

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  
(State or other jurisdiction of incorporation or  
organization)

2834  
(Primary Standard Industrial  
Classification Code)

22-2407152  
(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

Edgar Filing: NOVADEL PHARMA INC - Form S-1

**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.

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.

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.

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.

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

Accelerated filer

Non-accelerated filer  (Do not check if a smaller reporting company) Smaller reporting company

---

## 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)
<b>Total</b>	<b>\$ 10,000,000</b>	<b>\$ 713.00</b>

- (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.

Edgar Filing: NOVADEL PHARMA INC - Form S-1

**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

	<b>Page</b>
<u>PROSPECTUS SUMMARY</u>	1
<u>SUMMARY OF THE OFFERING</u>	4
<u>SUMMARY OF SELECTED FINANCIAL INFORMATION</u>	5
<u>RISK FACTORS</u>	6
<u>SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS</u>	26
<u>USE OF PROCEEDS</u>	27
<u>CAPITALIZATION</u>	28
<u>DILUTION</u>	29
<u>DESCRIPTION OF BUSINESS</u>	30
<u>MANAGEMENT</u>	46
<u>DESCRIPTION OF PROPERTY</u>	48
<u>LEGAL PROCEEDINGS</u>	48
<u>PRICE RANGE OF COMMON STOCK</u>	49
<u>DIVIDEND POLICY</u>	49
<u>SELECTED FINANCIAL INFORMATION</u>	50
<u>SUPPLEMENTARY FINANCIAL INFORMATION</u>	52
<u>MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</u>	53
<u>QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK</u>	62
<u>DIRECTORS AND NAMED EXECUTIVE OFFICERS</u>	63
<u>EXECUTIVE COMPENSATION</u>	66
<u>DIRECTOR COMPENSATION</u>	85
<u>SECURITY OWNERSHIP OF DIRECTORS, MANAGEMENT AND CERTAIN BENEFICIAL OWNERS</u>	88
<u>CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS</u>	90
<u>PLAN OF DISTRIBUTION</u>	91
<u>DESCRIPTION OF SECURITIES</u>	93
<u>LEGAL MATTERS</u>	94
<u>EXPERTS</u>	94
<u>WHERE YOU CAN FIND ADDITIONAL INFORMATION</u>	94
<u>INDEX TO DECEMBER 31, 2009 FINANCIAL STATEMENTS</u>	F-1
<u>INDEX TO UNAUDITED JUNE 30, 2010 FINANCIAL STATEMENTS</u>	F-28

---

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:

	<b>Active Ingredient or Class of Molecule</b>	<b>Indications</b>	<b>Stage of Development</b>	<b>Partner</b>
<b>Approved Products</b>				
NitroMist®	Nitroglycerin	Angina Pectoris	FDA Approved	Mist Acquisition ECR Pharmaceuticals
Zolpimist	Zolpidem	Insomnia	FDA Approved	
<b>Product Candidates</b>				
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.

	<b>Six months ended June 30,</b>		<b>Year ended December 31,</b>		
	<b>2010</b>	<b>2009</b>	<b>2009</b>	<b>2008</b>	<b>2007</b>
<b>(unaudited)</b>					
<b>Consolidated Statements of Operations Data</b>					
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

	<b>June 30, 2010</b>	<b>December 31, 2009</b>
<b>(unaudited)</b>		
<b>Balance Sheet Data:</b>		
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.

## Edgar Filing: NOVADEL PHARMA INC - Form S-1

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

## Edgar Filing: NOVADEL PHARMA INC - Form S-1

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 FDCA, as amended (21 U.S.C. 301 et. seq.), a new drug may not be commercialized or otherwise distributed in the U.S. without the prior approval of the FDA or pursuant to an applicable exemption from the FDCA. The FDA approval 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 FDCA. 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.

## Edgar Filing: NOVADEL PHARMA INC - Form S-1

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 FDCA was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, otherwise known as the Hatch-Waxman Act. Section 505(b)(2) permits the submission of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. For example, the Hatch-Waxman Act permits an applicant to rely upon the FDA's findings of safety and effectiveness for an approved product. The FDA may also require companies to perform one or more

## Edgar Filing: NOVADEL PHARMA INC - Form S-1

additional studies or measurements to support the change from the approved product. The FDA may then approve the new formulation for all or some of the label indications for which the referenced product has been approved, or a new indication sought by the Section 505(b)(2) applicant.

To the extent that the Section 505(b)(2) applicant is relying on the FDA's findings for an already-approved product, the applicant is required to certify to the FDA concerning any patents listed for the approved product in the FDA's Orange Book publication. Specifically, the applicant must certify that: (1) the required patent information has not been filed (paragraph I certification); (2) the listed patent has expired (paragraph II certification); (3) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration (paragraph III certification); or (4) the listed patent is invalid or will not be infringed by the manufacture, use or sale of the new product (paragraph IV certification). If the applicant does not challenge the listed patents, the Section 505(b)(2) application will not be approved until all the listed patents claiming the referenced product have expired, and once any pediatric exclusivity expires. The Section 505(b)(2) application may also not be approved until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the referenced product has expired.

If the applicant has provided a paragraph IV certification to the FDA, the applicant must also send notice of the paragraph IV certification to the NDA holder and patent owner once the NDA has been accepted for filing by the FDA. The NDA holder and patent owner may then initiate a legal challenge to the paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of their receipt of a paragraph IV certification automatically prevents the FDA from approving the Section 505(b)(2) NDA until the earliest of 30 months, expiration of the patent, settlement of the lawsuit or a decision in an infringement case that is favorable to the Section 505(b)(2) applicant. Thus, a Section 505(b)(2) applicant may invest a significant amount of time and expense in the development of its products only to be subject to significant delay and patent litigation before its products may be commercialized. Alternatively, if the NDA holder or patent owner does not file a patent infringement lawsuit within the required 45-day period, the applicant's NDA will not be subject to the 30-month stay.

Notwithstanding the approval of many products by the FDA pursuant to Section 505(b)(2), over the last few years, certain brand-name pharmaceutical companies and others have objected to the FDA's interpretation of Section 505(b)(2). If the FDA changes its interpretation of Section 505(b)(2), this could delay or even prevent the FDA from approving any Section 505(b)(2) NDA that we submit.

### **Even if we obtain patents to protect our products, those patents may not be sufficiently broad and others could compete with us.**

We, and the parties licensing technologies to us, have filed various U.S. and foreign patent applications with respect to the products and technologies under our development, and the USPTO and foreign patent offices have issued patents with respect to our products and technologies. These patent applications include international applications filed under the Patent Cooperation Treaty. Our pending patent applications, those we may file in the future and those we may license from third parties, may not result in the USPTO or any foreign patent office issuing patents. Also, if patent rights covering our products are not sufficiently broad, they may not provide us with sufficient proprietary protection or competitive advantages against competitors with similar products and technologies. Furthermore, if the USPTO or foreign patent offices issue patents to us or our licensors, others may challenge the patents or circumvent the patents, or the patent office or the courts may invalidate the patents. Thus, any patents we own or license from or to third parties may not provide any protection against competitors.

Furthermore, the life of our patents is limited. Such patents, which include relevant foreign patents, expire on various dates. We have filed, and when possible and appropriate, will file, other patent applications with respect to our product candidates and processes in the U.S. and in foreign countries. We may not be able to develop additional products or processes that will be patentable or additional patents may not be issued to us. See also Risk Factors - If We Cannot Meet Requirements Under our License Agreements, We Could Lose the Rights to our Products.

**Intellectual property rights of third parties could limit our ability to market our products.**

Our commercial success also significantly depends on our ability to operate without infringing the patents or violating the proprietary rights of others. The USPTO keeps U.S. patent applications confidential while the applications are pending. As a result, we cannot determine which inventions third parties claim in pending patent applications that they have filed. We may need to engage in litigation to defend or enforce our patent and license rights or to determine the scope and validity of the proprietary rights of others. It will be expensive and time consuming to defend and enforce patent claims. Thus, even in those instances in which the outcome is favorable to us, the proceedings can result in the diversion of substantial resources from our other activities. An adverse determination may subject us to significant liabilities or require us to seek licenses that third parties may not grant to us or may only grant at rates that diminish or deplete the profitability of the products to us. An adverse determination could also require us to alter our products or processes or cease altogether any related research and development activities or product sales.

**If we cannot meet requirements under our license agreements, we could lose the rights to our products.**

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

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

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

**We rely on confidentiality agreements that could be breached and may be difficult to enforce.**

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

they will breach these agreements;

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

our competitors will independently discover our proprietary information and trade secrets.



**We are dependent on existing management and board members.**

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

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

***Risk Related to Our Common Stock***

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

On December 24, 2009, we announced that our common stock 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.

## Edgar Filing: NOVADEL PHARMA INC - Form S-1

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

## Edgar Filing: NOVADEL PHARMA INC - Form S-1

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.

	<b>As of June 30, 2010</b>	
	Actual	As Adjusted
	(Unaudited)	(Unaudited)
<b>Stockholders' Deficiency:</b>		
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)	[ ]
<b>Total Stockholders' Deficiency</b>	<b>\$ (5,835,000)</b>	<b>\$ [ ]</b>

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
<i>Approved Products</i>				
NitroMist®	Nitroglycerin	Angina Pectoris	FDA Approved	Mist Acquisition
Zolpimist	Zolpidem	Insomnia	FDA Approved	ECR Pharmaceuticals
<i>Product Candidates</i>				
Duromist	Sildenafil	Erectile Dysfunction	Clinical development	Hana Biosciences Par Pharmaceuticals BioAlliance Pharma
Zensana	Ondansetron	Nausea/Vomiting	Clinical development	
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 ( $C_{\text{max}}$ ) than that of the 25 mg Viagra tablet was observed with the 20 mg oral spray dose. The  $T_{\text{max}}$  (or time point at  $C_{\text{max}}$ ) 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,



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 proprietary oral spray technology in animals. In September 2004, we received \$1,500,000 from Velcera as an upfront payment in connection with the commercialization agreement. The upfront payment has been included in deferred revenue and is being recognized in income over the 20-year term of the agreement. In addition, we received an equity stake of 529,500 shares of common stock in Velcera which did not have a material value. Such investment continues to be carried at its cost basis of \$0 as of December 31, 2009. In February 2007, Velcera merged with Denali Sciences, Inc., a publicly reporting Delaware corporation. In June 2007, Velcera announced that it had entered into a global license and development agreement with Novartis Animal Health. The agreement called for Novartis Animal Health to develop, register and commercialize a novel canine product utilizing Velcera's Promist platform, which is based on its patented oral spray technology. We may receive additional milestone payments and royalty payments over the 20-year term of the agreement. In November 2007, the common stock of the merged companies began trading on the OTC bulletin board. On March 5, 2008, Velcera announced that it had received notice from Novartis Animal Health that it was terminating the agreement, without cause. On August 24, 2009, we issued a press release to announce that we received a milestone payment of approximately \$150,000 from Velcera, Inc. relating to its license agreement. On March 5, 2010, the Company 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.

***Agreement with Manhattan Pharmaceuticals, Inc.***

In April 2003, we entered into a license and development agreement with Manhattan Pharmaceuticals for the worldwide, exclusive rights to our proprietary oral spray technology to deliver propofol for pre-procedural sedation. The terms of the agreement call for certain license, milestone and other payments, the first \$125,000 of which was received in June 2003. In November 2003, we received \$375,000 from Manhattan Pharmaceuticals for license fees. We have included these license fees in deferred revenue and are recognizing these license fees over the 20-year term of the license. In July 2007, Manhattan Pharmaceuticals, our partner for its propofol oral spray product candidate, announced that as part of its change in strategic focus it intends to pursue appropriate sub-licensing opportunities for this product candidate.

**Marketing and Distribution**

To date, we have chosen to license products developed with our technology to other drug companies. We intend to pursue additional strategic alliances, as well as to consider fully developing and commercializing product candidates internally.

We anticipate that promotion of our product candidates, whether conducted by us or by a strategic partner, will be characterized by an emphasis on their distinguishing characteristics, such as dosage form and packaging, as well as possible therapeutic advantages of such product candidates. We intend to position our product candidates as alternatives or as line extensions to brand-name products. We believe that to the extent our formulated products are patent-protected, such formulations may offer brand-name manufacturers the opportunity to expand their product lines. Alternatively, products which are not patented

may be offered to brand-name manufacturers as improved substitute products after patent protection on existing products expire.

In as much as we do not currently have the financial or other resources to undertake extensive marketing activities, we generally intend to seek to enter into marketing arrangements, including possible joint ventures or license or distribution arrangements, with third parties. We believe that such third-party arrangements will permit us to maximize the promotion and distribution of pharmaceutical products while minimizing our direct marketing and distribution costs. If we are unable to enter into additional agreements, we may not be able to successfully market our product candidates.

We have not yet determined strategies relating to marketing of our other proposed formulated products; these will be formulated in advance of anticipated completion of development activities relating to the particular formulated product. As a company, we have no experience in marketing or distribution of our product candidates, and our ability to fund such marketing activities will require us to raise additional funds and/or consummate a strategic alliance or combination with a well-funded business partner.

### **Manufacturing**

For our approved products that we have licensed to third parties, these licensees are primarily responsible for the manufacturing of these approved products. For our product candidate Duromist, we contract with DPT Laboratories for the manufacture of this product candidate. In addition, we entered into a Master Services Agreement with Rechon Life Sciences (Malmö, Sweden), whereby Rechon will provide services related to the manufacturing development and the manufacture of clinical supplies for certain of our products. Rechon provides these services on a fee-for-service basis. The manufacture of our approved products and product candidates is subject to current good manufacturing practices, or cGMP, prescribed by the FDA and pre-approval inspections by the FDA and foreign authorities prior to the commercial manufacture of any such products. See [Raw Materials and Suppliers](#) and [Government Regulation](#).

### **Raw Materials and Suppliers**

We believe that the active ingredients used in the manufacture of our product candidates are presently available from numerous suppliers located in the U.S., Europe and Japan and can be delivered to our manufacturing facility by such suppliers. We intend to enter into arrangements with such third-party suppliers for supplies of active and inactive pharmaceutical ingredients and packaging materials used in the manufacture of our product candidates. Accordingly, we may be subject to various import duties applicable to both finished products and raw materials and may be affected by various other import and export restrictions as well as other developments impacting upon international trade. These international trade factors will, under certain circumstances, have an impact on the manufacturing costs (which will, in turn, have an impact on the cost of our product candidates). To the extent that transactions relating to the

purchase of raw materials involve currencies other than U.S. dollars, our operating results will be affected by fluctuations in foreign currency exchange rates.

Generally, certain raw materials, including inactive ingredients, are available from a limited number of suppliers and certain packaging materials intended for use in connection with our product candidates may be available only from sole source suppliers. Although we believe that we will not encounter difficulties in obtaining the inactive ingredients or packaging materials necessary for the manufacture of our products, we may not be able to enter into satisfactory agreements or arrangements for the purchase of commercial quantities of such materials. A failure to enter into agreements or otherwise arrange for adequate or timely supplies of principal raw materials and the possible inability to secure alternative sources of raw material supplies could have a material adverse effect on our ability to manufacture formulated products.

Development and regulatory approval of our product candidates are dependent upon our ability to procure active ingredients and certain packaging materials from FDA-approved sources. Since the FDA approval process requires manufacturers to specify their proposed suppliers of active ingredients and certain packaging materials in their applications, FDA approval of a supplemental application to use a new supplier would be required if active ingredients or such packaging materials were no longer available from the specified supplier, which could result in manufacturing delays. Accordingly, we intend to locate alternative FDA approved suppliers.

### **Competition**

The markets which we intend to enter are characterized by intense competition, often from organizations which are larger and/or better capitalized than us. We will be competing against established pharmaceutical companies which currently market products which are equivalent or functionally similar to those we intend to market. Prices of drug products are significantly affected by competitive factors and tend to decline as competition increases. In addition, numerous companies are developing or may, in the future, engage in the development of products competitive with our proposed products. We expect that technological developments will occur at a rapid rate and that competition is likely to intensify as enhanced delivery system technologies gain greater acceptance. Additionally, the markets for formulated products which we have targeted for development are intensely competitive, involving numerous competitors and products. We intend to enhance our competitive position by focusing our efforts on our novel dosage forms.

We also face, and will continue to face, competition from colleges, universities, governmental agencies and other public and private research organizations. These competitors are becoming more active in seeking patent protection and licensing arrangements to collect royalties for use of technology that they have developed. Some of these technologies may compete directly with the technologies that we are developing. These institutions will also compete with us in recruiting highly qualified scientific personnel. We expect that developments in the areas in which we are active may occur at a rapid rate and that competition will intensify as advances in this field are made. As a result, we need to continue to devote substantial resources and efforts to research and development activities.

### **Patents and Protection of Proprietary Information**

We have applied for U.S. and foreign patent protection for our buccal spray delivery systems which are the primary focus of our development activities. Currently, we have nine patents which have been issued in the U.S. and 52 patents which have been issued outside of the U.S. Additionally, we have over 60 patents pending around the world. Additional patent applications may not be granted, or, if granted, may not provide adequate protection to us. We also intend to rely on whatever protection the law affords to trade secrets, including unpatented know-how. Other companies, however, may independently develop equivalent or superior technologies or processes and may obtain patents or similar rights with respect thereto.

FDA approval is not a prerequisite for patent approval. The expected year of marketability of a given product candidate will vary depending upon the patent expiration of the specific drug product with which the delivery system will be utilized. Each individual use of the delivery system will require registration with and/or approval by the FDA or other relevant health authority prior to marketability, and the amount of regulatory oversight required by the FDA or other regulatory agencies will also depend on the specific type of drug product for which the delivery system is implemented. Our aerosol and pump spray formulations release drugs in the form of a fine mist into the buccal portion of the mouth for rapid

absorption into the bloodstream via the mucosal membranes. Our proprietary technology offers, in comparison to conventional oral dosage forms, the potential for faster absorption of drugs into the bloodstream leading to quicker onset of therapeutic effects and possibly reduced first pass liver metabolism, which may result in lower doses. Oral sprays eliminate the requirement for water or the need to swallow, potentially improving patient convenience and adherence. Our oral spray technology is focused on addressing unmet medical needs for a broad array of existing and future pharmaceutical products.

Although we believe that we have developed our technology independently and have not infringed, and do not infringe, on the patents of others, third parties may make claims, however, that our technology does infringe on their patents or other intellectual property. In the event of infringement, we may, under certain circumstances, be required to modify our infringing product or process or obtain a license. We may not be able to do either of those things in a timely manner if at all, and failure to do so could have a material adverse effect on our business. In addition, we may not have the financial or other resources necessary to enforce a patent infringement or proprietary rights violation action or to defend ourselves against such actions brought by others. If any of the products we develop infringe upon the patent or proprietary rights of others, we could, under certain circumstances, be enjoined or become liable for damages, which would have a material adverse effect on our business.

We also rely on confidentiality and nondisclosure agreements with our licensees and potential development candidates to protect our technology, intellectual property and other proprietary property. Pursuant to the foregoing and for other reasons, we face the risk that our competitors may acquire information which we consider to be proprietary, that such parties may breach such agreements or that such agreements will be inadequate or unenforceable.

***Buccal Nonpolar Sprays.*** On April 12, 1996, we filed an application with the U.S. Patent and Trademark Office, or the USPTO, with claims directed to our buccal spray composition containing certain amounts of propellant, a non-polar solvent, and certain classes of drugs, as well as specific drugs within those classes. The application also included claims directed to soft-bite gelatin capsules containing these drugs. On September 1, 1998, the USPTO allowed the claims directed to buccal spray propellant compositions, but rejected the claims directed to the capsules. In November 1998, we deleted the capsule claims from this application to pursue issuance of a patent with claims directed to the buccal non-polar spray compositions and methods of administering the class of drugs using the buccal spray compositions. On September 21, 1999, U.S. Patent No. 5,955,098 was issued to us with claims directed to the above-described buccal non-polar spray propellant compositions and methods. This patent expires on April 12, 2016.

On February 21, 1997, we filed an application under the Patent Cooperation Treaty, or the PCT, (PCT Publication No. WO 97/38663) for the above-subject matter. The International Preliminary Examination Authority issued an International Preliminary Examination Report alleging that the subject matter of the invention lacked novelty and/or lacked an inventive step. This opinion, with which we disagree, is not dispositive.

