan to complete the clinical trial and to file a NDA in 2011.

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.

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 June 30, 2010 we have cash and cash equivalents of $3.1 million, negative working capital of $2.0 million, and accumulated deficit of $85.2 million. Based on our operating plan, we expect that our existing cash and cash equivalents, along with the milestone payments we expect to receive under our existing license agreements, 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 agreements. 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.

Corporate Information

We were incorporated in Delaware in 1982. Our principal business address is 1200 Route 22 East, Suite 2000, Bridgewater, New Jersey 08807, and our telephone number is (908) 203-4640. We maintain a website at http://www.novadel.com (this is not a hyperlink; you must visit this website through an Internet browser). Our website and the information contained therein or connected thereto are not incorporated into this prospectus.

SUMMARY OF THE OFFERING

Securities offered:	Up to [___] units. Each unit will consist of [__] shares of our common stock and warrants to purchase up to [__] shares of our common stock.
Offering Price:	$[__] per unit.
Description of Warrants:	The warrants will be exercisable at any time during the period commencing [__ months] after the date of closing and ending on the [___ anniversary] of the closing date at an exercise price of $[__] per share. We and the placement agent may, upon request of any investor in this offering, sell units to such investors that exclude the warrants, provided that the sale of units that exclude such warrants shall be at the same offering price per unit as all other investors.
Common stock outstanding prior to the offering:	98,383,458 shares.
Common stock outstanding after the offering:	[__] shares.
Over-allotment option:	The placement agent will have a 30-day option to arrange for the sale of up to an additional [__] units (consisting of [__] shares and warrants to purchase [__] shares of common stock) to cover over-allotments.
Use of proceeds:	We expect to use the proceeds received from the offering to further clinical development of Duromist and our other product candidates, and for working capital and other general corporate purposes.
OTCBB Symbol:	NVDL.OB
Risk Factors:	See Risk Factors beginning on page 6 and the other information in this prospectus for a discussion of the factors you should consider before you decide to invest in the units.

The total number of shares of our common stock outstanding after this offering is based on 98,383,458 shares outstanding as of June 30, 2010, and excludes the following:

[__] shares of common stock issuable upon exercise of the warrants offered hereby;

8,759,243 shares of common stock issuable upon exercise of stock options outstanding as of June 30, 2010 under our stock option plans at a weighted average exercise price of $0.73 per share;

27,203,338 additional shares of common stock reserved for issuance under various outstanding warrant agreements as of June 30, 2010, at a weighted average exercise price of $0.62 per share; and

10,391,257 additional shares of common stock reserved for future issuance under our 1998 Stock Option Plan and 2006 Equity Incentive Plan, as amended.

SUMMARY OF SELECTED FINANCIAL INFORMATION

The following table summarizes our selected financial information. You should read the selected financial information together with our consolidated financial statements and the related notes appearing at the end of this prospectus, and the Management s Discussion and Analysis of Financial Condition and Results of Operations section and other financial information included in this prospectus.

	Six months ended June 30,		Year ended December 31,		
	2010	2009	2009	2008	2007
	(unaudited)				
Consolidated Statements of Operations Data					
Total Revenues	$ 195,000	$ 133,000	$ 422,000	$ 361,000	$ 469,000
Total Expenses	2,793,000	3,644,000	6,517,000	8,951,000	18,656,000
Loss from Operations	(2,598,000)	(3,511,000)	(6,095,000)	(8,590,000)	(18,187,000)
Other, net	181,000	301,000	(385,000)		(66,000)
Interest Expense	1,000	636,000	2,160,000	1,868,000	
Interest Income		6,000	6,000	137,000	632,000
Income Tax Benefit			(1,057,000)	(735,000)	(658,000)
Net Loss	$ (2,418,000)	$ (3,840,000)	$ (7,577,000)	$ (9,586,000)	$ (16,963,000)
Basic and Diluted Loss Per Common Share	$ (0.03)	$ (0.06)	$ (0.12)	$ (0.16)	$ (0.29)
Weighted Average Number of Shares of Common Stock Used in Computation of Basic and Diluted Loss Per Share	93,194,701	59,987,277	61,346,000	59,592,000	59,497,000