With respect to the above PCT application, in October and November 1998, we entered the national phase in Canada and Europe, with claims directed to the above subject matter. On April 16, 2003, European Patent No. EP 0 904 055 was granted to us with claims directed to propellant containing buccal non-polar spray compositions containing similar drugs (i.e., anti-histamines, steroid hormones, non-steroidal anti-inflammatories, benzodiazepines, anti-depressants and nicotine) to those in the corresponding issued U.S. patent. This European patent has been validated in the UK, Germany, France, Italy, Belgium, Switzerland/Liechtenstein, Austria, Sweden, Denmark, Finland, Luxembourg, the Netherlands, Spain, Greece, Monaco, Portugal and Ireland so that there is patent protection in these countries. We have filed a divisional application based on this European patent. On April 17, 2007, this application issued to us as European Patent No. 1 275 374 with claims directed to a buccal spray composition containing a propellant, a non-polar solvent and an active compound selected from alkaloids and analgesics. This European patent has been validated in the U.K., Germany, France, Italy, Belgium, Switzerland/Liechtenstein, Sweden, the Netherlands, Spain, and Greece, so that there is patent protection in these countries. No opposition has been filed to this application and the time for filing any opposition has expired.

With respect to the Canadian application, we filed a request for examination with the Canadian Patent Office on February 7, 2002. We received an Office Action from the Canadian Patent Office dated April 13,

## Edgar Filing: NOVADEL PHARMA INC - Form S-1

2004, pursuant to which we were requested to elect for prosecution either claims directed to buccal spray compositions or claims to the soft-bite gelatin capsules. We elected to prosecute the claims directed to buccal spray compositions. The Canadian Patent Office granted the application on December 27, 2005 as Canadian Patent No. 2,252,050. The allowed claims are similar to those granted by the European Patent Office.

**Buccal Polar Sprays.** On April 12, 1996, we filed an application with the USPTO with claims directed to propellant free buccal polar spray compositions containing certain amounts of a polar solvent and certain classes of drugs (i.e., non-steroidal anti-inflammatories, anti-histamines, steroid hormones, benzodiazepams, and anti-depressants), as well as specific drugs within those classes. The application also contained claims to soft-bite gelatin capsules containing such drugs. A continuation-in-part, or CIP, application was filed directed to this subject matter before the original application was allowed to go abandoned. The USPTO initially rejected the claims in the CIP application. We deleted the claims from this application (including the soft-bite capsule claims) and replaced them with claims directed to methods of using the above-described propellant free buccal polar spray compositions to administer the drugs. On August 29, 2000, U.S. Patent No. 6,110,486 was issued to us with claims directed to the above-described methods of administering the drugs. This patent expires on April 12, 2016.

On February 21, 1997, we filed an application under the PCT (PCT Publication No. WO 97/38662) for the above-described subject matter. The International Preliminary Examination Authority issued an International Preliminary Examination Report alleging that the subject matter of the invention lacked novelty and/or lacked an inventive step. This opinion, with which we disagree, is not dispositive.

With respect to the above PCT application, in October and November 1998, we entered the national phase in Canada and Europe, respectively, with claims directed to the above subject matter.

On February 2, 2005, European Patent No. 0 910 339 was granted to us with claims directed to use of polar solvent containing pump sprays containing similar drugs to those in the corresponding issued U.S. patent. This European patent has been validated in the UK, Germany, France, Italy, Belgium, Switzerland/Liechtenstein, Austria, Sweden, Denmark, Finland, Luxembourg, the Netherlands, Spain, Greece, Monaco, Portugal and Ireland so that there was patent protection in these countries. In November 2005, Akzo Nobel N.V. filed a successful opposition against this patent in the European Patent Office alleging lack of inventive step. We have decided not to file any appeal in connection with this opposition. As a result, the European Patent is no longer in force.

With respect to the Canadian application, we filed a request for examination with the Canadian Patent Office on February 7, 2002. We received an Office Action from the Canadian Patent Office dated April 13, 2004, pursuant to which we were requested to elect for prosecution either claims directed to buccal spray compositions or claims to the soft-bite gelatin capsules. We elected to prosecute the claims directed to buccal spray compositions. On February 10, 2006, the Canadian Patent Office issued a Notice of Allowance for this application. On October 10, 2006, Canadian Patent No. 2,252,038 was granted to us with claims directed to the use of a pharmacologically active compound selected from the group consisting of non-steroidal anti-inflammatories, anti-histamines, steroid hormones, benzodiazepines, and anti-depressants for the preparation of a buccal aerosol pump spray composition for being absorbed through the oral mucosa.

**Buccal Nonpolar Spray for Nitroglycerin.** On April 12, 1996, we filed an application with the USPTO with claims directed to a buccal spray containing certain amounts of nitroglycerin, a non-polar solvent, and a propellant. The claims were allowed and on February 9, 1999, the USPTO issued U.S. Patent No. 5,869,082 to us for said nitroglycerin buccal spray. This patent expires on April 12, 2016.

On February 21, 1997, we filed a PCT application (PCT Publication No. WO 97/38687) directed to the above-described subject matter. The International Preliminary Examination Authority issued an International Preliminary Examination Report alleging that the subject matter of the invention lacks an inventive step. This opinion, with which we disagree, is not dispositive.

In October 1998, we entered the national phase in Canada. We filed a request for examination on February 7, 2002. The Canadian Patent Office issued a second office action to us dated July 11, 2005. We responded to the office action on January 11, 2006. As a result, Canadian Patent No. 2,251,564 was granted to us on

## Edgar Filing: NOVADEL PHARMA INC - Form S-1

January 9, 2007, with claims directed to a buccal spray containing certain amounts of nitroglycerin, a non-polar solvent and a propellant.

In November 1998, we entered the national phase in Europe. European Patent No. 0 927 032 was granted to us on April 16, 2003, with claims directed to a buccal spray containing certain amounts of nitroglycerin, a non-polar solvent and a propellant. This European patent has been validated in the UK, Germany, France, Italy, Belgium, Switzerland/Liechtenstein, Austria, Sweden, Denmark, Finland, Luxembourg, the Netherlands, Spain, Greece, Monaco, Portugal and Ireland so that there is patent protection in these countries.

***Buccal Polar/Nonpolar Sprays or Capsules.*** On October 1, 1997, we filed a PCT application (PCT Publication No. WO 99/16417) designating a large number of countries including the U.S., directed to the buccal sprays and soft-bite capsules. The application included claims directed to: (A) a buccal spray composition containing either (1) a polar solvent with certain classes of drugs, as well as specific drugs in those classes with or without a propellant or (2) a non-polar solvent with or without a propellant with certain classes of drugs, as well as specific drugs in those classes; (B) buccal spray composition containing a non-polar solvent, a flavoring agent and certain classes of drugs; and (C) methods of administering these drugs using the buccal spray compositions. The application also contained claims to soft-bite gelatin capsules containing such drugs. This application differs from the first three applications, discussed above, in that the claimed compositions include different classes of drugs from those described in the first three applications. The International Preliminary Examination Authority issued an International Preliminary Examination Report alleging that the subject matter of the invention lacked novelty and/or lacked an inventive step. This opinion, with which we disagree, is not dispositive.

On March 29, 2000, we entered the national phase in the U.S. by filing a CIP of the above-identified PCT application with the USPTO. The CIP application included claims directed to propellant free buccal spray compositions containing certain amounts of polar or non-polar solvents, and certain classes of drugs, as well as specific drugs in those classes; buccal spray compositions containing certain amounts of a propellant, a polar or non-polar solvent and certain classes of drugs, as well as specific drugs in those classes; and methods of administering said drugs using these types of buccal spray compositions. The application is currently being prosecuted with claims directed to the propellant free buccal spray compositions and methods of administering said drugs using these types of buccal spray compositions.

Subsequently, we filed two divisional applications claiming priority to the CIP. The first divisional application was issued to us as U.S. Patent No. 6,998,110 with claims directed to methods of administering a biologically active peptides, central nervous system active amines, sulfonyl ureas, antibiotics, antifungals, sleep inducers, antiasthmatics, antiemetics, antivirals, histamine H-2 receptor antagonists, barbiturates, prostaglandins, or bronchial dilators using the buccal spray compositions containing certain amounts of a propellant, a polar or non-polar solvent and certain classes of drugs. This patent expires on October 1, 2017. Another application has been filed directed to additional formulations relating to U.S. Patent No. 6,998,110. The second divisional application was issued to us as U.S. Patent No. 6,676,931. This patent expires on October 1, 2017. The claims of this patent are directed to a propellant free pump spray composition containing certain amounts of a polar solvent, certain amounts of a flavoring agent and certain amounts of cyclosporin or ondansetron hydrochloride. Another application has been filed directed to the additional classes of drugs and specific drugs and formulations that were not included in the claims of U.S. Patent No. 6,676,931.

Based on the above-identified PCT application, we entered the national phase in Canada on March 29, 2000. We filed a request for examination in Canada on August 29, 2002. An office action has been received from the Canadian Patent Office and we have responded to that office action.

Based on the above-identified PCT application, we also entered the national phase in Japan on April 3, 2000. An office action rejecting the pending claims has been received from the Japanese Patent Office. We have demanded a trial in response to that office action. In addition, we are in the process of filing a divisional application in Japan claiming priority to this application.

Based on the above-identified PCT application, we also entered the national phase in Europe in April 2000. The European application includes claims directed to propellant free buccal spray compositions containing certain amounts of a polar solvent and certain classes of drugs, as well as specific drugs in those classes and

the use thereof to prepare a medicament for use as a buccal spray for transmucosal administration. We have filed three applications related to this application in Europe. The first application included claims directed to buccal spray compositions containing certain amounts of a non-polar solvent, a propellant and certain classes of drugs as well as specific drugs in those classes and the use thereof to prepare a medicament for use as a buccal spray for transmucosal administration. This application was granted to us on April 18, 2007, as European Patent No. 1 295 536 with claims directed to a buccal spray composition including a propellant, a non-polar solvent, and one of the following active compounds: biologically active peptides, central nervous system active amines, sulfonyl ureas, antibiotics, antifungals, antivirals, sleep inducers, antihistamines, antiemetics, histamine H-2 receptor antagonists, barbiturates, prostoglandins, and bronchial dilators selected from the group consisting of terbutaline, and theophylline. A divisional application has been filed claiming priority from this patent. The second application included claims directed to propellant free buccal spray compositions containing certain amounts of a non-polar solvent and certain classes of drugs, as well as specific drugs in those classes. The third application included claims directed to a buccal spray composition containing certain amounts of a polar solvent, a propellant and certain classes of drugs, as well as specific drugs in those classes. Each of the above-identified European applications is currently being prosecuted.

Furthermore, in August 2002, we filed a number of U.S. patent applications directed to buccal spray compositions containing certain classes of drugs as well as specific drugs for treating particular types of disorders. In August 2003, we filed PCT applications related to these U.S. applications. We have subsequently filed corresponding applications in Europe, Japan and Canada for the subject matter for a majority of these CIP applications.

From these U.S. patent applications, we have been granted U.S. Patent No. 6,969,508 with claims directed to methods for administering an effective amount of anti-opioid agents, anti-migraine agents, pain control agents, anesthetics, and mixtures thereof using a buccal spray composition containing a polar solvent and a propellant. We have also been granted U.S. Patent No. 6,977,070 with claims directed to methods for administering an effective amount of a pharmacologically active compound to a mammal to provide transmucosal absorption of a pharmacologically effective amount of acetylcholinesterase inhibitors, nerve impulse inhibitors, anti-cholinergics, anti-convulsants, anti-psychotics, anxiolytic agents, dopamine metabolism inhibitors, agents to treat post stroke sequelae, neuroprotectants, agents to treat Alzheimer's disease, neurotransmitters, neurotransmitter agonists, sedatives, agents for treating attention deficit disorder, agents for treating narcolepsy, central adrenergic antagonists, anti-depression agents, agents for treating Parkinson's disease, benzodiazepine antagonists, stimulants, neurotransmitter antagonists, tranquilizers, and mixtures thereof using a buccal spray containing a polar solvent and a propellant.

In addition, in September 2003, we filed a number of U.S. patent applications directed to buccal spray compositions containing specific drugs. We have subsequently filed corresponding applications in Europe, Japan, Canada, Israel and Korea for the subject matter a majority of these CIP applications.

***Stable Hydroalcoholic Oral Spray Formulations and Methods.*** On April 19, 2007, we filed an application with the USPTO with claims directed to hydroalcoholic spray compositions and methods. The application was published on October 25, 2007, and is currently pending. Substantive examination of the application by the USPTO has not yet begun.

On April 19, 2007 we also filed a corresponding PCT application (PCT Publication No. WO 2007/123955) to the above noted subject matter. On October 30, 2008, the International Bureau issued an International Preliminary Report on Patentability alleging that the subject matter of the invention lacked novelty and/or lacked an inventive step. This opinion, with which we disagree, is not dispositive.

Based on the above-identified PCT application, we entered the national phase in Canada, Europe and Japan in October 2008.

***Anti-Migraine Oral Spray Formulations and Methods.*** On July 27, 2007 we filed an application with the USPTO with claims directed to compositions comprising a selective 5-hydroxytryptamine receptor subtype agonist and methods of treatment. The application was published on February 7, 2008, and is currently pending. Substantive examination of the application by the USPTO has not yet begun.

On July 27, 2007 we also filed a corresponding PCT application (PCT Publication No. W0 2008/013929) to the above noted subject matter. On April 25, 2008, the International Searching Authority issued a

## Edgar Filing: NOVADEL PHARMA INC - Form S-1

Written Opinion alleging that the subject matter of the invention lacked novelty and/or lacked an inventive step. This opinion, with which we disagree, is not dispositive.

Based on the above-identified PCT application, we entered the national phase in Canada, Europe and Japan in January 2009.

***Stable Anti-Nausea Oral Spray Formulations and Methods.*** On December 21, 2007 we filed an application with the USPTO with claims directed to formulations containing a selective 5-hydroxytryptamine receptor antagonist and methods of treatment. The application was published on July 17, 2008, and is currently pending. Substantive examination of the application by the USPTO has not yet begun.

On December 21, 2007 we also filed a corresponding PCT application (PCT Publication No. W0 2008/079295) to the above noted subject matter. On May 1, 2008, the International Searching Authority issued a Written Opinion alleging that the subject matter of the invention lacked novelty and/or lacked an inventive step. This opinion, with which we disagree, is not dispositive.

***Anti-Insomnia Compositions and Methods.*** On May 12, 2008 we filed an application with the USPTO with claims directed to administering an anti-insomnia composition by buccal spray for transmucosal absorption to a patient. The application was published on November 13, 2008, and is currently pending.

On May 12, 2008 we also filed a corresponding PCT application (PCT Publication No. W0 2008/141264) to the above noted subject matter. On July 30, 2008, the International Searching Authority issued a Written Opinion alleging that the subject matter of the invention lacked novelty and/or lacked an inventive step. This opinion, with which we disagree, is not dispositive.

***Antihistamine Syrup and Ointment.*** On November 10, 1997, we filed an application with the USPTO with claims directed to a spray composition for topical administration containing an antihistamine and a polar solvent or an antihistamine, a non-polar solvent and a propellant. In October 1998, the PTO rejected the claims. The claims were deleted and replaced with a claim directed to a method of controlling the occurrence of delayed contact dermatitis by applying a lotion composition containing certain amounts of certain antihistamines in certain amounts of a polar or non-polar solvent. On May 27, 2002, U.S. Patent No. 6,391,282 was issued to us for the above-described method. This patent expires on November 10, 2017.

***General Comment with Respect to Entering the National Phase for Each of the Foregoing PCT Applications.*** In addition to our patents and patent applications in the U.S., we are interested in entering the national phase and obtaining patent protection in Europe, Japan and Canada. At the present time, it is not possible to accurately predict the expenses involved in pursuing the foregoing applications in Canada, Japan and Europe. For example, we anticipate that, in the case of the European applications, it may become necessary to file appeals with the Board of Appeals in Munich. Expenses may exceed \$100,000 (in the aggregate) before a final disposition is obtained. We expect that this process may take between two and four years.

### **Government Regulation**

#### ***FDA approval process***

In the United States, pharmaceutical products are subject to extensive regulation by the FDA. The Federal Food, Drug, and Cosmetic Act, or the FDC Act, and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling, and import and export of pharmaceutical products. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to approve pending new drug applications or NDAs, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties, and criminal prosecution.

Pharmaceutical product development in the U.S. typically involves preclinical laboratory and animal tests, the submission to the FDA of a notice of claimed investigational exemption or an investigational new drug application, or IND, which must become effective before clinical testing may commence, and adequate and well-controlled clinical trials to establish the safety and effectiveness of the drug for each indication for



## Edgar Filing: NOVADEL PHARMA INC - Form S-1

which FDA approval is sought. Satisfaction of FDA pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity and novelty of the product or disease.

Preclinical tests include laboratory evaluation of product chemistry, formulation and toxicity, as well as animal trials to assess the characteristics and potential safety and efficacy of the product. The conduct of the preclinical tests must comply with federal regulations and requirements including good laboratory practices. The results of preclinical testing are submitted to the FDA as part of an IND along with other information including information about product chemistry, manufacturing and controls and a proposed clinical trial protocol. Long term preclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND is submitted.

A 30-day waiting period after the submission of each IND is required prior to the commencement of clinical testing in humans. If the FDA has not commented on or questioned the IND within this 30-day period, the clinical trial proposed in the IND may begin.

Clinical trials involve the administration of the investigational new drug to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted in compliance with federal regulations, good clinical practices or GCP, as well as under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND.

The FDA may order the temporary or permanent discontinuation of a clinical trial at any time or impose other sanctions if it believes that the clinical trial is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial subjects. The study protocol and informed consent information for subjects in clinical trials must also be submitted to an institutional review board, or IRB, for approval. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements, or may impose other conditions.

Clinical trials to support NDAs for marketing approval are typically conducted in three sequential phases, but the phases may overlap. In Phase 1, the initial introduction of the drug into healthy human subjects or patients, the drug is tested to assess metabolism, pharmacokinetics, pharmacological actions, side effects associated with increasing doses and, if possible, early evidence of effectiveness. Phase 2 usually involves trials in a limited patient population, to determine the effectiveness of the drug for a particular indication or indications, dosage tolerance and optimum dosage, and identify common adverse effects and safety risks. If a compound demonstrates evidence of effectiveness and an acceptable safety profile in Phase 2 evaluations, Phase 3 trials are undertaken to obtain additional information about clinical efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial sites, to permit FDA to evaluate the overall benefit-risk relationship of the drug and to provide adequate information for the labeling of the drug.

Under the Pediatric Research Equity Act of 2003, or PREA, NDAs or supplements to NDAs must contain data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the drug is safe and effective. The FDA may grant deferrals for submission of data or full or partial waivers.

After completion of the required clinical testing, an NDA is prepared and submitted to the FDA. FDA approval of the NDA is required before marketing of the product may begin in the U.S. The NDA must include the results of all preclinical, clinical and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture, and controls. The cost of preparing and submitting an NDA is substantial. Under federal law, the submission of most NDAs is additionally subject to a substantial application user fee, currently \$1,178,000, and the manufacturer and/or sponsor under an approved new drug application are also subject to annual product and establishment user fees, currently \$65,030 per product and \$392,700 per establishment. These fees are typically increased annually.

The FDA has 60 days from its receipt of a NDA to determine whether the application will be accepted for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. Once the submission is accepted for filing, the FDA begins an in-depth review. The FDA has agreed to certain performance goals in the review of new drug applications. Most such applications for non-

priority drug products are reviewed within ten months. The review process may be extended by FDA for three additional months to consider certain new information or clarification regarding information already provided in the submission. The FDA may also refer applications for novel drug products or drug products which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. Before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. Additionally, the FDA will inspect the facility or the facilities at which the drug is manufactured. FDA will not approve the product unless compliance with current good manufacturing practices is satisfactory and the NDA contains data that provide substantial evidence that the drug is safe and effective in the indication proposed for marketing.

After FDA evaluates the NDA and the manufacturing facilities, it issues an approval letter, an approvable letter or a not-approvable letter. Both approvable and not-approvable letters generally outline the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. If and when those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. FDA has committed to reviewing such resubmissions in 2 or 6 months depending on the type of information included.

An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. As a condition of NDA approval, the FDA may require substantial post-approval testing and surveillance to monitor the drug's safety or efficacy and may impose other conditions, including labeling restrictions which can materially affect the potential market and profitability of the drug. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

#### ***The Hatch-Waxman Act***

In seeking approval for a drug through an NDA, applicants are required to list with the FDA each patent with claims that cover the applicant's product. Upon approval of a drug, each of the patents listed in the application for the drug is then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential generic competitors in support of approval of an abbreviated new drug application, or ANDA. An ANDA provides for marketing of a drug product that has the same active ingredients in the same strengths and dosage form as the listed drug and has been shown through bioequivalence testing to be therapeutically equivalent to the listed drug. ANDA applicants are not required to conduct or submit results of pre-clinical or clinical tests to prove the safety or effectiveness of their drug product, other than the requirement for bioequivalence testing. Drugs approved in this way are commonly referred to as generic equivalents to the listed drug, and can often be substituted by pharmacists under prescriptions written for the original listed drug.

The ANDA applicant is required to certify to the FDA concerning any patents listed for the approved product in the FDA's Orange Book. Specifically, the applicant must certify that: (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the new product. A certification that the new product will not infringe the already approved product's listed patents or that such patents are invalid is called a Paragraph IV certification. If the applicant does not challenge the listed patents, the ANDA application will not be approved until all the listed patents claiming the referenced product have expired.

If the ANDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit or a decision in the infringement case that is favorable to the ANDA applicant.

The ANDA also will 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. Federal law provides a period of five years following approval of a drug containing no previously approved active ingredients, during which ANDAs for generic versions of those drugs cannot be submitted unless the submission contains a Paragraph IV challenge to a listed patent, in which case the submission may be made four years following the original product approval. Federal law provides for a period of three years of exclusivity following approval of a listed drug that contains previously approved active ingredients but is approved in a new dosage form, route of administration or combination, or for a new use, the approval of which was required to be supported by new clinical trials conducted by or for the sponsor, during which FDA cannot grant effective approval of an ANDA based on that listed drug.

#### ***Section 505(b)(2) New Drug Applications***

Most drug products obtain FDA marketing approval pursuant to an NDA or an ANDA. A third alternative is a special type of NDA, commonly referred to as a Section 505(b)(2) NDA, which enables the applicant to rely, in part, on the safety and efficacy data of an existing product, or published literature, in support of its application.

505(b)(2) NDAs often provide an alternate path to FDA approval for new or improved formulations or new uses of previously approved products. Section 505(b)(2) permits the filing 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. The applicant may rely upon certain preclinical or clinical studies conducted for an approved product. The FDA may also require companies to perform additional studies or measurements to support the change from the approved product. The FDA may then approve the new product candidate for all or some of the label indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant.

To the extent that the Section 505(b)(2) applicant is relying on studies conducted for an already approved product, the applicant is required to certify to the FDA concerning any patents listed for the approved product in the Orange Book to the same extent that an ANDA applicant would. Thus, approval of a 505(b)(2) NDA can be stalled until all the listed patents claiming the referenced product have expired, 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, and, in the case of a Paragraph IV certification and subsequent patent infringement suit, until the earlier of 30 months, settlement of the lawsuit or a decision in the infringement case that is favorable to the Section 505(b)(2) applicant.

We expect that the majority of our product candidates in development will require the filing of 505(b)(2) NDAs because, although such products contain previously approved chemical entities, we or our licensees may seek to make new claims regarding therapeutic effects or lessened side effects, or both.

#### ***Other Regulatory Requirements***

Once an NDA is approved, a product will be subject to certain post-approval requirements. For instance, FDA closely regulates the marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the internet.

Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved labeling. Changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new NDA or NDA supplement before the change can be implemented. An NDA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing NDA supplements as it does in reviewing NDAs.

Adverse event reporting and submission of periodic reports is required following FDA approval of an NDA. The FDA also may require post-marketing testing, known as Phase 4 testing, risk minimization action plans, and surveillance to monitor the effects of an approved product or place conditions on an approval that could restrict the distribution or use of the product. In addition, quality control as well as drug manufacture, packaging, and labeling procedures must continue to conform to cGMPs after approval. Drug manufacturers and certain of their subcontractors are required to

register their establishments with FDA and certain state agencies, and are subject to periodic inspections by the FDA during which the agency inspects manufacturing facilities to access compliance with cGMPs. Accordingly, manufacturers must continue to expend time, money and effort in the areas of production and quality control to maintain compliance with cGMPs. Regulatory authorities may withdraw product approvals or request product recalls if a company fails to comply with regulatory standards, if it encounters problems following initial marketing, or if previously unrecognized problems are subsequently discovered.

***Anti-Kickback, False Claims Laws & The Prescription Drug Marketing Act***

In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal laws have been applied to restrict certain marketing practices in the pharmaceutical industry in recent years. These laws include anti-kickback statutes and false claims statutes. The federal healthcare program anti-kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Violations of the anti-kickback statute are punishable by imprisonment, criminal fines, civil monetary penalties and exclusion from participation in federal healthcare programs. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exemption or safe harbor.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to have a false claim paid. Recently, several pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly inflating drug prices they report to pricing services, which in turn were used by the government to set Medicare and Medicaid reimbursement rates, and for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. In addition, certain marketing practices, including off-label promotion, may also violate false claims laws. The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

***Physician Drug Samples***

As part of the sales and marketing process, pharmaceutical companies frequently provide samples of approved drugs to physicians. The Prescription Drug Marketing Act, or the PDMA, imposes requirements and limitations upon the provision of drug samples to physicians, as well as prohibits states from licensing distributors of prescription drugs unless the state licensing program meets certain federal guidelines that include minimum standards for storage, handling and record keeping. In addition, the PDMA sets forth civil and criminal penalties for violations.

**Employees**

As of October 14, 2010, we had 4 employees, all of whom were full-time employees.

## Edgar Filing: NOVADEL PHARMA INC - Form S-1

### MANAGEMENT

The names and ages of our Directors and Executive Officers as of the date of filing this prospectus are set out below. All Directors are elected annually, to serve until the next annual meeting of stockholders and until their successors are duly elected and qualified. Executive Officers are elected annually by the Board of Directors and serve at the Board of Directors' pleasure.

Name	Age	Position With the Company
Mark J. Baric	52	Director
Thomas E. Bonney	45	Director
Charles Nemeroff, M.D., Ph.D.	61	Director
Steven B. Ratoff	68	Chairman of the Board of Directors, President and Chief Executive Officer
David H. Bergstrom, Ph.D.	55	Senior Vice President and Chief Operating Officer
Craig Johnson	48	Senior Vice President, Chief Financial Officer and Secretary

**Mark J. Baric**, Director, 52. Mr. Baric was elected to the Board in February 2007. Since 2005, Mr. Baric has been the President and co-founder of CeNeRx BioPharma, Inc., a privately-held development company with a therapeutic focus on diseases of the central nervous system. In 2001 he co-founded and served, until 2005, as Chief Executive Officer and Chairman of 2ThumbZ Entertainment Inc., a privately-held company which develops and markets entertainment applications for users of handheld wireless devices and networks. From 1996 to 2001, Mr. Baric was Chairman and Chief Executive Officer of Virtus Entertainment Corporation, an emerging company in the fast-growing interactive entertainment industry. From 1990 to 1996, Mr. Baric held various leadership positions, including Chief Operating Officer and Chief Financial and Administrative Officer of Seer Technologies Inc. (now known as Cicero, Inc.), a provider of business integration software. Prior to 1990, Mr. Baric held various leadership positions at several firms, including CS First Boston and Coopers and Lybrand. Mr. Baric serves on the boards of CeNeRx BioPharma, Inc. and 2ThumbZ Entertainment Inc. Mr. Baric received an M.B.A. from the Wharton School of the University of Pennsylvania and a B.S. from Clarion University. He is our chair of our Corporate Governance and Nominating Committee, and a member of our Audit and Compensation Committees.

**Thomas E. Bonney**, CPA, Director, 45. Mr. Bonney was elected to the Board in March 2005. From 2002 to the present, Mr. Bonney has been Managing Director of CMF Associates, LLC, a financial and management consulting firm. Since December 2006, Mr. Bonney has been a General Partner in West Place LLC, and West Place Restaurant Group, LLC, privately-held companies that invest in and manage hotels and real estate. Since June 2005, Mr. Bonney has been a Director of Leblon Holdings LLC, a privately-held beverage supplier and from June 2005 through July 2007 was the Chief Financial Officer of Leblon Holdings, LLC. From 2001 to 2002, he was Chief Financial Officer of Akcelerant Holdings, Inc., a technology holding company. From 1995 to 2001, Mr. Bonney was President and a Director of Polaris Consulting & Information Technologies, a technology solutions provider. Mr. Bonney was at Deloitte & Touche from 1987 to 1995 in various positions including Senior Manager. Mr. Bonney received his B.S. in Accounting at the Pennsylvania State University and is a member of the Pennsylvania Institute of Certified Public Accountants. He is our lead director, chair of our Audit Committee and a member of our Compensation and Corporate Governance and Nominating Committees.

**Charles Nemeroff**, M.D., Ph.D., Director, 61. Dr. Nemeroff was elected to the Board in September 2003. Dr. Nemeroff is the Leonard M. Miller Professor and Chairman of the Department of Psychiatry and Behavioral Sciences at the University of Miami Leonard M. Miller School of Medicine in Miami, Florida since 2009. Previously, he served as the Reunette W. Harris Professor and Chairman of the Department of Psychiatry and Behavioral Sciences at Emory University School of Medicine in Atlanta, Georgia. Dr. Nemeroff has served on the Scientific Advisory Board of numerous publicly-traded pharmaceutical companies, including Astra-Zeneca Pharmaceuticals and Forest Laboratories. In 2002, he was elected to the Institute of Medicine of the National Academy of Sciences. Dr. Nemeroff received his B.S. from the City College of New York, his M.S. from Northeastern University, and his M.D., Ph.D. and post doctoral training from the University of North Carolina. Dr. Nemeroff is chair of our Scientific Advisory

Board. He is also chair of our Compensation Committee and a member of our Audit and Corporate Governance and Nominating Committees.

**Steven B. Ratoff**, Chairman of the Board, President and Chief Executive Officer, 68. Mr. Ratoff was elected to the Board in January 2006 and was elected Chairman of the Board on September 15, 2006. He was appointed as Interim President and Chief Executive Officer of NovaDel on July 23, 2007. On December 31, 2009, he was appointed President and Chief Executive Officer. Mr. Ratoff is a private investor and since December 2004 has served as a venture partner with ProQuest, a health care venture capital firm. Mr. Ratoff served as director, since May 2005, and was Chairman of the Board, from September 2005 to October 2006, of Torrey Pines Therapeutics Inc. (formerly Axonyx Inc.), a NASDAQ development stage pharmaceutical company which has recently merged with Raptor. Mr. Ratoff served as a director of Inkind Pharmaceuticals, Inc. from February 1998 to its sale to Salix, Inc. in September 2005. He also served as a board member since March 1995 and as Chairman of the Board and Interim Chief Executive Officer of CIMA Labs, Inc. from May 2003 to its sale to Cephalon, Inc. in August 2004. Mr. Ratoff also served as a director, since 1998 and as President and Chief Executive Officer of MacroMed, Inc. from February to December 2001. From December 1994 to February 2001, Mr. Ratoff served as Executive Vice President and Chief Financial Officer of Brown-Forman Corporation, a publicly-traded manufacturer and marketer of alcoholic beverages. Mr. Ratoff also was employed by Bristol Myers Squibb from 1975 to 1991, serving in a number of executive positions, the last of which was as Senior Vice President and Chief Financial Officer of the Pharmaceutical Group. Mr. Ratoff received his B.S. in Business Administration from Boston University and an M.B.A. with Distinction from the University of Michigan.

**David H. Bergstrom**, Ph.D., Senior Vice President and Chief Operating Officer, 55. Dr. Bergstrom joined NovaDel in December 2006 as Senior Vice President and Chief Operating Officer. From 1999 to November 2006, Dr. Bergstrom served in several capacities at Cardinal Health, Inc., including Vice President, Research & Development and Senior Vice President and General Manager. From 1998 to 1999, Dr. Bergstrom was Vice President of Pharmaceutical & Chemical Development at Guilford Pharmaceuticals Inc. Dr. Bergstrom was employed by Hoechst Marion Roussel, Inc. as the Director of Pharmaceutical and Analytical Sciences from 1996 to 1998. Dr. Bergstrom served as Director of Pharmaceutical and Analytical Development for the predecessor company, Hoechst-Roussel Pharmaceuticals Inc., from 1991 to 1996, and Group Manager, Formulations, Pharmaceutical Research from 1990 to 1991. Prior thereto, Dr. Bergstrom held various positions at Ciba-Geigy Corporation. Dr. Bergstrom received his Ph.D. in Pharmaceutics at the University of Utah in 1985. In addition, he received his M.S. in Pharmaceutical Chemistry at the University of Michigan in 1982 and his B.S. degree in Pharmacy in 1978 at Ferris State University.

**Craig Johnson**, Senior Vice President, Chief Financial Officer and Secretary, 48. Mr. Johnson joined NovaDel in June 2010 as Senior Vice President, Chief Financial Officer and Secretary. Prior to joining NovaDel, Mr. Johnson served as Vice President and Chief Financial Officer of TorreyPines Therapeutics from 2004 until its sale to Raptor Pharmaceutical Corp. in September 2009. Following the sale, he served as Vice President of TPTX, Inc., a subsidiary of Raptor Pharmaceutical Corp., until April 2010. From 1994 to 2004, Mr. Johnson was employed by MitoKor, Inc. where he last held the position of Chief Financial Officer and Senior Vice President of Operations. Prior to MitoKor, he served as a senior financial executive for several early-stage technology companies, and he also practiced as a Certified Public Accountant with Price Waterhouse. Currently, Mr. Johnson is a member of the board of directors of Ardea Biosciences, a publicly-traded biotechnology company, where he serves as the chairman of the audit committee. Mr. Johnson received his BBA in accounting from the University of Michigan and is a certified public accountant.

#### **Employment Agreements**

Messrs. Ratoff, Bergstrom and Johnson have entered into employment agreements with us. Messrs. Ratoff and Bergstrom's employment agreements are described in greater detail in *Executive Compensation - Employment Agreements*. A description of Mr. Johnson's employment agreement is contained below.

Mr. Johnson's agreement became effective June 16, 2010 and does not have an expiration date. His agreement currently provides for:

annual base salary of \$150,000, subject to periodic and customary review for increase by the Board or Compensation Committee;

an annual bonus of equal to 30% of base salary, with a maximum equal to 150% of the target award; and

options to purchase 750,000 shares of Common Stock pursuant to our 1998 Equity Incentive Plan and our 2006 Equity Incentive Plan.

If Mr. Johnson's employment is terminated without cause (as defined in the agreement), Mr. Johnson will be entitled to receive an amount equal to six months base salary at the time of termination. In addition, Mr. Johnson shall be entitled to receive the pro rata portion of the annual incentive bonus to the extent performance measures were met. All previously awarded equity grants would immediately vest upon such termination and Mr. Johnson will have a period of twelve months following such termination to exercise any unexercised stock options.

If Mr. Johnson's employment is terminated by (i) us as a result of Mr. Johnson's disability, (ii) mutual agreement of the parties, or (iii) Mr. Johnson for a change of control (as defined in the agreement), Mr. Johnson will be entitled to receive his base salary through the date of termination, the pro rata portion of his annual incentive bonus for that year and all other amounts to which he was entitled for portion of the year up to his termination. In the event of Mr. Johnson's death, Mr. Johnson's legal representatives will be entitled to receive the same amounts that Mr. Johnson would have been entitled to receive for a termination as a result of the foregoing events. All previously awarded equity grants shall immediately vest upon such termination and Mr. Johnson shall have a period of twelve months following such termination to exercise any unexercised stock options.

#### **DESCRIPTION OF PROPERTY**

As of February 1, 2010, our executive offices are located at 1200 Route 22 East, Suite 2000, Bridgewater, New Jersey 08807. We no longer maintain laboratory and warehousing space. Before February 1, 2010, our executive offices, laboratory, and warehousing space was located at 25 Minneakoning Road, Flemington, New Jersey, known as the Facility. The Facility, constituting approximately 31,800 square feet, was occupied under a 10-year lease, expiring in August 2013. During 2009, we only occupied a portion of our space in the Facility. During the years ended December 31, 2007, 2008 and 2009, we paid rent for the Facility of approximately \$443,000, \$453,000 and \$257,000, respectively. We have contracted out manufacturing for our product candidates. The manufacture of our product candidates is subject to current Good Manufacturing Practices, or cGMP, prescribed by the Food & Drug Administration, or FDA, and pre-approval inspections by the FDA and foreign authorities prior to the commercial manufacture of any such products.

#### **LEGAL PROCEEDINGS**

We are not a named party in any material legal proceedings.

**PRICE RANGE OF COMMON STOCK**

Our common stock is currently listed for trading on the Over-the-counter Bulletin Board, or OTCBB, under the symbol NVDL.OB and was previously traded on the NYSE Amex LLC from May 11, 2004 to December 23, 2009 under the symbol NVD. The following table sets forth, for the periods indicated, the high and low intraday sales prices per share of our common stock as report by the OTCBB or the NYSE Amex LLC, as applicable. These prices do not include retail markups, markdowns or commissions.

Fiscal Quarter Ended	High	Low
<b>2008 Fiscal Year:</b>		
December 31, 2008	\$ 0.46	0.06
<b>2009 Fiscal Year:</b>		
March 31, 2009	\$ 0.40	0.20
June 30, 2009	0.42	0.20
September 30, 2009	0.32	0.23
December 31, 2009	0.32	0.13
<b>2010 Fiscal Year:</b>		
March 31, 2010	\$ 0.29	0.16
June 30, 2010	0.24	0.18
September 30, 2010	0.21	0.15
Through October 14, 2010	0.18	0.14

On October 14, 2010, the last reported sale price of our common stock on the OTCBB was \$0.18 per share. On October 14, 2010, there were 62 holders of record and approximately 3,634 beneficial holders of our common stock.

**DIVIDEND POLICY**

We have never declared or paid any cash dividends on our common stock. We currently intend to retain our future earnings, if any, to finance the expansion of our business and do not expect to pay any cash dividends in the foreseeable future. Payment of future cash dividends, if any, will be at the discretion of our board of directors after taking into account various factors, including our financial condition, operating results, current and anticipated cash needs and plans for expansion and restrictions imposed by lenders, if any.



## SELECTED FINANCIAL INFORMATION

The following Selected Financial Data should be read in conjunction with our Financial Statements and the related Notes thereto, Management's Discussion and Analysis of Financial Condition and Results of Operations and other financial information included elsewhere in this prospectus. The data set forth below with respect to our Statements of Operations for the six months ended June 30, 2010 and 2009, the years ended December 31, 2009, 2008 and 2007, and the Balance Sheet data as of June 30, 2010 and December 31, 2009, 2008 and 2007 are derived from our Financial Statements which are included elsewhere in this prospectus and are qualified by reference to such Financial Statements and related Notes thereto.

There are no seasonal or other significant factors which affect comparability. The data set forth below with respect to our Statements of Operations for the fiscal years ended December 31, 2006, July 31, 2006 and 2005 and the five months ended December 31, 2006 and 2005, and the Balance Sheet data as of December 31, 2006 and July 31, 2006 and 2005 are derived from our Financial Statements, which are not included elsewhere in this prospectus. Our historical results are not necessarily indicative of future results of operations.