	June 30, 2010	December 31, 2009
	(unaudited)	
Balance Sheet Data:		
Cash, cash equivalents, and short-term investments	$ 3,117,000	$ 2,663,000
Total Assets	3,648,000	4,453,000
Total Current Liabilities	5,414,000	4,588,000
Total Liabilities	9,483,000	8,794,000
Accumulated deficit	(85,184,000)	(82,766,000)
Total Stockholders Deficiency	(5,835,000)	(4,341,000)

RISK FACTORS

You should carefully consider the following risks and all of the other information set forth in this prospectus before deciding to invest in our securities. The risks described below are not the only ones facing us. Additional risks not presently known to us or that we currently deem immaterial may also impair our business operations.

If any of the following risks actually occurs, our business, financial condition or results of operations would likely suffer. In such case, the market price of our common stock would likely decline due to the occurrence of any of these risks, and you may lose all or part of your investment.

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 licensing agreement with privately-held Mist Acquisition, LLC to manufacture and commercialize the NitroMist lingual spray version of nitroglycerine, a widely-prescribed and leading short-acting nitrate for the treatment of angina pectoris. Under the terms of the agreement, we received a $1,000,000 licensing fee upon execution of the agreement, and we expect to receive milestone payments totaling an additional $1,000,000 by the end of 2010 and ongoing performance payments of up to seventeen percent (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. As of 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 announced we would receive 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 milestone payments that we expect to receive under our existing license agreements, will fund our operations only through December 31, 2010.

We cannot assure you that we will receive the expected milestone payments. Certain milestone payments are based upon a fixed date, whereas other milestone payments are based upon other regulatory events, which we believe are probable, but cannot be guaranteed.

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 second 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. 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 June 30, 2010 of approximately $85,184,000. We incurred losses in each of our last ten fiscal years, including net losses of approximately $2,418,000 for the six months ended June 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 $1,063,000 for the six months ended June 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, 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, the Company had 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 the Company s common stock, referred to herein as the 2008 Financing. In May 2008, the Company sold securities in the initial closing of the 2008 Financing, resulting in the issuance of notes convertible into 5,000,000 shares of the Company s common stock, and warrants to purchase 3,000,000 shares of the Company s common stock. The sale of the notes and warrants resulted in gross proceeds to the Company of $1,475,000, before deducting certain fees and expenses. In October 2008, the Company sold securities in the subsequent closing of the 2008 Financing, resulting in the issuance of notes convertible into

10,744,681 shares of the Company s common stock, and warrants to purchase 6,446,809 shares of the Company s common stock. The sale of the notes and warrants resulted in gross proceeds to the Company of $2,525,000, before deducting certain fees and expenses.

In December 2009, the Company 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 in the Company consisted of (i) 29,504,653 shares of common stock and (ii) warrants to purchase 11,433,345 shares of the 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 June 30, 2010, ProQuest, directly and indirectly, of us, beneficially owns approximately 44% of our outstanding common stock (assuming full exercise of certain 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.

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.

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 the Company s 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 June 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 lost 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 began trading on the Over-the-Counter Bulletin Board, or OTCBB. Our new ticker symbol on OTCBB is NVDL.OB. We filed Form 25 on December 14, 2009, voluntarily withdrawing our listing and registration from NYSE Amex LLC. The final day of trading on NYSE Amex LLC was December 23, 2009.

Because our common stock is listed 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 traded on NYSE Amex LLC or another national securities exchange.

As of June 30, 2010, our net worth position was a deficit of $5,835,000 and as of December 31, 2009, our net worth position was a deficit of $4,341,000.

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 June 30, 2010, management and our affiliates currently beneficially own, including shares they have the right to acquire, approximately 45% 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 listed for trading on the OTCBB under the symbol NVDL.OB and was previously traded on the NYSE Amex LLC from May 11, 2004 to December 23, 2009. During the six-month period ended June 30, 2010, the closing price of our common stock has ranged from $0.16 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 June 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 June 30, 2010, we had outstanding stock options and warrants to purchase approximately 36.5 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 June 30, 2010, 210,000 and 10,181,000 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 June 30, 2010, we have 98,383,000 shares of common stock issued and outstanding and approximately 36.5 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.