Statement of Operations Data:	Six Months Ended June 30,	
	2010	2009
	(unaudited)	(unaudited)
Total Revenues	\$ 195,000	\$ 133,000
Total Expenses	2,793,000	3,644,000
Loss from Operations	(2,598,000)	(3,511,000)
Other, net	181,000	301,000
Interest Expense	1,000	636,000
Interest Income		6,000
Income Tax Benefit		
Net Loss	\$ (2,418,000)	\$ (3,840,000)
Basic and Diluted Loss Per Common Share	\$ (0.03)	\$ (0.06)
Weighted Average Number of Shares of Common Stock Used in Computation of Basic and Diluted Loss Per Share	93,194,701	59,987,277

Edgar Filing: NOVADEL PHARMA INC - Form S-1

Statement of Operations Data:	Years Ended December 31,				Five Months Ended December 31,		Years Ended July 31,	
	2009	2008	2007	2006	2006	2005	2006	2005
				(unaudited)		(unaudited)		
Total Revenues	\$ 422,000	\$ 361,000	\$ 469,000	\$ 3,280,000	\$ 2,067,000	\$ 677,000	\$ 1,890,000	\$ 439,000
Total Expenses	6,517,000	8,951,000	18,656,000	13,544,000	6,519,000	5,429,000	12,454,000	10,217,000
Loss from Operations	(6,095,000)	(8,590,000)	(18,187,000)	(10,264,000)	(4,452,000)	(4,752,000)	(10,564,000)	(9,778,000)
Other, net	(385,000)		(66,000)					
Interest Expense	2,160,000	1,868,000						
Interest Income	6,000	137,000	632,000	337,000	180,000	67,000	224,000	87,000
Income Tax Benefit	(1,057,000)	(735,000)	(658,000)	(467,000)	(467,000)	(256,000)	(256,000)	(241,000)
Net Loss	\$ (7,577,000)	\$ (9,586,000)	\$ (16,963,000)	\$ (9,460,000)	(3,805,000)	\$ (4,429,000)	\$ (10,084,000)	\$ (9,450,000)
Basic and Diluted Loss Per Common Share	\$ (0.12)	\$ (0.16)	\$ (0.29)	\$ (0.20)	\$ (0.08)	\$ (0.11)	\$ (0.23)	\$ (0.27)
Weighted Average Number of Shares of Common Stock Used in Computation of Basic and Diluted Loss Per Share	61,346,000	59,592,000	59,497,000	46,732,000	49,522,000	40,619,000	43,000,000	34,808,000

BALANCE SHEET DATA:	Six Months Ended June 30,	December 31,				July 31,	
	2010	2009	2008	2007	2006	2006	2005
	(unaudited)				(unaudited)		
Cash, cash equivalents, and short-term investments	\$ 3,117,000	\$ 2,663,000	\$ 4,328,000	\$ 6,384,000	\$ 20,276,000	\$ 10,138,000	\$ 8,223,000
Total Assets	3,648,000	4,453,000	7,316,000	10,363,000	24,316,000	14,822,000	13,028,000
Total Current Liabilities	5,414,000	4,588,000	5,563,000	4,211,000	3,146,000	2,200,000	2,405,000
Total Liabilities	9,483,000	8,794,000	10,057,000	6,189,000	5,718,000	4,777,000	5,079,000
Accumulated Deficit	(85,184,000)	(82,766,000)	(74,829,000)	(65,243,000)	(48,280,000)	(44,475,000)	(34,391,000)
Total Stockholders Equity (Deficiency)	\$ (5,835,000)	\$ (4,341,000)	\$ (2,741,000)	\$ 4,174,000	\$ 18,598,000	\$ 10,045,000	\$ 7,949,000

Edgar Filing: NOVADEL PHARMA INC - Form S-1

**SUPPLEMENTARY FINANCIAL INFORMATION**

The following table presents our condensed operating results for each quarter for the years ended December 31, 2009 and 2008, and for each subsequent quarter for which our financial statements are included in this prospectus. The information for each of these quarters is unaudited. In the opinion of management, all necessary adjustments, which consist only of normal and recurring accruals, have been included to fairly present the unaudited quarterly results. This data should be read together with our consolidated financial statements and the notes thereto, the Report of Independent Registered Public Accounting Firm and Management's Discussions and Analysis of Financial Condition and Results of Operations.

	Jun 30 2010	Mar 31 2010	Dec 31 2009	Sep 30 2009	Jun 30 2009	Mar 31 2009
Total revenues	\$ 66,000	\$ 129,000	\$ 66,000	\$ 223,000	\$ 67,000	\$ 66,000
Net loss	\$ (1,126,000)	\$ (1,421,000)	\$ (2,376,000)	\$ (1,361,000)	\$ (1,701,000)	\$ (2,139,000)
Net loss per basic common share:	\$ (0.01)	\$ (0.01)	\$ (0.04)	\$ (0.02)	\$ (0.03)	\$ (0.04)
Net loss per diluted common share:	\$ (0.01)	\$ (0.01)	\$ (0.04)	\$ (0.02)	\$ (0.03)	\$ (0.04)
Shares used in computing basic per common share amounts:	97,918,000	88,372,000	65,282,000	61,386,000	60,081,000	59,892,000
Shares used in computing diluted per common share amounts:	97,918,000	88,372,000	65,282,000	61,386,000	60,081,000	59,892,000

	Dec 31 2008	Sep 30 2008	June 30 2008	Mar 31 2008
Total revenues	\$ 103,000	\$ 104,000	\$ 51,000	\$ 103,000
Net loss	\$ (1,909,000)	\$ (2,503,000)	\$ (3,202,000)	\$ (1,972,000)
Net loss per basic common share:	\$ (0.03)	\$ (0.04)	\$ (0.05)	\$ (0.03)
Net loss per diluted common share:	\$ (0.03)	\$ (0.04)	\$ (0.05)	\$ (0.03)
Shares used in computing basic per common share amounts:	59,592,000	59,592,000	59,592,000	59,592,000
Shares used in computing diluted per common share amounts:	59,592,000	59,592,000	59,592,000	59,592,000

**MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND  
RESULTS OF OPERATIONS**

The following discussion of our financial condition and results of operations should be read in conjunction with the financial statements and the notes to those statements included elsewhere in this prospectus. The discussion includes forward-looking statements that involve risks and uncertainties. As a result of many factors, such as those set forth in the Risk Factors of this prospectus, our actual results may differ materially from those anticipated in these forward looking statements.

**Overview**

**Company Overview**

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

	<b>Active Ingredient or Class of Molecule</b>	<b>Indications</b>	<b>Stage of Development</b>	<b>Partner</b>
<b>Approved Products</b>				
NitroMist®	Nitroglycerin	Angina Pectoris	FDA Approved	Mist Acquisition ECR Pharmaceuticals
Zolpimist	Zolpidem	Insomnia	FDA Approved	
<b>Product Candidates</b>				
Duromist	Sildenafil	Erectile Dysfunction	Clinical development	Hana Biosciences Par Pharmaceutical BioAlliance Pharma
Zensana	Ondansetron	Nausea/Vomiting	Clinical development	
NVD-201 NVD-301	Sumatriptan Midazolam	Migraine headache Pre-Procedure Anxiety	Clinical development Preclinical development	

**NitroMist®**

NitroMist, our oral spray formulation of nitroglycerin, has been approved by the FDA for acute relief of an attack of angina pectoris, or acute prophylaxis of angina pectoris, due to coronary artery disease. In October 2009, we entered into a 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 in 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.

## Edgar Filing: NOVADEL PHARMA INC - Form S-1

### *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 ( $AUC_{0-inf}$ ). The mean  $AUC_{0-inf}$  for the 10 mg dose (one spray) was approximately 40% of the 25 mg Viagra tablet, as expected. The mean  $AUC_{0-inf}$  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, ambulatory surgery centers and dental offices. In order to pursue further clinical development, we will need to secure project financing, equity financing or a development partner.



*Other Product Candidates*

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

We also have a license and development agreement with Manhattan Pharmaceuticals, Inc., or Manhattan, for the development of propofol oral spray. Propofol is the active ingredient in Diprivan®, a leading intravenous anesthetic marketed by AstraZeneca. We entered into this agreement in April 2003. In July 2007, Manhattan announced its intention to pursue appropriate sub-licensing opportunities for this product candidate.

Since inception, substantially all of our revenue has been derived from license fees and milestone payments in connection with our partnership agreements, and from consulting fees in connection with our product development activities for various pharmaceutical companies. Our future growth and profitability will be principally dependent upon our ability to successfully develop our product candidates, and to market and distribute the final products either internally or with the assistance of strategic partners.

*Going Concern and Management's Plan*

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

We have incurred net losses since inception, and as of 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.

**Results of Operations**

*Six Months Ended June 30, 2010 and June 30, 2009*

License fees and milestone fees earned for the six months ended June 30, 2010 were \$195,000 as compared to \$133,000 for the six months ended June 30, 2009. The increase was due to a milestone payment received from Velcera resulting from Velcera's global licensing agreement with a multinational animal health company for the first canine pain management product delivered in a transmucosal mist form.

Total operating expenses for the first half of 2010 decreased by \$851,000 or 23% from \$3,644,000 in 2009 to \$2,793,000 in 2010.

Research and development expenses decreased by \$444,000 or 31% from \$1,450,000 for the six months ended June 30, 2009 to \$1,006,000 for the same period in 2010. This decrease is related to the Company's sole focus on the development of Duromist due to limited cash resources. Expenses also decreased due to

## Edgar Filing: NOVADEL PHARMA INC - Form S-1

restructuring activities, a new smaller office facility and reduced headcount. The Duromist expenditures include clinical trial material costs and consulting costs related to preparations for the pilot PK study.

General and administrative expenses decreased by \$407,000 or 19% from \$2,194,000 for the six months ended June 30, 2009 to \$1,787,000 for the same period in 2010. General and administrative expenses consist primarily of salaries and related expenses for executive, finance, legal and other administrative personnel, professional fees and other corporate expenses. The decrease in general and administrative expenses is primarily attributable to the Company's employee-related costs due to decrease in headcount and relocation of facilities.

Other income from the derivative liability valuation adjustment for the six months ended June 30, 2010 of \$181,000 reflects the gain resulting from the decline in the derivative liability fair value determination at June 30, 2010 related to the warrants issued in conjunction with the March 31, 2010 common stock offering. Other income from a derivative liability valuation adjustment for the six months ended June 30, 2009 of \$360,000 was recorded upon the expiration of warrants that were deemed to be derivative instruments that were issued in conjunction with convertible notes.

Interest expense decreased by \$635,000 or 99% from \$636,000 for the six months ended June 30, 2009 to \$1,000 for the same period in 2010. The interest was incurred on convertible notes issued by the Company. This decrease in interest expense reflects the conversion of the convertible notes to common stock in 2009.

The resulting net loss for the six months ended June 30, 2010 was \$2,418,000 as compared to \$3,840,000 for the six months ended June 30, 2009.

### *Years Ended December 31, 2009 and December 31, 2008*

License fees and milestone fees earned for the year ended December 31, 2009 were \$422,000 as compared to \$361,000 for the year ended December 31, 2008.

Research and development expenses for the year ended December 31, 2009 were \$2,473,000 as compared to \$3,878,000 for the year ended December 31, 2008. Research and development costs consist primarily of salaries and benefits, contractor and consulting fees, clinical drug supplies of preclinical and clinical development programs, consumable research supplies and allocated facility and administrative costs. Below is a summary of our research and development expenses for the years ended December 31, 2009 and December 31, 2008.

	<b>Fiscal Year Ended</b>	
	<b>December 31, 2009</b>	<b>December 31, 2008</b>
NitroMist	\$ 592,000	\$ 135,000
Zolpimist	322,000	893,000
Sumatriptan	170,000	369,000
Zensana	5,000	37,000
Tizanidine		41,000
Other research and development costs	210,000	242,000
Internal costs	1,174,000	2,161,000
	<b>\$ 2,473,000</b>	<b>\$ 3,878,000</b>
Total research and development expenses		

In the preceding table, research and development expenses are set forth in the following categories:

NitroMist, Zolpimist, Sumatriptan and Tizanidine - third-party direct project expenses relating to the development of the respective product candidates. The majority of our research and development resources were devoted to our zolpidem and sumatriptan product candidates. Although we have significantly reduced clinical development activities on our product candidate pipeline since the fourth quarter 2007 and continuing throughout 2009, such that we have limited our expenditures primarily to those required to support our two approved products NitroMist and Zolpimist and minor expenditures to support formulation development activities for certain other products, we believe that 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. 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;

Zensana - third-party direct project expenses relating to the development of Zensana . As our partner for the Zensana , Par, is overseeing all clinical development and regulatory approval activities, we do not expect to devote a significant amount of resources to this product candidate. In light of Hana Biosciences' announcements in February 2007 and March 2007 regarding the status of Zensana , as described above, we devoted resources to this project during the year ended December 31, 2007, including approximately \$204,000 in third-party costs;

Other research and development costs - direct expenses not attributable to a specific product candidate; and

Internal costs - costs related primarily to personnel and overhead. We do not allocate these expenses to specific product candidates as these costs relate to all research and development activities.

Research and development expenses in the year ended December 31, 2009 decreased primarily as a result of the following items:

\$457,000 increase in costs associated with our NitroMist product candidate primarily due to process validation, method transfer activities and lab supplies in the year ended December 31, 2009;

\$571,000 decrease in product development costs for our Zolpimist product candidate, as development efforts were substantially completed during 2007, including filing of an NDA. Costs for zolpidem in the year ended December 31, 2009 related to usage and lab supplies;

\$199,000 decrease in product development costs for our Sumatriptan product candidate, due to delayed activity on this project;

\$987,000 decrease in internal costs is due to restructuring activities and substantially reduced efforts on R&D activities.

Consulting, selling, general and administrative expenses for the year ended December 31, 2009 were \$4,044,000 as compared to \$4,722,000 for the year ended December 31, 2008. General and administrative expenses consist primarily of salaries and related expenses for executive, finance, legal and other administrative personnel, recruitment expenses, professional fees and other corporate expenses. The decrease in general and administrative expenses is primarily attributable to our employee-related costs and reduction in stock compensation expense due to decrease in headcount during the year.

Primarily as a result of the factors described above, total expenses for the year ended December 31, 2009 were \$6,517,000, as compared to \$8,951,000 for the year ended December 31, 2008.

Other income/(expense) for the year ended December 31, 2009 was \$(385,000) which relates to the reversal of the warrant liability (upon expiration of the related warrants) initially recorded upon our adoption of ASC 815-40-15 in the amount of \$360,000, offset with a loss on disposition of fixed assets in the amount of \$745,000.

Interest expense for the year ended December 31, 2009 was \$2,160,000 primarily related to the convertible notes that were issued during the year ended December 31, 2008.

Interest income for the year ended December 31, 2009 was \$6,000 as compared to \$137,000 for the year ended December 31, 2008, due to lower average cash and cash equivalent balances.

The resulting net loss for the year ended December 31, 2009 was \$7,577,000 as compared to \$9,586,000 for the year ended December 31, 2008.

## Edgar Filing: NOVADEL PHARMA INC - Form S-1

### *Years Ended December 31, 2008 and December 31, 2007*

License fees and milestone fees earned for the year ended December 31, 2008 were \$361,000, as compared to \$469,000 for the year ended December 31, 2007. The decrease is primarily due to a non-recurring milestone payment received in the year ended December 31, 2007 from our license agreement with Velcera for veterinary products, which more than offset a one-time payment received during 2008 in connection with a product candidate that had been in development several years ago, and was no longer in our active product candidate pipeline.

Research and development expenses for the year ended December 31, 2008 were \$3,878,000 as compared to \$11,940,000 for the year ended December 31, 2007. Research and development costs consist primarily of salaries and benefits, contractor and consulting fees, clinical drug supplies of preclinical and clinical development programs, consumable research supplies and allocated facility and administrative costs. Below is a summary of our research and development expenses for the years ended December 31, 2008 and 2007:

	<b>Fiscal Year Ended</b>	
	<b>December 31, 2008</b>	<b>December 31, 2007</b>
NitroMist	\$ 135,000	\$ 558,000
Zolpimist	893,000	5,669,000
Sumatriptan	369,000	813,000
Zensana	37,000	213,000
Tizanidine	41,000	75,000
Ropinirole		3,000
Other research and development costs	242,000	1,763,000
Internal costs	2,161,000	2,846,000
	\$ 3,878,000	\$ 11,940,000

In the preceding table, research and development expenses are set forth in the following categories:

NitroMist , Zolpimist , Sumatriptan, Tizanidine and Ropinirole - third-party direct project expenses relating to the development of the respective product candidates. The majority of our research and development resources were devoted to our zolpidem and sumatriptan product candidates. Since the fourth quarter 2007 and continuing throughout 2008, we have significantly reduced clinical development activities on our product candidate pipeline, such that we have limited our expenditures primarily to those required to support our two approved products NitroMist and Zolpimist and minor expenditures to support formulation activities for certain other products, as we did not believe that we had sufficient cash to sustain such activities. As of the current date, we have not yet secured sufficient additional financing, and have therefore not resumed clinical development activity. There can be no assurances that we will be able to secure additional capital, and as a result, there can be no assurances as to whether, and when, we will be able to resume our clinical development activities;

Zensana - third-party direct project expenses relating to the development of Zensana . As our partner for the Zensana , Par, is overseeing all clinical development and regulatory approval activities, we do not expect to devote a significant amount of resources to this product candidate. In light of Hana Biosciences' announcements in February 2007 and March 2007 regarding the status of Zensana , as described above, we devoted resources to this project during the year ended December 31, 2007, including approximately \$204,000 in third-party costs;

Other research and development costs direct expenses not attributable to a specific product candidate; and

Internal costs costs related primarily to personnel and overhead. We do not allocate these expenses to specific product candidates as these costs relate to all research and development activities.

Research and development expenses in the year ended December 31, 2008 decreased primarily as a result of the following items:

\$4,776,000 decrease in product development costs for our Zolpimist product candidate, as development efforts were substantially completed during the fourth quarter 2007, including filing of an NDA. Development costs for zolpidem in the first quarter 2007 included costs for clinical trials, manufacturing preparedness and other NDA preparatory costs;

\$176,000 decrease in product development costs related to Zensana, as noted above;

\$423,000 decrease in costs associated with our NitroMist product candidate primarily due to process validation and method transfer activities in the year ended December 31, 2007, which were substantially lower in the year ended December 31, 2008;

\$444,000 decrease in product development costs for our Sumatriptan product candidate, as we substantially reduced our development activities on our product candidate pipeline beginning in the fourth quarter 2007; and

\$1,521,000 decrease in other research and development costs as we substantially reduced our development activities on our product candidate pipeline beginning in the fourth quarter 2007.

Consulting, selling, general and administrative expenses for the year ended December 31, 2008 were \$4,722,000 as compared to \$6,716,000 for the year ended December 31, 2007. General and administrative expenses consist primarily of salaries and related expenses for executive, finance, legal and other administrative personnel, recruitment expenses, professional fees and other corporate expenses. The decrease in general and administrative expenses is primarily attributable to reduced salaries, benefits and other employee-related expenses, and to lower stock compensation charges.

The loss on disposal of assets held for sale was \$351,000 for the year ended December 31, 2008.

Primarily as a result of the factors described above, total expenses for the year ended December 31, 2008 were \$8,951,000, as compared to \$18,656,000 for the year ended December 31, 2007.

Other, net for the year ended December 31, 2007 was \$66,000, as further detailed below in the comparison for the years ended December 31, 2007. There was no Other, net for the year ended December 31, 2008.

Interest expense for the year ended December 31, 2008 was \$1,868,000, of which \$1,837,000 related to the convertible notes that were issued during 2008. This included \$1,498,000 related to the amortization of the debt discount related to the beneficial conversion feature and fair value of the warrants, as well as \$213,000 related to the amortization of the deferred financing costs.

Interest income for the year ended December 31, 2008 was \$137,000 as compared to \$632,000 for the year ended December 31, 2007 due to lower average cash and short-term investment balances.

The resulting net loss for the year ended December 31, 2008 was \$9,586,000, as compared to \$16,963,000 for the year ended December 31, 2007.

### **Liquidity and Capital Resources**

From our inception, our principal sources of capital have been revenue from our partnership agreements, consulting revenues, private placements and public offerings of our securities, as well as loans and capital contributions from our principal stockholders. We have had a history of recurring losses, giving rise to an accumulated deficit as of June 30, 2010 of \$85,184,000, as compared to \$82,766,000 as of December 31, 2009. As of June 30, 2010, we had working capital deficiency of \$2,045,000 which includes a derivative liability of \$732,000, as compared to working capital deficiency of \$495,000 as of December 31, 2009, representing a net decrease in working capital of approximately \$1,550,000.