Risks Related to this Offering

We will have immediate and broad discretion over the use of the net proceeds from this offering.

There is no minimum offering amount required as a condition to closing this offering and therefore net proceeds from this offering will be immediately available to us to use at our discretion. We intend to use

the net proceeds to further clinical development of Duromist and our other product candidates, and for working capital and other general corporate purposes. Our judgment may not result in positive returns on your investment and you will not have an opportunity to evaluate the economic, financial, or other information upon which we base our decisions.

You will experience immediate and substantial dilution as a result of this offering.

You will incur immediate and substantial dilution as a result of this offering. After giving effect to the sale by us of up to [__] units offered in this offering at an assumed offering price of $[__] per unit, and after deducting the placement agent fees and estimated offering expenses payable by us, investors in this offering can expect an immediate dilution of $[__] per share, or [__]%, at the assumed public offering price, assuming no exercise of the warrants.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

Certain statements contained in this prospectus, any prospectus supplement and in the documents incorporated by reference herein constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements other than statements of historical fact may be deemed to be forward-looking statements. Forward-looking statements frequently, but not always, use the words may , intends , plans , believes , anticipates or expects or similar words and may include statements concerning our strategies, goals and plans. All forward-looking statements are management s present expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. These risks and uncertainties include, but are not limited to: the inherent risks and uncertainties in developing products of the type the Company is developing (independently and through collaborative arrangements); the inherent risks and uncertainties in completing the pilot pharmacokinetic feasibility studies being conducted by the Company; possible changes in the Company s financial condition; the progress of the Company s research and development; inadequate supplies of drug substance and drug product; timely obtaining sufficient patient enrollment in the Company s clinical trials; the impact of development of competing therapies and/or technologies by other companies; the Company s ability to obtain additional required financing to fund its research programs and ongoing operations; the Company s ability to enter into agreements with collaborators and the failure of collaborators to perform under their agreements with the Company; the progress of the U.S. Food and Drug Administration, or FDA, approvals in connection with the conduct of the Company s clinical trials and the marketing of the Company s products; the additional costs and delays which may result from requirements imposed by the FDA in connection with obtaining the required approvals; acceptance for filing by the FDA does not mean that the New Drug Application, or NDA, has been or will be approved, nor does it represent an evaluation of the adequacy of the data submitted; the risks related to the Company s internal controls and procedures; and other factors discussed under the caption Risk Factors included in any prospectus supplement and under the caption Risks Related to Our Business in our Annual Report on Form 10-K for the year ended December 31, 2009, which is incorporated by reference into the Registration Statement of which this prospectus forms a part.

The following documents, among others, describe these assumptions, risks, uncertainties, and other factors. You should read and interpret any forward-looking statements together with these documents:

- the risk factors contained in any prospectus supplement under the caption Risk Factors ;
- our most recent annual report on Form 10-K, including the sections entitled Business , Risk Factors and Management s Discussion and Analysis of Financial Condition and Results of Operations ;
- our quarterly reports on Form 10-Q; and
- our other SEC filings.

In light of these assumptions, risks and uncertainties, the results and events discussed in the forward-looking statements contained in this prospectus, any prospectus supplement or in any document incorporated by reference in this prospectus might not occur. Investors are cautioned not to place undue reliance on the forward-looking statements, which speak only of the date of this prospectus, the date of any prospectus supplement or the date of the document incorporated by reference in this prospectus. We are not under any obligation, and we expressly disclaim any obligation, to update or alter any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required by applicable law. All subsequent forward-looking statements attributable to us are expressly qualified in their entirety by the cautionary statements contained or referred to in this section.

USE OF PROCEEDS

We estimate that we will receive up to $[__] in net proceeds from the sale of units in this offering, based on an assumed price of $[__] per unit and after deducting estimated placement agent fees and estimated offering expenses payable by us. We will use the net proceeds from this offering to further clinical development of Duromist and our other product candidates, and for working capital and other general corporate purposes.