Our cash used in operating activities was \$1,063,000 and \$2,788,000 for the six months ended June 30, 2010 and 2009, respectively. The decrease in cash used was primarily due to the \$1,057,000 received in



## Edgar Filing: NOVADEL PHARMA INC - Form S-1

first quarter 2010 from the sale of net operating losses in the prior year quarter and an overall reduction in expenses. Net cash flows provided by financing and investing activities were \$1,517,000 for the six months ended June 30, 2010, primarily due to net proceeds received relating to issuance of common stock during the first quarter 2010.

Based on our operating plan, we expect that our existing cash and cash equivalents, along with the milestone payments that 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.

### Contractual Obligations

The following table sets forth our aggregate contractual cash obligations as of December 31, 2009.

	<b>Total</b>	<b>Payments Due By Period</b>			
		<b>&lt;1 year</b>	<b>1-3 years</b>	<b>3-5 years</b>	<b>5 years +</b>
Capital leases	\$ 14,000	\$ 10,000	\$ 4,000	\$	\$
Operating leases	42,500	39,000	3,500		
Employment agreements	627,000	627,000			
<b>Total contractual cash obligations</b>	<b>\$ 683,500</b>	<b>\$ 676,000</b>	<b>\$ 7,500</b>	<b>\$</b>	<b>\$</b>

### Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, results of operations, liquidity or capital resources.

### Critical Accounting Policies and Estimates

The discussion and analysis of our financial condition and results of operations are based on our unaudited condensed financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States, or GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues, expenses, and related disclosure of contingent assets and liabilities. We evaluate our estimates on an ongoing basis, including those related to revenue, accrued expenses and stock-based compensation. We base our estimates on historical experience and on other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

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

***Cash and Cash Equivalents***

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

***Revenue Recognition***

We receive revenue from consulting services and license agreements. Consulting revenues from contract clinical research are recognized in the period in which the services are rendered, provided that collection is reasonably assured. Upfront license agreement payments are recognized as earned or deferred and subsequently amortized into revenue over the contractual period. Milestone payments related to license agreements are recognized as revenue when earned.

***Deferred Financing Costs***

We capitalize the costs related to the issuance of our convertible notes, and amortize such deferred costs to interest expense on a straight-line basis over the life of the related notes.

***Warrants Issued with Financing***

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

***Valuation of Long-Lived Assets***

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

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

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

***Stock-Based Compensation***

We calculate the fair value of stock based compensation using the Black-Scholes method. Stock based compensation costs are recorded as earned for all unvested stock options outstanding. The charge is being recognized in research and development and consulting, selling, general and administrative expenses over the remaining service period after the adoption date based on the original estimate of fair value of the options as of the grant date.

**Recent Accounting Pronouncement**

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

**QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

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



**DIRECTORS AND NAMED EXECUTIVE OFFICERS*****Directors and Director Independence***

Pursuant to our By-Laws, generally the number of Directors is fixed and may be increased or decreased from time to time by resolution of our Board. Currently, our By-Laws provide that the number of Directors must be not less than three (3) nor more than nine (9). The Board has fixed the number of Directors at four (4) members. Effective January 1, 2010, Mr. Ratoff, the then acting Interim President, Chief Executive Officer and Chief Financial Officer, was appointed as President and Chief Executive Officer. The Board, based on the recommendation of the Corporate Governance and Nominating Committee, affirmatively determined that for 2009 all of our Directors are independent of NovaDel and management under the standards set forth in the NYSE Amex Company Guide, with the exception of our Chairman, Mr. Steven B. Ratoff, who was not independent because of his role as Interim President, Chief Executive Officer and Chief Financial Officer. In addition, the Board, based on the recommendation of the Corporate Governance and Nominating Committee, affirmatively determined that William F. Hamilton, Ph.D. and J. Jay Lobell were independent of NovaDel and management under the standards set forth in the NYSE Amex Company Guide during their service on the Board in 2009.

NAME	AGE	POSITION WITH NOVADEL
Mark J. Baric	52	Director
Thomas E. Bonney, CPA	45	Director
Charles Nemeroff, M.D., Ph.D.	61	Director
Steven B. Ratoff	68	Director and Chairman of the Board, President and Chief Executive Officer

The names, ages, principal occupations, current directorships and any directorship held during the past 5 years, and certain other information with respect to our directors, are shown below as of October 14, 2010.

**Mark J. Baric**, Director, 52. Mr. Baric was elected to the Board in February 2007. Since 2005, Mr. Baric has been the President and co-founder of CeNeRx BioPharma, Inc., a privately-held development company with a therapeutic focus on diseases of the central nervous system. In 2001, he co-founded and served until 2005 as Chief Executive Officer and Chairman of 2ThumbZ Entertainment Inc., a privately-held company which develops and markets entertainment applications for users of handheld wireless devices and networks. From 1996 to 2001, Mr. Baric was Chairman and Chief Executive Officer of Virtus Entertainment Corporation, an emerging company in the fast-growing interactive entertainment industry. From 1990 to 1996, Mr. Baric held various leadership positions, including Chief Operating Officer and Chief Financial and Administrative Officer of Seer Technologies Inc. (now known as Cicero, Inc.), a provider of business integration software. Prior to 1990, Mr. Baric held various leadership positions at several firms, including CS First Boston and Coopers and Lybrand. Mr. Baric serves on the boards of CeNeRx BioPharma, Inc. and 2ThumbZ Entertainment Inc. Mr. Baric received an M.B.A. from the Wharton School of the University of Pennsylvania and a B.S. from Clarion University. He is our chair of our Corporate Governance and Nominating Committee and a member of our Audit and Compensation Committees.

**Thomas E. Bonney, CPA**, Director, 45. Mr. Bonney was elected to the Board in March 2005. From 2002 to the present, Mr. Bonney has been Managing Director of CMF Associates, LLC, a financial and management consulting firm. Since December 2006, Mr. Bonney has been a General Partner in West Place LLC, and West Place Restaurant Group, LLC, privately-held companies that invest in and manage hotels and real estate. Since June 2005, Mr. Bonney has been a Director of Leblon Holdings LLC, a privately-held beverage supplier and from June 2005 through July 2007 was the Chief Financial Officer of Leblon Holdings, LLC. From 2001 to 2002, he was Chief Financial Officer of Akcelarent Holdings, Inc., a technology holding company. From 1995 to 2001, Mr. Bonney was President and a Director of Polaris Consulting & Information Technologies, a technology solutions provider. Mr. Bonney was at Deloitte & Touche from 1987 to 1995 in various positions including Senior Manager. Mr. Bonney received his B.S. in

## Edgar Filing: NOVADEL PHARMA INC - Form S-1

Accounting at the Pennsylvania State University and is a member of the Pennsylvania Institute of Certified Public Accountants. He is our Lead Director, chair of our Audit Committee and a member of our Compensation and Corporate Governance and Nominating Committees.

**Charles Nemeroff, M.D., Ph.D.**, Director, 61. Dr. Nemeroff was elected to the Board in September 2003. Since 2009, Dr. Nemeroff has served as the Leonard M. Miller Professor and Chairman of the Department of Psychiatry and Behavioral Sciences at the University of Miami Leonard M. Miller School of Medicine in Miami, Florida. From 1991 through 2009, he served as the Reunette W. Harris Professor and Chairman of the Department of Psychiatry and Behavioral Sciences at Emory University School of Medicine in Atlanta, Georgia. Dr. Nemeroff has served on the Scientific Advisory Board of numerous publicly-traded pharmaceutical companies, including Astra-Zeneca Pharmaceuticals and Forest Laboratories. In 2002, he was elected to the Institute of Medicine of the National Academy of Sciences. Dr. Nemeroff received his B.S. from the City College of New York, his M.S. from Northeastern University, and his M.D., Ph.D. and post doctoral training from the University of North Carolina. Dr. Nemeroff is chair of our Scientific Advisory Board. He is also chair of our Compensation Committee and a member of our Audit and Corporate Governance and Nominating Committees.

**Steven B. Ratoff**, Chairman of the Board, President and Chief Executive Officer, 68. Mr. Ratoff was elected to the Board in January 2006 and was elected Chairman of the Board on September 15, 2006. He was appointed as Interim President and Chief Executive Officer of NovaDel on July 23, 2007. Effective January 1, 2010, he was appointed President and Chief Executive Officer. Mr. Ratoff is a private investor and since December 2004 has served as a venture partner with ProQuest Investments, a health care venture capital firm. Mr. Ratoff served as director, since May 2005, and was Chairman of the Board, from September 2005 to October 2006, of Torrey Pines Therapeutics Inc. (formerly Axonyx Inc.), a NASDAQ development stage pharmaceutical company. Mr. Ratoff served as a director of Inkin Pharmaceuticals, Inc. from February 1998 to its sale to Salix, Inc. in September 2005. He also served as a board member since March 1995 and as Chairman of the Board and Interim Chief Executive Officer of CIMA Labs, Inc. from May 2003 to its sale to Cephalon, Inc. in August 2004. Mr. Ratoff also served as a director, since 1998 and as President and Chief Executive Officer of MacroMed, Inc. from February to December 2001. From December 1994 to February 2001, Mr. Ratoff served as Executive Vice President and Chief Financial Officer of Brown-Forman Corporation, a publicly-traded manufacturer and marketer of alcoholic beverages. Mr. Ratoff also was employed by Bristol Myers Squibb from 1975 to 1991, serving in a number of executive positions, the last of which was as Senior Vice President and Chief Financial Officer of the Pharmaceutical Group of the company. Mr. Ratoff received his B.S. in Business Administration from Boston University and an M.B.A. with Distinction from the University of Michigan.

### ***Director Experience, Qualifications, Attributes and Skills***

We believe that the backgrounds and qualifications of our directors, considered as a group, provide a broad mix of experience, knowledge and abilities that will allow the Board to fulfill its responsibilities. Our Board is composed of a diverse group of leaders in their respective fields. Many of the current directors have leadership experience at major domestic and international companies with operations inside and outside the United States, as well as experience serving on other companies' boards, which provides an understanding of different business processes, challenges and strategies facing boards and other companies. Further, our directors also have other experience that makes them valuable members, such as prior experience with financing transactions or mergers and acquisitions that provides insight into issues faced by companies.

The following highlights the specific experience, qualification, attributes and skills of our individual Board members that have led our Corporate Governance and Nominating Committee to conclude that these individuals should serve on our Board:

**Mark J. Baric**, brings his extensive background in the biotechnology and information technology industry acquired through a variety of management positions at several privately-held and publically held companies. He currently serves on the board of several companies including CeNeRx Biopharma Inc, and 2ThumbZ Entertainment, Inc. Previously he has served on the boards of Concert Technologies and Virtual

## Edgar Filing: NOVADEL PHARMA INC - Form S-1

Scopics, a company established in partnership with the University of Rochester. Mr. Baric has a CPA and an MBA from the Wharton School of Business.

**Thomas E. Bonney, CPA**, our lead independent director, brings his extensive accounting and financial background to the Board, as well as expertise in mergers and acquisitions, transaction financing, and the life sciences industry from his experience as a managing partner of a financial and management consulting firm. Furthermore, from 2004 to 2008, Mr. Bonney was an adjunct professor at Temple University teaching business case study capstone courses to graduating undergraduates

**Charles Nemeroff, M.D., Ph.D.**, brings his extensive background in the pharmaceutical and biotechnology industry. He has served on various Scientific Advisory Boards and has been chairman of the department of psychiatry and behavioral sciences at various universities.

**Steven B. Ratoff**, our chairman of the board, president and chief executive officer, brings over 30 years of experience in the pharmaceutical industry. His experience as an operating executive in a number of companies as well as his board experience in small development stage companies well qualifies him as a board member of the Company.

### **Executive Officers**

The names, ages, principal occupations during the past 5 years, and certain other information with respect to our named executive officers for 2009 are shown below as of October 14, 2010. To the extent that any named executive officer is also serving as a member of the Board, then such named executive officer's biography is set forth under *Directors and Director Independence* above.

The named executive officers are elected annually by the Board and serve at the pleasure of the Board. The Board has determined that the following individuals are our named executive officers for the 2010 fiscal year: Mr. Ratoff, Dr. Bergstrom, Mr. Warusz and Mr. Johnson.

NAME	AGE	POSITION WITH NOVADEL
Steven B. Ratoff	68	President, Chief Executive Officer, Interim Chief Financial Officer and Chairman of the Board
David H. Bergstrom, Ph.D.	55	Senior Vice President and Chief Operating Officer
Michael E. Spicer, CPA <sup>(1)</sup>	56	Chief Financial Officer and Corporate Secretary
Deni M. Zodda, Ph.D. <sup>(2)</sup>	56	Senior Vice President and Chief Business Officer
Joseph Warusz <sup>(3)</sup>	53	Principal Accounting Officer

(1) On March 19, 2009, Mr. Spicer resigned from his positions with the Company, effective April 1, 2009. There was no disagreement between us and Mr. Spicer on any matter relating to our operations, policies or practices. On March 25, 2009, the Board appointed Dr. Deni M. Zodda to the positions of Interim Chief Financial Officer and Corporate Secretary.

(2) On March 25, 2009, the Board appointed Dr. Deni M. Zodda to the positions of Interim Chief Financial Officer and Corporate Secretary. On April 28, 2009, Dr. Zodda agreed with the Board that due to a reorganization of the executive team, his services as Senior Vice President and Chief Business Officer would no longer be required effective April 30, 2009. There was no disagreement between us and Dr. Zodda on any matter relating to our operations, policies or practices. In connection with his departure, Dr. Zodda and the Company entered into a Separation, Consulting and General Release Agreement whereby Dr. Zodda provided the Company with certain consulting services ending on October 31, 2009.

(3) On April 28, 2009, the Company appointed Mr. Warusz as Principal Accounting Officer. Simultaneously with the appointment of Mr. Johnson as Chief Financial Officer, Mr. Warusz resigned from the position of Principal Accounting Officer. Mr. Warusz continued in his capacity as a consultant to the Company until July 31, 2010.

**David H. Bergstrom, Ph.D.**, Senior Vice President and Chief Operating Officer, 55. Dr. Bergstrom joined NovaDel in December 2006 as Senior Vice President and Chief Operating Officer. From 1999 to November 2006, Dr. Bergstrom served in several capacities at Cardinal Health, Inc., including Vice President, Research & Development and Senior Vice President and General Manager, where he gained



## Edgar Filing: NOVADEL PHARMA INC - Form S-1

extensive experience in biopharmaceutical research and development. From 1998 to 1999, Dr. Bergstrom was Vice President of Pharmaceutical & Chemical Development at Guilford Pharmaceuticals Inc. Dr. Bergstrom was employed by Hoechst Marion Roussel, Inc. as the Director of Pharmaceutical and Analytical Sciences from 1996 to 1998. Dr. Bergstrom served as Director of Pharmaceutical and Analytical Development for the predecessor company, Hoechst-Roussel Pharmaceuticals Inc., from 1991 to 1996, and Group Manager, Formulations, Pharmaceutical Research from 1990 to 1991. Prior thereto, Dr. Bergstrom held various positions at Ciba-Geigy Corporation. Dr. Bergstrom received his Ph.D. in Pharmaceutics at the University of Utah in 1985. In addition, he received his M.S. in Pharmaceutical Chemistry at the University of Michigan in 1982 and his B.S. degree in Pharmacy in 1978 at Ferris State University.

**Michael E. Spicer**, CPA, Chief Financial Officer and Corporate Secretary, 56. Mr. Spicer joined NovaDel as Chief Financial Officer in December 2004 and was named Corporate Secretary in April 2006. From December 2001 to December 2004, Mr. Spicer was Chief Financial Officer of Orchid Biosciences, Inc. (now known as Orchid Cellmark Inc.). From September 1998 to December 2001, Mr. Spicer served as Vice President, Chief Financial Officer of Lifecodes Corporation until it was acquired by Orchid. Mr. Spicer is a Certified Public Accountant and holds an undergraduate degree in Accounting from the University of Virginia and an M.B.A. from Harvard Business School. On March 19, 2009, Mr. Spicer resigned from his positions with the Company, effective April 1, 2009. There was no disagreement between us and Mr. Spicer on any matter relating to our operations, policies or practices.

**Deni M. Zodda**, Ph.D., Senior Vice President and Chief Business Officer, 56. Dr. Zodda joined NovaDel in February 2007 as Senior Vice President and Chief Business Officer. From May 2006 to February 2007, Dr. Zodda was Principal of Medignostica, LLC, a consulting firm he owns which provided business development services to various clients and was acting Chief Executive Officer of StemCapture, Inc., a privately-held stem cell research company. From 2000 to May 2006, Dr. Zodda served in varying capacities, including Senior Vice President, Business Development and Principal Financial Officer of Discovery Laboratories, Inc. From 1998 to 2000, Dr. Zodda served as Managing Director of the Life Sciences Practice at KPMG. During the course of his career, Dr. Zodda also held senior management positions in business development, marketing and commercial operations at Cephalon, Inc., Wyeth, Baxter International Inc. and SmithKline Beckman, Inc. Dr. Zodda received his M.B.A. in Marketing and Finance from the University of Santa Clara in 1986, his Ph.D. in Biology from the University of Notre Dame in 1980 and his B.S. in Biology from Villanova University in 1975. On April 28, 2009, Dr. Zodda agreed with the Board that due to a reorganization of the executive team, his services as Senior Vice President and Chief Business Officer would no longer be required effective April 30, 2009. There was no disagreement between us and Dr. Zodda on any matter relating to our operations, policies or practices. In connection with his departure, Dr. Zodda and the Company entered into a Separation, Consulting and General Release Agreement whereby Dr. Zodda would provide the Company with certain consulting services ending on October 31, 2009.

**Joseph M. Warusz**, Principal Accounting Officer, 53. Mr. Warusz joined NovaDel as a consultant in April, 2009, serving as Principal Accounting Officer. Since March 2006, Mr. Warusz has been providing consulting services to a broad range of clients in the life sciences sector. From August 2005 to March 2006, Mr. Warusz was Vice President, Finance, of Orchid Biosciences, Inc. (now known as Orchid Cellmark Inc.), which provided public company finance experience. From May 2000 to June 2005, Mr. Warusz held several senior executive positions at Bristol-Meyers Squibb. Prior to October 1983, Mr. Warusz acted as Senior Auditor at KPMG, LLP. Mr. Warusz is a Certified Public Accountant and holds an undergraduate degree in accounting and an MBA from Drexel University. Simultaneously with the appointment of Mr. Johnson as Chief Financial Officer, Mr. Warusz resigned from the position of Principal Accounting Officer. Mr. Warusz continued in his capacity as a consultant to the Company until July 31, 2010.

### EXECUTIVE COMPENSATION

#### Compensation Discussion and Analysis

This Compensation Discussion and Analysis discusses the principles underlying our compensation policies and decisions and the principal elements of compensation paid to our named executive officers during the 2009 fiscal year and as anticipated for our fiscal year 2010. Our Chief Executive Officer, Chief Financial Officer and the other named executive

officers included in the Summary Compensation Table will be referred to as the named executive officers for purposes of this discussion.

**Compensation Objectives and Philosophy**

The Committee is responsible for reviewing and approving the compensation payable to our named executive officers and other key employees. As part of such process, the Committee seeks to accomplish the following objectives with respect to our executive compensation programs:

- motivate, recruit and retain executives capable of meeting our strategic objectives;
- provide incentives to ensure superior executive performance and successful financial results for NovaDel; and
- align the interests of the named executive officers with the long-term interests of our stockholders.

The Committee seeks to achieve these objectives by:

- establishing a compensation structure that is both market competitive and internally fair;
- linking a substantial portion of compensation to our achievement of financial objectives and the individual's contribution to the attainment of those objectives;
- providing upward leverage for overachievement of goals; and
- providing long-term equity-based incentives.

In order to achieve the above goals, our total compensation package includes base salary and annual bonus, all paid in cash, as well as long-term compensation in the form of stock options and restricted stock. We believe that appropriately balancing the total compensation package is necessary in order to provide market-competitive compensation.