If a warrant holder elects to pay the exercise price, rather than exercising the warrants on a cashless basis, we may also receive proceeds from the exercise of warrants. We cannot predict when or if the warrants will be exercised. It is possible that the warrants may expire and may never be exercised.

CAPITALIZATION

The following table sets forth our capitalization as of June 30, 2010:

- on an actual basis; and
- on an as adjusted basis to reflect our sale of [__] units offered by us at a price of $[__] per unit, less the placement agent fees and estimated offering expenses payable by us.

The information set forth in this table does not reflect the issuance of up to [__] units that we may sell to the placement agent upon exercise of its over-allotment option. You should read the information in this table together with Management s Discussion and Analysis of Financial Condition and Results of Operations and our financial statements and the accompanying notes incorporated in this prospectus.

	As of June 30, 2010	
	Actual	As Adjusted
	(Unaudited)	(Unaudited)
Stockholders Deficiency:		
Preferred stock: $0.001 par value: Authorized 1,000,000 shares, none issued.	$	$
Common stock: $0.001 par value; Authorized 200,000,000 shares, Issued 98,383,458 at June 30, 2010	99,000	[__]
Additional paid-in capital	79,256,000	[__]
Accumulated deficit	(85,184,000)	[__]
Treasury stock	(6,000)	[__]
Total Stockholders Deficiency	$ (5,835,000)	$ [__]

The number of shares in the table above excludes:

- [__] shares of common stock issuable upon exercise of the warrants offered hereby;
- 8,759,243 shares of common stock issuable upon exercise of stock options outstanding as of June 30, 2010 under our stock option plans at a weighted average exercise price of $0.73 per share;
- 27,203,338 additional shares of common stock reserved for issuance under various outstanding warrant agreements as of June 30, 2010, at a weighted average exercise price of $0.62 per share; and
- 10,391,257 additional shares of common stock reserved for future issuance under our 1998 Stock Option Plan and 2006 Equity Incentive Plan, as amended.

DILUTION

If you purchase units in this offering, and assuming no value is attributed to the warrants, your interest will be diluted immediately to the extent of the difference between the assumed public offering price of $[___] per unit and the as adjusted net tangible book value per share of our common stock immediately following this offering.

Our net tangible book value as of June 30, 2010 was approximately $[__] million, or approximately $[__] per share. Net tangible book value per share represents our total tangible assets less total tangible liabilities, divided by the number of shares of common stock outstanding as of June 30, 2010.

Net tangible book value dilution per unit to new investors represents the difference between the amount per unit paid by purchasers in this offering and the as adjusted net tangible book value per share of common stock immediately after completion of this offering, assuming that no value is attributed to the warrants. After giving effect to our sale of [__] units in this offering at an assumed public offering price of $[__] per unit, and after deducting the placement agent commissions and estimated offering expenses, our as adjusted net tangible book value as of June 30, 2010 would have been $[__] million, or $[__] per share. This represents an immediate increase in net tangible book value of $[__] per share to existing stockholders and an immediate dilution in net tangible book value of $[__] per unit to purchasers of units in this offering, as illustrated in the following table:

Assumed public offering price per unit	$ [__]
Net tangible book value per share as of June 30, 2010	$ [__]
Increase in net tangible book value per unit attributable to new investors	$ [__]
Adjusted net tangible book value per share as of June 30, 2010, after giving effect to the offering	$ [__]
Dilution per unit to new investors in the offering	$ [__]

The above discussion and tables do not include the following:

- [__] shares of common stock issuable upon exercise of the warrants offered hereby;
- 8,759,243 shares of common stock issuable upon exercise of stock options outstanding as of June 30, 2010 under our stock option plans at a weighted average exercise price of $0.73 per share;
- 27,203,338 additional shares of common stock reserved for issuance under various outstanding warrant agreements as of June 30, 2010, at a weighted average exercise price of $0.62 per share; and
- 10,391,257 additional shares of common stock reserved for future issuance under our 1998 Stock Option Plan and 2006 Equity Incentive Plan, as amended.

DESCRIPTION OF BUSINESS

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. All references to NovaDel, we, us, our or the Company refer to NovaDel Pharma Inc.

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 Par Pharmaceuticals BioAlliance Pharma
NVD-201	Sumatriptan	Migraine headache	Clinical development	
NVD-301	Midazolam	Pre-Procedure Anxiety	Preclinical development	

Our Approved Products

NitroMist®

NitroMist, our oral spray formulation of nitroglycerin, has been approved by the United States Food and Drug Administration, or 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 licensing 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, and we expect to receive milestone payments totaling $1,000,000 by the end of 2010. We are also eligible to receive royalty payments of up to 17% of net sales. Mist is expected to begin marketing NitroMist in late 2010.

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.

Our Product Candidates

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 pharmacokinetic, or 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 new drug application, or 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 ($AUC_{0\text{-}inf}$). The mean $AUC_{0\text{-}inf}$ for the 10 mg dose (one spray) was approximately 40% of the 25 mg Viagra tablet, as expected. The mean $AUC_{0\text{-}inf}$ 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 25 mg Viagra tablet is suggestive of absorption of sildenafil via the oral transmucosal route.

A slightly lower maximum measured plasma concentration (C_{max}) than that of the 25 mg Viagra tablet was observed with the 20 mg oral spray dose. The T_{max} (or time point at C_{max}) 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.

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,

31

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.

Our Business Strategy

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

Significant prescription sales already exist;

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

Applicability of an efficient regulatory pathway to approval using the 505(b)(2) pathway.

In today s environment of escalating drug development costs and time to market, we believe that the ability to bring products with some degree of differentiation and competitive advantage to the marketplace in a timely and cost-effective manner is a viable strategy.

We expect to secure marketing partners for these product candidates after we have generated sufficient clinical data to demonstrate the effectiveness of these product candidates. We anticipate that such marketing partners for both our approved and our development products would provide us with milestone payments and royalties based on revenues

Strategic Alliance, License and Other Commercial Agreements

To date, we have entered into license agreements with (i) Mist Acquisition, LLC to manufacture and commercialize the NitroMist® lingual spray version of nitroglycerine, (ii) ECR Pharmaceuticals Company, Inc., to commercialize and manufacture ZolpiMist in the United States and Canada, (iii) Hana Biosciences, for the development and marketing rights in the U.S. and Canada for Zensana , which was further sublicensed to Par Pharmaceutical, (iv) BioAlliance Pharma SA, for the European rights for Zensana, (v) Velcera, in connection with veterinary applications for currently marketed veterinary drugs, and (vi) Manhattan Pharmaceuticals, in connection with propofol.

We intend to enter into additional agreements and strategic alliances as may be appropriate for the remaining present and future products in our development pipeline.

Agreement with Mist Acquisition LLC

On October 27, 2009, we and privately-held Mist Acquisition, LLC, entered into a licensing agreement to manufacture and commercialize the NitroMist® lingual spray version of nitroglycerine, a widely-prescribed and leading short-acting nitrate for the treatment of angina pectoris, in the United States, Canada and Mexico. Under terms of the agreement, Mist paid us a $1,000,000 licensing fee upon execution of the

agreement, and we expect to receive milestone payments totaling an additional $1,000,000 by the end of 2010, and ongoing performance payments of seventeen percent (17%) of net sales, subject to the terms of the agreement.

Through a separate license agreement with Mist, Akrimax Pharmaceuticals, LLC will receive the exclusive right to manufacture, distribute, market and sell NitroMist® in North America. NitroMist® provides acute relief of an attack or acute prophylaxis of angina pectoris due to coronary artery disease. The lingual spray form of the drug is conveniently administered and is rapidly absorbed into the bloodstream via the oral mucosa, providing patients a fast and tolerable treatment option for the prevention or relief of pain associated with such attacks.

Agreement with ECR Pharmaceuticals Company, Inc.