**Setting Executive Compensation**

***Role of Compensation Committee and Chief Executive Officer.*** The Committee oversees the design, development and implementation of the compensation program for the Chief Executive Officer and the other named executive officers. The Committee evaluates the performance of the Chief Executive Officer and determines the Chief Executive Officer's compensation in light of the goals and objectives of the compensation program. The Chief Executive Officer and the Committee together assess the performance of the other named executive officers employed by us as of December 31 and determine their compensation, based on initial recommendations from the Chief Executive Officer. Our Interim Chief Executive Officer provided the Committee with a detailed review of the performance of the other named executive officers and made recommendations to the Committee with respect to the compensation packages for those officers for the 2009 fiscal year.

Mr. Steven B. Ratoff, the Company's Chairman of the Board, also serves as the Company's Interim President and Chief Executive Officer, Interim Chief Financial Officer and Corporate Secretary. On April 28, 2009, Mr. Ratoff was appointed Interim Chief Financial Officer, Principal Financial Officer and Corporate Secretary concurrent with the resignation of Dr. Deni M. Zodda. Mr. Ratoff did not have an employment agreement with the Company in connection with his service as Interim President and Chief Executive Officer in 2009. In connection with Mr. Ratoff's services as Chairman of the Board, the Board entered into a consulting arrangement to compensate Mr. Ratoff for his efforts in such position. Such arrangement was on a month-to-month basis. From September 15, 2006 until March 16, 2007, Mr. Ratoff was compensated at a rate of \$17,500 per month and reimbursement of reasonable expenses. From March 16, 2007 until June 6, 2007, his monthly rate was reduced to \$10,000 and reimbursement of reasonable expenses. Effective June 6, 2007, his monthly rate was increased to \$17,500. During the year ended December 31, 2009, Mr. Ratoff received \$210,000 in consulting fees. Effective January 1, 2010, Mr. Ratoff was appointed as President and Chief Executive Officer and entered into an employment agreement in connection therewith, and will continue to serve as Chairman, Interim Chief Financial Officer and Corporate Secretary.

## Edgar Filing: NOVADEL PHARMA INC - Form S-1

The other named executive officers do not play a role in their own compensation determination, other than discussing individual performance objectives and results with the Chief Executive Officer.

**Role of Compensation Consultant.** In 2007 and 2008, the Compensation Committee engaged Compensation Resources, Inc., a nationally recognized compensation consulting firm, or CRI, to advise it on certain compensation-related matters, as needed. In December 2009, the Committee utilized CRI to provide competitive compensation data on the proposed compensation package of our Chief Executive Officer. CRI performed a market analysis of the compensation paid by comparable pharmaceutical and drug delivery companies and provided the Committee with compensation ranges for our Chief Executive Officer as further described below. Other than the services described above, CRI did not provide any other service to the Company in determining the compensation of the named executive officers or Directors.

Our named executive officers did not participate in the selection of the consultant.

We have not used the services of any other compensation consultant in matters affecting the compensation of named executive officers or Directors. In the future, we, or the Committee, may engage or seek the advice of other compensation consultants.

### Competitive Position

The Committee has structured our annual and long-term incentive-based cash and non-cash executive compensation to motivate executives to achieve the business goals set by the Board and reward the executives for achieving such goals. At the end of the year, the Committee reviews the performance of each named executive officer in achieving the established objectives. These results are included with the overall performance review provided by the Chief Executive Officer, after which the Committee votes upon any recommendations for salary adjustments, stock option grants and cash incentives. The Chief Executive Officer then executes the actions recommended by the Committee with respect to such matters.

In CRI's market analysis of compensation performed in 2009, the relevant peer group for compensation and benefit programs consists primarily of companies of comparative size, similar businesses and geographic scope. These are the firms with which NovaDel competes for talent. The comparator group was chosen to include companies with similar market capitalization, similar revenue size, and some direct competitors. The comparator group is different from the companies used in the Performance Graph on page 46 of our Annual Report on Form 10-K for the period ended December 31, 2009. The reason for this is that NovaDel has business competitors with whom we benchmark against for financial performance, but also have business and talent competitors against whom we benchmark for pay purposes. Additionally, the positions were compared to published survey data from nationally recognized sources to ensure the accuracy and validity of the proxy peer group. The companies from the peer analysis are listed below:

Company Name	Market Cap (Millions)
Adeona Pharmaceuticals, Inc.	12.0
Advanced Life Sciences Holdings, Inc.	12.9
Aeolus Pharmaceuticals, Inc.	18.0
Anesiva, Inc.	6.8
Barrier Therapeutics, Inc.	17.9
Cardiovascular Systems, Inc.	21.2
Catalyst Pharm Partners, Inc.	8.8
China Shenghuo Pharm Holdings	15.3
Cortex Pharmaceuticals, Inc.	6.8
Cpex Pharmaceuticals, Inc.	28.8

68

Company Name	Market Cap (Millions)
Elite Pharmaceuticals, Inc.	8.1
Derma Sciences	32.5
Healthsport, Inc.	27.9
Helix Biomedix, Inc.	8.7
Icagen, Inc.	21.2
IGI Laboratories, Inc.	13.4
Imagenetix, Inc.	5.5
Insite Vision, Inc.	32.2
Manhattan Pharmaceuticals, Inc.	4.9
Metabasis Therapeutics, Inc.	13.7
Quigley Corporation	26.6
Raptor Pharmaceuticals Corp	33.0
RegeneRx Biopharmaceuticals, Inc.	33.2
Repros Therapeutics Inc.	13.3
Scolr Pharma, Inc.	19.7
Somaxon Pharmaceuticals, Inc.	29.3
Stellar Pharmaceuticals, Inc.	23.0
Synovics Pharmaceuticals, Inc.	11.2
Threshold Pharmaceuticals	28.5
Uluru, Inc.	14.5

### **Components of Compensation**

The key components of NovaDel's executive compensation package are cash compensation (salary & annual incentives), long term incentives and company-sponsored benefit plans. These components are administered with the goal of providing total compensation that recognizes meaningful differences in individual performance, is competitive, varies the opportunity based on individual and corporate performance, and is valued by our named executive officers. We seek to achieve our compensation objectives through five key compensation elements:

base salary;

annual short-term cash incentives;

long-term equity incentive awards;

special benefits; and

change in control and other severance agreements.

**Base Salary. In General** It is the Committee's objective to set a competitive rate of annual base salary for each named executive officer. The Committee believes competitive base salaries are necessary to attract and retain top quality executives, since it is common practice for public companies to provide their named executive officers with a guaranteed annual component of compensation that is not subject to performance risk. The Committee works with outside consultants as necessary to establish salary ranges for the named executive officers, with minimum to maximum opportunities that cover the normal range of market variability. The actual base salary for each named executive officer is then derived from those salary ranges based on his responsibility, tenure and past performance and market comparability. Annual base salaries for the named executive officers are reviewed and approved by the Committee in the first fiscal quarter following the end of the previous performance year. Changes in base salary are based on the scope of an





individual's current job responsibilities, individual performance in the previous performance year, target pay position relative to the peer group, and our salary budget guidelines. The Committee reviews established goals and objectives, and determines an individual's achievement of those goals and objectives and considers the recommendations provided by the Chief Executive Officer to assist it in determining appropriate salaries for the named executive officers other than the Chief Executive Officer. For any given performance year, actual salary increases may range from 0% to 10% of the salary guidelines based on individual performance. This broad range allows for meaningful differentiation on a pay for performance basis.

**Changes for Fiscal Year 2010** The Committee met in December 2009 to evaluate the performance and compensation for each named executive officer. The Committee reviewed compensation of comparable companies and recognized the need to retain current management given individual and collective performance. As a result of the Company's cash position and requirement for additional funding, the Committee recommended to the Board that no merit increases be granted to our named executive officers for 2010.

**Annual Bonuses. In General** As part of their compensation package, our named executive officers have the opportunity to earn annual bonuses. Annual bonuses are designed to reward superior executive performance while reinforcing our short-term strategic operating goals. Pursuant to the individual employment agreements, the Committee establishes each year a target award for each named executive officer based on a percentage of base salary. Annual bonus targets as a percentage of salary increase with executive rank so that for the more senior executives, a greater proportion of their total cash compensation is contingent upon annual performance.

At the beginning of the performance year, each named executive officer, in conjunction with the Chief Executive Officer, establishes annual goals and objectives. Actual bonus awards are based on an assessment against the pre-established goals for each named executive officer's individual performance, the performance of the business function for which he is responsible, and/or our overall performance for the year. For any given performance year, proposed annual bonuses may range from 0% to 100% of target, or higher under certain circumstances, based on corporate and individual performance. Corporate and individual performance has a significant impact on the annual bonus amounts because the Committee believes it is a precise measure of how the named executive officer contributed to business results.

**Fiscal 2009 Performance Measures and Payouts** In 2009, annual bonus targets were 30% of base salary for the named executive officers and were payable based on the Committee's subjective review of both the performance of NovaDel as well as individual performance. The Committee utilizes annual bonuses to compensate officers for achieving financial and operational goals and for achieving individual annual performance objectives. These objectives will vary depending on the individual executive, but will relate generally to (i) operational goals such as the development of our product candidates and the identification and advancement of additional product candidates, (ii) strategic goals such as the establishment of operating plans and budgets, review of organization and staff, and (iii) the enhancement of stockholder value.

Our objectives relating to development and clinical goals for 2009 included the following:

- pursuit of strategic partners for our NitroMist<sup>®</sup> oral spray;
- pursuit of strategic partners for our ZolpiMist<sup>®</sup> oral spray;
- continued development of the Company's technology and operating platform; and
- other strategic transactions that benefit the Company and its stockholders.

At the end of each fiscal year, the Committee determines the level of achievement with respect to each corporate goal, and decides the overall percent of corporate goal achievement for purposes of annual bonuses. For this assessment, the Committee evaluates the status of NovaDel's development programs and clinical progress, corporate development and regulatory compliance activities. These qualitative factors are also typically used by comparable companies to evaluate performance and involve a subjective assessment of corporate performance by the Committee. Moreover, the Committee does not base its considerations on a single performance factor, but rather considers a mix of factors and evaluates company and individual

## Edgar Filing: NOVADEL PHARMA INC - Form S-1

performance against that mix. The Chief Executive Officer provides written evaluations for the named executive officers, other than himself, to the Committee along with his recommendations for each individual performance factor. The Committee reviews the performance and assessment of each named executive officer and then evaluates the Chief Executive Officer and assigns a weight to each individual achievement factor. Although we entered into license agreements for the manufacture and commercialization of NitroMist<sup>®</sup> and ZolpiMist<sup>®</sup>, the Compensation Committee determined that, in the interest of the Company and its stockholders, cash bonuses were not paid for fiscal year 2009 performance in order to conserve the Company's cash position. The table below details fiscal 2009 annual bonus targets and actual payouts for each of our named executives.

Name	Title	2009 Target Bonus (\$)	2009 Target Bonus (% Salary)	2009 Actual Bonus (\$)	2009 Actual Bonus (% Salary)
Steven B. Ratoff <sup>(1)</sup>	Interim President and Chief Executive Officer, Interim Chief Financial Officer and Corporate Secretary	\$ 0	0%	\$ 0	0%
David H. Bergstrom, Ph.D. <sup>(2)</sup>	Chief Operating Officer	\$ 90,000	30%	\$ 0	0%
Deni M. Zodda <sup>(3)</sup>	Chief Business Officer	\$ 83,500	30%	\$ 0	0%
Michael E. Spicer, CPA <sup>(4)</sup>	Chief Financial Officer and Corporate Secretary	\$ 76,900	30%	\$ 0	0%
Joseph Warusz <sup>(5)</sup>	Principal Accounting Officer	\$ 0	0%	\$ 0	0%

- (1) Mr. Ratoff entered into a consulting arrangement with the Company in 2006, and was compensated under that arrangement at a rate of \$17,500 per month, plus reimbursement of reasonable expenses during the 2009 fiscal year. As a result, Mr. Ratoff was not entitled to a bonus. Effective January 1, 2010, Mr. Ratoff was appointed as President and Chief Executive Officer and will continue to serve as Interim Chief Financial Officer and Corporate Secretary. In connection with such appointment, Mr. Ratoff entered into an employment agreement with the Company, which was effective January 1, 2010. For a further discussion of the terms of Mr. Ratoff's employment agreement, please see *Employment Agreements*.
- (2) In January 2009, Dr. Bergstrom received a one-time special cash bonus of \$50,000 in recognition of his individual efforts in 2008 in connection with the Company's research and development efforts and clinical activities including, but not limited to, the U.S. Food and Drug Administration's approval of the New Drug Application for Zolpimist<sup>®</sup> (zolpidem tartrate) Oral Spray for the short-term treatment of insomnia.
- (3) On April 28, 2009, Dr. Zodda agreed with the Board that due to a reorganization of the executive team, his services as Senior Vice President and Chief Business Officer would no longer be required effective April 30, 2009. There was no disagreement between us and Dr. Zodda on any matter relating to our operations, policies or practices. In connection with his departure, Dr. Zodda and the Company entered into a Separation, Consulting and General Release Agreement whereby Dr. Zodda would provide the Company with certain consulting services ending on October 31, 2009.
- (4) On March 19, 2009, Mr. Spicer resigned from his positions with the Company, effective April 1, 2009. There was no disagreement between us and Mr. Spicer on any matter relating to our operations, policies or practices. On March 25, 2009, the Board appointed Dr. Deni M. Zodda to the positions of Interim Chief Financial Officer and Corporate Secretary.
- (5) On April 28, 2009, the Company appointed Mr. Warusz as Principal Accounting Officer. Simultaneously with the appointment of Mr. Johnson as Chief Financial Officer, Mr. Warusz resigned from the position of Principal Accounting Officer. Mr. Warusz continued in his capacity as a consultant to the Company until July 31, 2010. Mr. Warusz provided services to the Company pursuant to a consulting agreement, under which Mr. Warusz received a monthly retainer of \$20,000 and an hourly rate of \$180 for hours in excess of 160 hours per month.

**Change for Fiscal Year 2010** As in 2009, annual bonuses for 2010, if any, will be based on achievement of pre-established company objectives and individual goals for each named executive officer and, for each named executive officer other than the Chief Executive Officer, a subjective review of that individual's performance. Corporate performance targets may include such measures as strategic plan metrics while individual performance targets may include operational and financial metrics, regulatory compliance metrics, and delivery of specific programs, plans, and budgetary objectives identified and documented at the beginning of each fiscal year. It is the Committee's intention to base a greater percentage of the annual award payout on corporate as opposed to individual performance for higher level executives, with 100% of the Chief Executive Officer's annual bonus tied to the attainment of corporate performance objectives. For each of our named executive officers for fiscal year 2010, the Compensation Committee has provided the following corporate performance targets, as well as the weighting of each component as a percentage of such named executive officer's target bonus amount:

Edgar Filing: NOVADEL PHARMA INC - Form S-1

Performance Milestone:	Weighting of Components as a Percentage of Target Bonus	
	Steven Ratoff	David Bergstrom
Achieve 2010 budgeted cash plan as of December 31, 2010.	25%	50%
Complete pilot PK, FDA meeting and pivotal study for a product candidate by a specific date.	25%	50%
Meet defined finance and business development objectives by a specific date.	50%	

For the 2010 fiscal year awards, the potential payout may range from 0 to 100% of target, or higher under certain circumstances. The Committee has not yet determined the performance targets for the target bonus amount of Mr. Johnson. The Committee has also retained the discretion to reduce the dollar amount of the awards otherwise payable to the named executive officers.

The table below shows the dollar amount of the 2009 and 2010 annual target bonus for each named executive officer, together with percentage of base salary represented by that target:

Name	Title	2009 Target Bonus (\$)	2009 Target Bonus (% Salary)	2010 Target Bonus (\$)	2010 Target Bonus (% Salary)
Steven B. Ratoff <sup>(1)</sup>	President and Chief Executive Officer	\$ 0	0%	\$ 175,000	50%
David H. Bergstrom, Ph.D.	Senior Vice President and Chief Operating Officer	\$ 90,000	30%	\$ 90,000	30%
Craig Johnson <sup>(2)</sup>	Senior Vice President, Chief Financial Officer and Secretary			\$ 45,000	30%
Michael E. Spicer, CPA <sup>(3)</sup>	Chief Financial Officer and Corporate Secretary	\$ 76,900	30%		
Deni M. Zodda, Ph.D. <sup>(4)</sup>	Senior Vice President and Chief Business Officer	\$ 82,500	30%		
Joseph Warusz <sup>(5)</sup>	Principal Accounting Officer				

- (1) Mr. Ratoff entered into a consulting arrangement with the Company in 2006, and was compensated under that arrangement at a rate of \$17,500 per month, plus reimbursement of reasonable expenses, during the 2009 fiscal year. As a result, Mr. Ratoff was not entitled to a bonus in 2009. Effective January 1, 2010, Mr. Ratoff was appointed as President and Chief Executive Officer and will continue to serve as Interim Chief Financial Officer and Corporate Secretary. In connection with such appointment, Mr. Ratoff entered into an employment agreement with the Company, which was effective January 1, 2010. Based on the Chief Executive Officer's broader range of responsibilities at the Company, the Compensation Committee deemed it appropriate to set the Chief Executive Officer's 2010 Target Bonus at a greater percentage of base salary than the other named executive officers. For a further discussion of the terms of Mr. Ratoff's employment agreement, please see *Employment Agreements*.
- (2) On June 8, 2010, the Company appointed Mr. Johnson to serve as Senior Vice President, Chief Financial Officer and Secretary of the Company effective June 16, 2010.
- (3) On March 19, 2009, Mr. Spicer resigned from his positions with the Company, effective April 1, 2009. There was no disagreement between us and Mr. Spicer on any matter relating to our operations, policies or practices.
- (4) On April 28, 2009, Dr. Zodda agreed with the Board that due to a reorganization of the executive team, his services as Senior Vice President and Chief Business Officer would no longer be required effective April 30, 2009. There was no disagreement between us and Dr. Zodda on any matter relating to our operations, policies or practices. In connection with his departure, Dr. Zodda and the Company entered into a Separation, Consulting and General Release Agreement whereby Dr. Zodda would provide the Company with certain consulting services ending on October 31, 2009.
- (5) On April 28, 2009, the Company appointed Mr. Warusz as Principal Accounting Officer. Simultaneously with the appointment of Mr. Johnson as Chief Financial Officer, Mr. Warusz resigned from the position of Principal Accounting Officer. Mr. Warusz continued in his capacity as a consultant to the Company until July 31, 2010. Mr. Warusz provided services to the Company pursuant to a consulting agreement, under which Mr. Warusz received a monthly retainer of \$20,000 and an hourly rate of \$180 for hours in excess of 160 hours per month.

## Edgar Filing: NOVADEL PHARMA INC - Form S-1

Based on the Chief Executive Officer's broader range of responsibilities, the Compensation Committee deemed it appropriate to set the Chief Executive Officer's 2010 Target Bonus at a greater percentage of base salary than the other named executive officers.

**Long-Term Incentive Equity Awards. In General** - We believe that long-term performance is achieved through an ownership culture that encourages high performance by our named executive officers through the use of stock-based awards. Our equity plans have been established to provide our employees, including our named executive officers, with incentives to help align employees' interests with the interests of our stockholders. The Committee believes that the use of stock-based awards offers the best approach to

achieving our compensation goals. We have historically elected to use stock options as the primary long-term equity incentive vehicle; however, the Committee has used restricted stock and may in the future utilize restricted stock as part of our long-term incentive program. We have selected the Black-Scholes method of valuation for share-based compensation effective August 1, 2005. Due to the early stage of our business and our desire to preserve cash, we expect to provide a greater portion of total compensation to our named executive officers through stock options and restricted stock grants than through cash-based compensation.

**Stock Options.** Our stock plans authorize us to grant options to purchase shares of Common Stock to our employees, Directors and consultants. The Committee generally oversees the administration of our stock option plans. In 2009, the Committee delegated the authority to our Chief Executive Officer to make initial option grants to certain new employees within an approved range. All new employee grants in excess of the Chief Executive Officer's limit and any grant to a named executive officer are approved by the Committee. Stock options may be granted at the commencement of employment, annually, occasionally following a significant change in job responsibilities or to meet other objectives.

The Committee reviews and approves stock option awards to named executive officers based upon a review of competitive compensation data, its assessment of individual performance, a review of each named executive officer's existing long-term incentives, and retention considerations. Periodic stock option grants are made at the discretion of the Committee to eligible employees and, in appropriate circumstances, the Committee considers the recommendations of members of management, such as Steven B. Ratoff, our Interim President and Chief Executive Officer.

In 2009, certain named executive officers were awarded stock options in the amounts included in the Grants of Plan-Based Awards table. Stock options granted by us have an exercise price equal to the fair market value of our Common Stock on the day of grant, typically vest annually over a three-year period or upon the achievement of certain performance-based milestones and are based upon continued employment, and generally expire ten (10) years after the date of grant. The fair value of the options granted to the named executive officers in the Summary Compensation Table is determined in accordance with the Black-Scholes method of valuation for share-based compensation. The Committee has also granted performance based options to certain of our named executive officers. Incentive stock options also include certain other terms necessary to ensure compliance with the Internal Revenue Code of 1986, as amended.

We expect to continue to use stock options as a long-term incentive vehicle because:

Stock options align the interests of our named executive officers with those of our stockholders, supporting a pay-for performance culture, foster employee stock ownership, and focus the management team on increasing value for our stockholders.

Stock options are performance-based. All of the value received by the recipient of a stock option is based on the growth of the stock price.

Stock options help to provide a balance to the overall executive compensation program as base salary and annual bonuses focus on the short term compensation, while the vesting of stock options increases stockholder value over the longer term.

The vesting period of stock options encourages executive retention and the preservation of stockholder value. In determining the number of stock options to be granted to our named executive officers, we take into account the individual's position, scope of responsibility, ability to affect profits and stockholder value and the individual's historic and recent performance and the value of stock options in relation to other elements of the individual named executive officer's total compensation.

**Restricted Stock.** Our 2006 Equity Incentive Plan authorizes us to grant restricted stock. No restricted stock grants were awarded during the 2009 fiscal year. In order to implement our long-term incentive goals, we anticipate that we may grant shares of restricted stock in the future.

**Executive Benefits and Perquisites**

Our named executive officers, who are parties to employment agreements, will continue to be parties to such employment agreements in their current form until the expiration of the employment agreement or until such time as the Committee determines in its discretion that revisions to such employment agreements are advisable. In addition, consistent with our compensation philosophy, we intend to continue to maintain our current benefits for our named executive officers, including medical, dental and life insurance and the ability to contribute to a 401(k) plan; however, the Committee in its discretion may revise, amend or add to the officer's executive benefits if it deems it advisable. We believe these benefits are currently comparable to benefit levels for comparable companies. We have no current plans to change either the employment agreements (except as required by law or as required to clarify the benefits to which our named executive officers are entitled as set forth herein) or level of benefits.

**Severance and Change in Control Arrangements**

The specific terms of our severance and change in control arrangements are discussed in detail below under the headings Potential Payments Upon Termination or Change in Control and Employment Agreements. As a general matter, however, we believe that reasonable severance and change in control protection for our named executive officers is necessary in order for us to recruit and retain qualified executives.

**Equity Grant Policy**

All grants to our named executive officers are at the discretion of the Board, following review and input by the Committee.

**IRC Section 162(m) compliance**

Section 162(m) of the Internal Revenue Code of 1986, as amended (the Code), generally disallows a tax deduction to public companies for certain compensation in excess of \$1 million paid to our named executive officers. Certain compensation, including qualified performance-based compensation, will not be subject to the deduction limit if certain requirements are met. In general, our compensation program is designed to reward executives for the achievement of our performance objectives. The stock plan is designed in a manner intended to comply with the performance-based exception to Section 162(m). Nevertheless, compensation attributable to awards granted under the plans may not be treated as qualified performance-based compensation under Section 162(m). In addition, the Committee considers it important to retain flexibility to design compensation programs that are in the best interests of NovaDel and its stockholders and, to this end, the Committee reserves the right to use its judgment to authorize compensation payments that may be subject to the limitations under Section 162(m) when the Committee believes that compensation is appropriate and in the best interests of NovaDel and our stockholders, after taking into consideration changing business conditions and performance of our employees.

Edgar Filing: NOVADEL PHARMA INC - Form S-1

Summary Compensation Table

The following table sets forth a summary for the fiscal year ended December 31, 2009 of the cash and non-cash compensation awarded, paid or accrued by us to our Chief Executive Officer, and Chief Financial Officer and our three most highly compensated officers other than the Chief Executive Officer and Chief Financial Officer who served in such capacities in 2009 (collectively, the named executive officers ).

Name and Principal Position	Year	Salary (\$)	Bonus (\$)	Stock Awards (\$)	Option Awards (\$) <sup>(1)</sup>	Non-Equity Incentive Plan Compensation (\$)	Change in Pension Value and Nonqualified Deferred Compensation Earnings (\$)	All Other Compensation (\$) <sup>(6)</sup>	Total (\$)
Steven B. Ratoff <i>Interim President and Chief Executive Officer</i>	2009	210,000 <sup>(2)</sup>			434,188 <sup>(3)</sup>			67,500 <sup>(4)</sup>	711,688
	2008	210,000 <sup>(2)</sup>		141,000 <sup>(7)</sup>	6,899 <sup>(3)</sup>			20,000 <sup>(4)</sup>	377,899
	2007	206,500 <sup>(2)</sup>			57,335 <sup>(3)</sup>			6,000 <sup>(4)</sup>	269,835
David H. Bergstrom, Ph.D. <i>Senior Vice President and Chief Operating Officer</i>	2009	302,598			165,887			24,986	493,471
	2008	311,538	50,000 <sup>(5)</sup>	70,000 <sup>(7)</sup>				25,156	457,195
	2007	300,000	100,000					19,799	419,799
Michael E. Spicer, CPA <i>Chief Financial Officer and Corporate Secretary</i> <sup>(8)</sup>	2009	66,021			23,536			20,475	110,031
	2008	266,054		70,500 <sup>(7)</sup>				40,114	376,618
	2007	255,731			256,124			62,443	574,298
Deni M. Zodda, Ph.D. <i>Chief Business Officer</i> <sup>(9)</sup>	2009	94,444			23,536			176,038	294,018
	2008	288,577		70,500 <sup>(7)</sup>				35,783	394,860
	2007	236,692			364,576			25,541	622,809
Joseph Warusz <i>Principal Accounting Officer</i> <sup>(10)</sup>	2009	206,640							206,640

(1) Option awards reflect the aggregate grant date fair value computed in accordance with FASB ASC Topic 718, based on the fair value of the option on the grant date as estimated using the Black-Scholes model. For a discussion of assumptions used to estimate fair value, please see Note 12, "Stock Options and Warrants", to our financial statements in our Annual Report on Form 10-K for the year ended December 31, 2009. The actual amount ultimately realized from the equity awards will likely vary based on a number of factors, including, but not limited to, NovaDel's actual performance, stock price fluctuations, differences from the valuation assumptions used and the timing of exercise or applicable vesting.

(2) Amount represents fees paid to Mr. Ratoff as part of his consulting agreement with NovaDel.

(3) Reflects the aggregate grant date fair value of options granted to Mr. Ratoff in his capacity as a director and a named executive officer of NovaDel during 2009, 2008 and 2007. In 2009, the aggregate grant date fair value of Mr. Ratoff's options was \$429,121 for options granted to Mr. Ratoff in his capacity as a named executive officer and \$5,067 for options granted to Mr. Ratoff in his capacity as a director. In 2008 and 2007, Mr. Ratoff was only granted options in his capacity as a director.

(4) Amounts represent Board fees paid to Mr. Ratoff during 2009, 2008 and 2007, as previously discussed under director compensation.



- (5) Dr. Bergstrom received a one-time special cash bonus of \$50,000, paid in January 2009, in recognition of his individual efforts in 2008 in connection with the Company's research and development efforts and clinical activities including, but not limited to, the U.S. Food and Drug Administration's approval of the New Drug Application for Zolpimist (zolpidem tartrate) Oral Spray for the short-term treatment of insomnia.
- (6) See All Other Compensation 2009 chart below for amounts.
- (7) Stock awards reflect the aggregate grant date fair value computed in accordance with FASB ASC Topic 718, based on the closing price of the Company's common stock on the grant date. The named executives each received restricted stock awards in February 2008: Mr. Ratoff received 300,000 restricted shares, and each of Dr. Bergstrom, Mr. Spicer and Dr. Zodda received 150,000 restricted shares. The restrictions on the restricted stock awarded in February 2008 shall lapse over a three-year period, subject to reduction as follows: (1) in the event of a \$5 million non-dilutive financing by the Company on or before December 31, 2008, the three-year restriction shall be accelerated such that the restrictions on the restricted stock shall lapse over a two-and-one-half year period; (2) in the event of an additional \$5 million (or \$10 million in the aggregate) non-dilutive financing by the Company on or before December 31, 2008, the three-year restriction shall be accelerated such that the restrictions on the restricted stock shall lapse over a two-year period; and (3) in the event of a \$20 million (or \$20 million in the aggregate) non-dilutive financing by the Company, the restrictions shall immediately lapse. Mr. Spicer and Dr. Zodda forfeited their respective shares of restricted stock. Additionally, the Board, upon the recommendation of the Compensation Committee, agreed that, in the case of the Company's Chief Executive Officer, an additional 200,000 shares of restricted stock shall be granted as follows: (1) upon achieving a \$5 million non-dilutive financing by the Company on or before December 31, 2008, an additional 100,000 shares of restricted stock shall be granted; and (2) upon achieving an additional \$5 million (or \$10 million in the aggregate) in non-dilutive financing by the Company on or before December 31, 2008, an additional 100,000 shares of restricted stock shall be granted. The restrictions on such additional shares shall lapse over a three-year period. Neither of these events occurred on or before December 31, 2008. Neither of the restricted stock criteria was met on or before December 31, 2008.
- (8) On March 19, 2009, Mr. Spicer resigned from his positions with the Company, effective April 1, 2009. There was no disagreement between us and Mr. Spicer on any matter relating to our operations, policies or practices.
- (9) On April 28, 2009, Dr. Zodda agreed with the Board that due to a reorganization of the executive team, his services as Senior Vice President and Chief Business Officer would no longer be required effective April 30, 2009. There was no disagreement between us and Dr. Zodda on any matter relating to our operations, policies or practices. In connection with his departure, Dr. Zodda and the Company entered into a Separation, Consulting and General Release Agreement whereby Dr. Zodda would provide the Company with certain consulting services ending on October 31, 2009.
- (10) On April 28, 2009, the Company appointed Mr. Warusz as Principal Accounting Officer. Simultaneously with the appointment of Mr. Johnson as Chief Financial Officer, Mr. Warusz resigned from the position of Principal Accounting Officer. Mr. Warusz continued in his capacity as a consultant to the Company until July 31, 2010. Mr. Warusz provided services to the Company pursuant to a consulting agreement, under which Mr. Warusz received a monthly retainer of \$20,000 and an hourly rate of \$180 for hours in excess of 160 hours per month.

Edgar Filing: NOVADEL PHARMA INC - Form S-1

All Other Compensation 2009

Name	401(K) (\$)	Health Care Coverage (\$)	Relocation (\$)	Severance Payment (\$)	Vacation Payout (\$)	Consulting (\$)	Total (\$)
Steven B. Ratoff							
David H. Bergstrom, Ph.D.	12,185	12,801					24,986
Michael E. Spicer, CPA	2,838	8,310			4,927	4,400	20,475
Deni M. Zodda, Ph.D.	3,808	23,434		137,500	11,296		176,038
Joseph Warusz							

Grants of Plan-Based Awards

The following table sets forth information with respect to the named executive officers concerning stock options granted during the fiscal year ended December 31, 2009. There were no grants of restricted stock to the named executive officers during the fiscal year ended December 31, 2009

Name	Grant Date	Estimated Future Payouts Under Non-Equity Incentive Plan Awards			Estimated Future Payouts Under Equity Incentive Plan Awards			All Other Stock Awards: Number of Shares of Stock or Units (#) <sup>(1)</sup>	All Other Option Awards: Number of Securities Underlying Options (#)	Exercise or Base Price of Option Awards (\$/Sh)	Grant Date Fair Value of Stock and Option Awards (\$)
		Threshold (\$)	Target (\$)	Maximum (\$)	Threshold (#)	Target (#)	Maximum (#)				
Steven B. Ratoff	1/22/09								1,250,000	0.34	
	12/31/09								2,000,000	0.17	
David H. Bergstrom, Ph.D.	1/22/09								400,000	0.34	
	11/24/09								700,000	0.23	
Michael E. Spicer, CPA <sup>(1)</sup>	1/22/09								125,000	0.34	
Deni M. Zodda, Ph.D. <sup>(2)</sup>	1/22/09								125,000	0.34	
Joseph Warusz											

- (1) On March 19, 2009, Mr. Spicer resigned from his positions with the Company, effective April 1, 2009. There was no disagreement between us and Mr. Spicer on any matter relating to our operations, policies or practices. As a result of Mr. Spicer's resignation, his 125,000 share option award lapsed.
- (2) On April 28, 2009, Dr. Zodda agreed with the Board that due to a reorganization of the executive team, his services as Senior Vice President and Chief Business Officer would no longer be required effective April 30, 2009. There was no disagreement between us and Dr. Zodda on any matter relating to our operations, policies or practices. In connection with his departure, Dr. Zodda and the Company entered into a Separation, Consulting and General Release Agreement whereby Dr. Zodda would provide the Company with certain consulting services ending on October 31, 2009. As a result of Dr. Zodda's departure, his 125,000 share option award lapsed.



Edgar Filing: NOVADEL PHARMA INC - Form S-1

Outstanding Equity Awards at Fiscal Year-End

The following table provides a summary of equity awards outstanding at December 31, 2009 for each of our named executive officers.

Name	Option Awards					Stock Awards			
	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Options (#)	Option Exercise Price (\$)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested (\$)	Equity Incentive Plan Awards: Number of Unearned Shares, Units or Other Rights That Have Not Vested (#)	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or Other Rights That Have Not Vested (\$)
Steven B. Ratoff	100,000			\$ 1.36	1/16/2011	300,000 <sup>(5)</sup>	\$ 51,000		
	29,645 <sup>(2)</sup>			\$ 1.52	1/15/2012				
	33,333 <sup>(1)</sup>	16,667		\$ 1.52	1/15/2010				
	16,667	33,333		\$ 0.24	9/7/2013				
		50,000		\$ 0.23	10/15/2014				
	1,250,000			\$ 0.34	1/22/2014				
		2,000,000		\$ 0.17	12/31/2014				
David H. Bergstrom, Ph.D.	30,701 <sup>(3)</sup>	27,778		\$ 1.71	12/3/2016	50,000 <sup>(5)</sup>	\$ 8,333		
	441,799 <sup>(3)</sup>	399,722		\$ 1.71	12/3/2016				
	183,333	216,667		\$ 0.34	1/22/2014				
	29,167	670,833		\$ 0.23	11/24/2014				
Michael E. Spicer, CPA <sup>(6)</sup>									
Deni M. Zodda, Ph.D. <sup>(7)</sup>	15,625 <sup>(4)</sup>			\$ 1.47	2/21/2017				
Joseph Warusz									

(1) The options vest in one-third installments per year in years 1, 2 and 3. An additional 1/3 of these options vested in January 2010.

(2) These options are fully vested.

(3) Dr. Bergstrom's options are performance based and vest 12.5% upon acceptance by the Food & Drug Administration (FDA) of our New Drug Application (NDA) submission for our product candidate zolpidem; 12.5% upon FDA acceptance of a NDA submission for our product candidate sumatriptan; 12.5% upon Board approval and successful implementation of portfolio plan for next generation compounds; 12.5% upon Chief Executive Officer approval and successful implementation of organization plan to address issues in analytical, clinical and regulatory; 15% upon completion of a Board approved licensing deal for our product candidate zolpidem; 15% upon completion of a Board approved licensing deal for our product candidate sumatriptan; and 20% at Board discretion upon completion of approved licensing deal for our product candidates zolpidem or sumatriptan.



- (4) Dr. Zodda's options are the residual vested options that expire on April 28, 2010.
- (5) Dr. Bergstrom was awarded 100,000 shares of restricted stock in December 2006, which restricted stock vests in one-third installments in years 1, 2 and 3. In addition, the named executives each received restricted stock awards in February 2008: Mr. Ratoff received 300,000 restricted shares, and each of Dr. Bergstrom, Mr. Spicer and Dr. Zodda received 150,000 restricted shares. The restrictions on the restricted stock awarded in February 2008 shall lapse over a three-year period, subject to reduction as follows: (1) in the event of a \$5 million non-dilutive financing by the Company on or before December 31, 2008, the three-year restriction shall be accelerated such that the restrictions on the restricted stock shall lapse over a two-and-one-half year period; (2) in the event of an additional \$5 million (or \$10 million in the aggregate) non-dilutive financing by the Company on or before December 31, 2008, the three-year restriction shall be accelerated such that the restrictions on the restricted stock shall lapse over a two-year period; and (3) in the event of a \$20 million (or \$20 million in the aggregate) non-dilutive financing by the Company, the restrictions shall immediately lapse. Mr. Spicer and Dr. Zodda forfeited their respective shares of restricted stock. Additionally, the Board, upon the recommendation of the Compensation Committee, agreed that, in the case of the Company's Chief Executive Officer, an additional 200,000 shares of restricted stock shall be granted as follows: (1) upon achieving a \$5 million non-dilutive financing by the Company on or before December 31, 2008, an additional 100,000 shares of restricted stock shall be granted; and (2) upon achieving an additional \$5 million (or \$10 million in the aggregate) in non-dilutive financing by the Company on or before December 31, 2008, an additional 100,000 shares of restricted stock shall be granted. The restrictions on such additional shares shall lapse over a three-year period. Neither of the restricted stock criteria was met on or before December 31, 2008.
- (6) On March 19, 2009, Mr. Spicer resigned from his positions with the Company, effective April 1, 2009. There was no disagreement between us and Mr. Spicer on any matter relating to our operations, policies or practices.
- (7) On April 28, 2009, Dr. Zodda agreed with the Board that due to a reorganization of the executive team, his services as Senior Vice President and Chief Business Officer would no longer be required effective April 30, 2009. There was no disagreement between us and Dr. Zodda on any matter relating to our operations, policies or practices. In connection with his departure, Dr. Zodda and the Company entered into a Separation, Consulting and General Release Agreement whereby Dr. Zodda would provide the Company with certain consulting services ending on October 31, 2009.

**Option Exercises and Stock Vested During 2009**

There were no options or other derivative securities exercised in 2009 by our named executive officers. In addition, there were no shares acquired by our named executive officers upon the vesting of restricted stock.

Edgar Filing: NOVADEL PHARMA INC - Form S-1

Potential Payments Upon Termination or Change in Control

The following table shows the potential payments upon death or disability, termination, resignation or a change of control of NovaDel for each of the named executive officers. For purposes of disclosure, the table assumes that the death or disability, termination, resignation or a change of control occurred as of December 31, 2009.

Name	Executive Benefits and Payments Upon Termination	Death or Disability(\$)	Termination for Cause(\$)	Resignation(\$)	Termination Without Cause Or For Good Reason(\$)	Termination in Connection With Change in Control(\$)
Steven B. Ratoff <sup>(1)</sup>						
David H. Bergstrom, Ph.D.	Base Salary	72,000			300,000	300,000
	Bonus <sup>(2)</sup>	90,000			90,000	90,000
	Stock Options/Restricted Stock Accelerated <sup>(3)</sup>	8,500				8,500
	Health Care Continuation	1,200			1,200	1,200
	Accrued Vacation Pay	28,846	28,846	28,846	28,846	28,846
	Life Insurance Benefits <sup>(4)</sup>	100,000				
Michael E. Spicer, CPA <sup>(5)</sup>						
Deni M. Zodda, Ph.D. <sup>(6)</sup>						
Joseph Warusz						
TOTAL (\$)		300,546	28,846	28,846	420,046	428,546

- (1) Mr. Ratoff was appointed as the Interim President and Chief Executive Officer of the Company on July 25, 2007, but had no employment agreement. Effective January 1, 2010, Mr. Ratoff was appointed as President and Chief Executive Officer and entered into an employment agreement in connection therewith, and will continue to serve as Interim Chief Financial Officer and Corporate Secretary.
- (2) Assumes the named executive officer has earned 100% of the potential bonus payable per the individual employment agreement.
- (3) Represents the intrinsic value of the options or restricted stock as of December 31, 2009 (the difference between the market value of \$0.17 as of December 31, 2009 and the exercise price).
- (4) Pursuant to our current benefit plans, each named executive officer would receive a \$50,000 death benefit plus an additional \$50,000 for an accidental death or a maximum benefit of \$100,000.
- (5) Represents maximum amount vacation payable to executive. Vacation time accrued ratably throughout the calendar year, and lapses as of December 31 of each year if not otherwise utilized.
- (6) On March 10, 2009, Mr. Spicer resigned from his positions with the Company, effective April 1, 2009. There was no disagreement between us and Mr. Spicer on any matter relating to our operations, policies or practices.
- (7) On April 28, 2009, Dr. Zodda agreed with the Board that due to a reorganization of the executive team, his services as Senior Vice President and Chief Business Officer would no longer be required effective April 30, 2009. There were no disagreements between us and Dr. Zodda on any matter relating to our operations, policies or practices. In connection with his departure, Dr. Zodda and the Company entered into a Separation, Consulting and General Release Agreement whereby Dr. Zodda would provide the Company with certain consulting services ending on October 31, 2009.