On November 13, 2009, we entered into an exclusive license and distribution agreement with ECR Pharmaceuticals Company, Inc. (a wholly-owned subsidiary of Hi-Tech Pharmacal Co., Inc.) to commercialize and manufacture ZolpiMist in the United States and Canada. ZolpiMist is our oral spray formulation of zolpidem tartrate approved by the FDA in December of 2008.

Under the terms of the agreement, we received a $3,000,000 licensing fee from ECR upon execution of the agreement. ECR will assume responsibility for manufacturing and marketing the product in the United States and Canada. In addition, ECR will pay royalties of up to 15% on net sales of ZolpiMist as well as an additional milestone payment if sales reach a specified level.

Agreement with Par Pharmaceutical, Inc. and Hana BioSciences, Inc.

In October 2004, we entered into a license and development agreement pursuant to which we granted to Hana Biosciences an exclusive license to develop and market Zensana , our oral spray version of ondansetron, in the U.S. and Canada. Pursuant to the terms of the agreement, in exchange for $1,000,000, Hana Biosciences purchased 400,000 shares of our common stock at a per share price equal to $2.50, a premium of $0.91 per share or $364,000 over the then market value of our common stock. We accounted for this premium as deferred revenue related to the license. In connection with the agreement, Hana Biosciences issued to us $500,000 worth of common stock of Hana Biosciences (73,121 shares based on a market value of $6.84 per share). The fair value of the common stock received from Hana Biosciences was included in deferred revenue and was being recognized over the 20-year term of the agreement.

In July 2007, we entered into a Product Development and Commercialization Sublicense Agreement, or the Sublicense Agreement, with Hana Biosciences and Par, pursuant to which Hana Biosciences granted a non-transferable, non-sublicenseable, royalty-bearing, exclusive sublicense to Par to develop and commercialize Zensana . In connection therewith, Hana Biosciences amended and restated their existing License and Development Agreement, as amended, with us relating to the development and commercialization of Zensana , referred to herein as the Amended and Restated License Agreement, to coordinate certain of the terms of the Sublicense Agreement. Under the terms of the Sublicense Agreement, Par is responsible for all development, regulatory, manufacturing and commercialization activities of Zensana in the United States and Canada. We retain our rights to Zensana outside of the United States and Canada.

In addition, under the terms of the Amended and Restated License Agreement, Hana Biosciences relinquished its right to pay reduced royalty rates to us until such time as Hana Biosciences had recovered one-half of its costs and expenses incurred in developing Zensana from sales of Zensana and we agreed to surrender for cancellation all 73,121 shares of the Hana Biosciences common stock, with a fair value of $140,000, that had been acquired by us in connection with execution of the original License Agreement.

During the three months ended March 31, 2007, we recorded a $360,000 impairment charge to the statement of operations, the only component of other loss, to establish a new cost basis of $140,000 for the investment as of March 31, 2007. The remaining investment balance was written off in the quarter ended September 30, 2007, to reflect the surrender of our 73,121 shares to Hana in connection with the Amended and Restated License Agreement. We may receive additional milestone payments and royalties over the term of the agreement.

Agreement with BioAlliance Pharma SA

On May 19, 2008, we and BioAlliance Pharma SA or BioAlliance, entered into an agreement where BioAlliance acquired the European rights for Zensana, our ondansetron oral spray. Under the terms of the agreement, BioAlliance paid us a license fee of $3,000,000 upon closing. We are eligible for additional milestone payments totaling approximately $24 million (an approval milestone of $5,000,000 and sales-related milestone payments of approximately $19 million) as well as a royalty on net sales. BioAlliance and us anticipate collaborating in the completion of development activities for Europe, with BioAlliance responsible for regulatory and pricing approvals and then commercialization throughout Europe. We will be responsible for supplying the product. The upfront payment has been included in deferred revenue and is being recognized in income over the term of the agreement (nineteen and one half-years). During the six months ended June 30, 2010 and twelve months ended December 31, 2009, we recognized $77,000 and $154,000 of income related to this contract, respectively.

Agreement with Velcera Pharmaceuticals, Inc.

In June 2004, we entered into a 20-year worldwide exclusive license agreement with Velcera, a veterinary company. The license agreement is for the exclusive rights to our propriety oral spray technology in animals. In S