**Employment Agreements**

In 2009, we had employment agreements with Dr. Bergstrom, Mr. Spicer and Dr. Zodda. Mr. Spicer's and Dr. Zodda's employment agreements are no longer effective as of their respective dates of termination. We have no outstanding obligations under these agreements. In exchange for the benefits offered under the agreements, these executives have agreed not to engage in competitive activities or to interfere with our business relations for a specified period of time following the termination of their employment. Effective

## Edgar Filing: NOVADEL PHARMA INC - Form S-1

January 1, 2010, we entered into an employment agreement with Mr. Ratoff. The individual agreements of the named executive officers are summarized below.

**David H. Bergstrom, Ph.D.** Dr. Bergstrom's agreement expires on December 4, 2010. His agreement currently provides for:

annual base salary of \$300,000, subject to periodic and customary review for increase by the Board or Compensation Committee;

an annual bonus of \$100,000 for the period commencing on January 1, 2007 and ending on December 31, 2007 and thereafter eligible to receive an annual bonus equal to 30% of base salary; and

options to purchase 900,000 shares of Common Stock and 100,000 shares of restricted stock pursuant to our 2006 Equity Incentive Plan.

If Dr. Bergstrom's employment is terminated as a result of his death or disability, we shall (i) pay to Dr. Bergstrom or to Dr. Bergstrom's estate, as applicable, (x) his base salary and any accrued and unpaid bonus and expense reimbursement amounts through the date of his death or disability and (y) the pro rata portion of the guaranteed bonus and stock options earned by Dr. Bergstrom during the year of his death or disability (which, for this purpose, shall be prorated in accordance with the number of full months in such year during which Dr. Bergstrom was employed hereunder), and (ii) for the longer of twelve (12) months following his death or disability or the balance of the agreement (as if such termination had not occurred) provide continuation coverage to the members of Dr. Bergstrom's family and, in the case of termination for disability, Dr. Bergstrom under all major medical and other health, accident, life or other disability plans and programs in which such family members and, in the case of termination for disability, Dr. Bergstrom participated immediately prior to his death or disability. All stock options that are scheduled to vest by the end of the calendar year in which such termination occurs shall be accelerated and deemed to have vested as of the termination date. All stock options that have not vested (or been deemed pursuant to the immediately preceding sentence to have vested) as of the date of termination shall be deemed to have expired as of such date. Any stock options that have vested as of the date of Dr. Bergstrom's death (including the options described in the immediately preceding sentence) shall remain exercisable for a period of one hundred and eighty (180) days after the date of his death; in the event of a disability, any unexercised option may be exercised in whole or in part, within the first ninety (90) days after such termination of employment or service. If Dr. Bergstrom's employment is terminated by us for Cause or by Dr. Bergstrom other than for Good Reason, we shall pay: (i) base salary through the date of termination; (ii) all options that have not vested as of the date of any such termination shall be deemed to have expired; (iii) Dr. Bergstrom's right to exercise any vested options shall terminate as of such date; and (iv) any restricted shares that are then forfeitable shall be forfeited immediately. If Dr. Bergstrom is terminated by us (or our successor) upon a Change of Control, we (or our successor, as applicable) shall pay: (i) base salary for a period of one year following termination; (ii) any bonus that would otherwise be due to Dr. Bergstrom by the end of the calendar end of the year in which such termination occurs; (iii) any expense reimbursement amounts owed through the date of termination; and (iv) all options not vested shall be accelerated and deemed to have vested. If Dr. Bergstrom is terminated prior to end of term by us other than as a result of death or disability or Dr. Bergstrom's employment is terminated by Dr. Bergstrom for Good Reason or we provide notice to Dr. Bergstrom that the agreement will not be renewed, we shall pay: (i) twelve (12) month severance from date of public announcement of same; (ii) the bonus that would have otherwise been due, unless there is documentation on file for a period of at least three (3) months regarding performance issues which have not been cured, to Dr. Bergstrom in the calendar year in which such termination or non-renewal occurs; (iii) any expense reimbursement amounts owed through the date of termination; and (iv) all options that are granted shall be accelerated and deemed to have vested and all vested options at date of termination shall expire ninety (90) days post termination of employment. However, our obligation will be reduced if compensation is received from other employment for these amounts otherwise actually earned by Dr. Bergstrom during the one year period following the termination of his employment.

**Michael E. Spicer.** Mr. Spicer's agreement was renewed on January 22, 2008, to be effective from December 20, 2007. The agreement was renewed on December 20, 2008, and the agreement as renewed expires on December 20, 2009, and would be subject to automatic extension for successive one-year



## Edgar Filing: NOVADEL PHARMA INC - Form S-1

periods on the anniversary of the effective date unless either party gives written notice, no later than 90 days preceding the date of any such extension, of an intention not to further extend the term. On April 1, 2009, the Board of Directors accepted the resignation of Mr. Spicer from his position as Chief Financial Officer and Corporate Secretary. There was no disagreement between Mr. Spicer and the Company on any matter relating to the Company's operations, policies or practices. Options and restricted shares previously granted to Mr. Spicer that had not yet vested were canceled, and remaining vested options are exercisable through June 30, 2009. Mr. Spicer's original agreement with the Company, which was further amended on September 2, 2005 and March 12, 2007, expired on December 20, 2007. His current agreement provides for:

an annual base salary of \$256,200, subject to periodic and customary review for increase by the Board or Compensation Committee;

eligible to receive an annual bonus equal to 30% of base salary; and

eligible to receive additional grants of stock options and other equity awards, in addition to equity awards which Mr. Spicer has already received.

If Mr. Spicer's employment is terminated as a result of his death or disability, we shall (i) pay to Mr. Spicer or to Mr. Spicer's estate, as applicable, (x) his base salary through the date of his death or disability and (y) the bonus, if any, that would otherwise have been due at the end of the calendar year in which such death or disability occurs; and the pro rata portion of the stock options earned by Mr. Spicer during the year of his death or disability, prorated in accordance with the number of full months in such year during which Mr. Spicer was employed by us; (ii) for the longer of twelve (12) months following his death or disability or the balance of the agreement (as if such termination had not occurred) provide continuation coverage to the members of Mr. Spicer's family and, in the case of termination for disability, to Mr. Spicer under all major medical and other health, accident, life or other disability plans and programs in which such family members and, in the case of termination for disability, Mr. Spicer participated immediately prior to his death or disability; and (iii) pay any expense reimbursement amounts owed through the date of death or disability. All stock options that are scheduled to vest by the end of the calendar year in which such termination occurs shall be accelerated and deemed to have vested as of the termination date. All stock options that have not vested (or been deemed pursuant to the immediately preceding sentence to have vested) as of the date of termination shall be deemed to have expired as of such date. Any stock options that have vested as of the date of Mr. Spicer's death (including the options described in the immediately preceding sentence) shall remain exercisable for a period of one hundred and eighty (180) days after the date of his death; in the event of a disability, any unexercised option may be exercised in whole or in part, within the first ninety (90) days after such termination of employment or service. If Mr. Spicer's employment is terminated by us for Cause or by Mr. Spicer other than for Good Reason, we shall pay (i) base salary through the date of termination; (ii) all options that have not vested shall be deemed to have expired as of such date and; (iii) all rights to exercise any vested options shall terminate. If Mr. Spicer is terminated by us (or our successor) upon a Change of Control, we (or our successor, as applicable), upon receiving a copy of a release and separation agreement signed by Mr. Spicer, shall pay within ten (10) business days: (i) a lump sum equivalent to twelve (12) months of base salary, and (ii) a lump sum equivalent to the bonus, if any, that would otherwise have been due at the end of the calendar year in which such termination occurs; and (iii) any expense reimbursement amounts owed through the date of termination; and (iv) all stock options that have not vested as of the date of such termination shall be accelerated and deemed to have vested. If Mr. Spicer is terminated by us other than as a result of death or disability or Mr. Spicer terminates for Good Reason, we shall pay: (i) base salary for a period of twelve (12) months following termination; and (ii) any accrued and unpaid bonus and expense reimbursement amounts through the date of termination.

On March 19, 2009, Mr. Spicer resigned from his positions with the Company, effective April 1, 2009. There was no disagreement between us and Mr. Spicer on any matter relating to our operations, policies or practices.

## Edgar Filing: NOVADEL PHARMA INC - Form S-1

*Deni M. Zodda*, Ph.D. Dr. Zodda's agreement expires on February 22, 2010. His agreement currently provides for:

annual base salary of \$275,000, subject to periodic and customary review for increase by the Board or Compensation Committee;

eligible to receive an annual bonus equal to 30% of base salary; and

an incentive stock option to purchase 68,027 shares of Common Stock and a non-qualified stock option to purchase 598,973 shares of Common Stock pursuant to our 2006 Equity Incentive Plan.

If Dr. Zodda's employment is terminated as a result of his death or disability, we shall (i) pay to Dr. Zodda or to Dr. Zodda's estate, as applicable, (x) his base salary through the date of his death or disability and (y) the bonus, if any, that would otherwise have been due at the end of the calendar year in which such death or disability occurs; and the pro rata portion of the stock options earned by Dr. Zodda during the year of his death or disability, prorated in accordance with the number of full months in such year during which Dr. Zodda was employed by us; (ii) for the longer of twelve (12) months following his death or disability or the balance of the agreement (as if such termination had not occurred) provide continuation coverage to the members of Dr. Zodda's family and, in the case of termination for disability, to Dr. Zodda under all major medical and other health, accident, life or other disability plans and programs in which such family members and, in the case of termination for disability, Dr. Zodda participated immediately prior to his death or disability; and (iii) pay any expense reimbursement amounts owed through the date of death or disability. All stock options that are scheduled to vest by the end of the calendar year in which such termination occurs shall be accelerated and deemed to have vested as of the termination date. All stock options that have not vested (or been deemed pursuant to the immediately preceding sentence to have vested) as of the date of termination shall be deemed to have expired as of such date. Any stock options that have vested as of the date of Dr. Zodda's death (including the options described in the immediately preceding sentence) shall remain exercisable for a period of one hundred and eighty (180) days after the date of his death; in the event of a disability, any unexercised option may be exercised in whole or in part, within the first ninety (90) days after such termination of employment or service. If Dr. Zodda's employment is terminated by us for Cause or by Dr. Zodda other than for Good Reason, we shall pay (i) base salary through the date of termination; (ii) all options that have not vested shall be deemed to have expired as of such date and; (iii) all rights to exercise any vested options shall terminate. If Dr. Zodda is terminated by us (or our successor) upon a Change of Control, we (or our successor, as applicable), upon receiving a copy of a release and separation agreement signed by Dr. Zodda, shall pay within ten (10) business days: (i) a lump sum equivalent to twelve (12) months of base salary, and (ii) a lump sum equivalent to the bonus, if any, that would otherwise have been due at the end of the calendar year in which such termination occurs; and (iii) any expense reimbursement amounts owed through the date of termination; and (iv) all stock options that have not vested as of the date of such termination shall be accelerated and deemed to have vested. During the first year of Dr. Zodda's agreement, if he is terminated by us other than as a result of death or disability or Dr. Zodda terminates for Good Reason, we shall pay: (i) base salary for a period of six (6) months following termination; and (ii) any accrued and unpaid bonus and expense reimbursement amounts through the date of termination. However, our obligation shall be reduced, by amounts otherwise actually earned by Dr. Zodda during the six (6) month period following termination. If Dr. Zodda is terminated during the second and third year of the agreement by us other than as a result of death or disability or Dr. Zodda terminates for Good Reason, we shall pay: (i) base salary for a period of twelve (12) months following termination; and (ii) any accrued and unpaid bonus and expense reimbursement amounts through the date of termination. However, our obligation shall be reduced, by amounts otherwise actually earned by Dr. Zodda during the twelve (12) month period following termination.

The foregoing agreements also provide for certain non-competition and non-disclosure covenants on the part of such executive. However, with respect to the non-competition covenants, a court may determine not to enforce such provisions or only partially enforce such provisions. Additionally, each of the foregoing agreements provides for certain fringe benefits, such as inclusion in pension, profit sharing, stock option, savings, hospitalization and other benefit plans at such times as we may adopt them.

## Edgar Filing: NOVADEL PHARMA INC - Form S-1

On April 28, 2009, Dr. Zodda agreed with the Board that due to a reorganization of the executive team, his services as Senior Vice President and Chief Business Officer would no longer be required effective April 30, 2009.

**Steven B. Ratoff.** Mr. Ratoff's agreement became effective January 1, 2010 and does not have an expiration date. His agreement currently provides for:

annual base salary of \$350,000, subject to periodic and customary review for increase by the Board or Compensation Committee;

an annual bonus of equal to 50% of base salary, with a maximum equal to 150% of the target award; and

options to purchase 2,000,000 shares of Common Stock pursuant to our 2006 Equity Incentive Plan.

If Mr. Ratoff's employment is terminated as a result of his death or disability or a Change in Control, we (or our successor) shall (i) pay to Mr. Ratoff or to Mr. Ratoff's estate, as applicable, (x) his base salary and any accrued and unpaid bonus and expense reimbursement amounts through the date of his death or disability and (y) the pro rata portion of the guaranteed bonus and stock options earned by Mr. Ratoff during the year of his death or disability (which, for this purpose, shall be prorated in accordance with the number of full months in such year during which Mr. Ratoff was employed hereunder), and (ii) for the longer of twelve (12) months following his death or disability or the balance of the agreement (as if such termination had not occurred) provide continuation coverage to the members of Mr. Ratoff's family and, in the case of termination for disability, Mr. Ratoff under all major medical and other health, accident, life or other disability plans and programs in which such family members and, in the case of termination for disability, Mr. Ratoff participated immediately prior to his death or disability. All unvested equity grants shall immediately vest upon the date of termination and shall have twelve (12) months following the date of termination to exercise these equity grants. If Mr. Ratoff is terminated by us for other than for Good Reason, we shall pay: (i) base salary through the date of termination; (ii) all vested and non-vested options will be forfeited; (iii) any restricted shares that are then forfeitable shall be forfeited immediately; and (iv) Mr. Ratoff will not be entitled to receive any APIP payments even if the performance measures were met and he would otherwise be entitled to such award. If Mr. Ratoff is terminated by us, we shall be obligated to pay: (i) the greater of twelve (12) months base salary at the time of termination or the intrinsic value of any unvested and vested but unexercised stock grants as of the date of termination, in the event the twelve (12) months base salary at the time of termination is greater than the intrinsic value of the equity awards, all unvested and vested but unexercised equity grants shall be forfeited; (ii) any APIP payments that Mr. Ratoff would have been entitled if performance measures were met; however, such payment will not be made until the end of the full performance period and the will be prorated for the performance period up until the date of termination; (iii) any expense reimbursement amounts owed through the date of termination; and (iv) Mr. Ratoff and his covered beneficiaries will continue to be covered by the Company's health benefits for twelve (12) months following the date of termination. Should Mr. Ratoff's employment be voluntarily terminated, he will receive the base salary through the date of termination and any unpaid APIP will be forfeited upon the date of termination, additionally all unvested and vested but unexercised options will be forfeited as of the date of termination. Mr. Ratoff will no longer be eligible to participate in the Company sponsored benefit plans, other than his ability to apply for and participate in the health benefits provided by COBRA.

**DIRECTOR COMPENSATION**

The general policy of the Board is that compensation for independent Directors should be a mix of cash and equity-based compensation. NovaDel does not pay employee Directors for Board service in addition to their regular employee compensation. The Compensation Committee, which consists solely of independent Directors, has the primary responsibility for reviewing and considering any revisions to Director compensation. The Board reviews the Compensation Committee's recommendations and determines the amount of Director compensation.

Pursuant to its charter, the Compensation Committee may engage the services of outside advisors, experts, and others to assist them. During 2009, the Compensation Committee did not engage the services of outside advisors, experts or others to assist in setting Director compensation.

The following table shows amounts earned by each Director in the fiscal year ended December 31, 2009.

Director	Fees Earned or Paid in Cash (\$)	Stock Awards (\$)	Option Awards (\$) <sup>(1)</sup>	Non-Equity Incentive Plan Compensation (\$)	Change in Pension Value and Nonqualified Deferred Compensation Earnings	All Other Compensation (\$)	Total (\$)
Mark J. Baric	\$ 65,500		\$ 5,067				\$ 70,567
Thomas E. Bonney, CPA	\$ 72,000		\$ 5,067				\$ 77,067
William F. Hamilton, Ph.D. <sup>(2)</sup>	\$ 47,252						\$ 47,252
J. Jay Lobell <sup>(2)</sup>	\$ 38,544						\$ 38,544
Charles Nemeroff, M.D., Ph.D.	\$ 63,500		\$ 5,067				\$ 68,567
Steven B. Ratoff <sup>(3)</sup>	\$ 67,500		\$ 5,067				\$ 72,567

(1) Represents estimated fair value of the option award on the grant date using a Black-Scholes option pricing model that assumes the following: expected volatility of 85%; dividend yield of 0%; expected term until exercise of 1.8 years; and a risk-free interest rate of 2.0%.

(2) On October 15, 2009, Mr. Lobell and Dr. Hamilton did not stand for re-election at our 2009 Annual Meeting.

(3) Does not include fees earned by Mr. Ratoff pursuant to his consulting arrangement with us, or stock awards received by Mr. Ratoff pursuant to his role as the Company's Interim President and Chief Executive Officer, Interim Chief Financial Officer and Corporate Secretary.

## Edgar Filing: NOVADEL PHARMA INC - Form S-1

The following table shows the options granted to each Director in the fiscal year ended December 31, 2009.

Director	Number of Shares Underlying Options Granted	Grant Date	Exercise Price Per Share
Mark J. Baric	50,000	10/15/2009	\$ 0.23
Thomas E. Bonney, CPA	50,000	10/15/2009	\$ 0.23
William F. Hamilton, Ph.D. <sup>(1)</sup>			\$
J. Jay Lobell <sup>(1)</sup>			\$
Charles Nemeroff, M.D., Ph.D.	50,000	10/15/2009	\$ 0.23
Steven B. Ratoff	50,000	10/15/2009	\$ 0.23

(1) On October 15, 2009, Mr. Lobell and Dr. Hamilton did not stand for re-election at our 2009 Annual Meeting.

In September 2006, Mr. Ratoff was elected Chairman of the Board. In connection with Mr. Ratoff's appointment as Chairman of the Board, the Board entered into a consulting arrangement to compensate Mr. Ratoff for his efforts in such position. Such arrangement was on a month-to-month basis. Effective June 6, 2007, his monthly rate was \$17,500 per month and reimbursement of reasonable expenses. Mr. Ratoff also received compensation as a member of the Board. Effective January 1, 2010, Mr. Ratoff was appointed as President and Chief Executive Officer and entered into an employment agreement in connection therewith, and will continue to serve as Interim Chief Financial Officer. As a result, Mr. Ratoff no longer qualifies as a non-employee Director as of January 1, 2010.

The Board followed the recommendation of the Compensation Committee and determined non-employee Director compensation as follows:

**Fiscal 2009 Policy** -- Directors who were not employees and were independent received fees in the following amounts:

**Equity Compensation** -- Each new non-employee Director will, upon initially joining the Board, receive options to purchase 100,000 shares of our Common Stock pursuant to our 2006 Equity Incentive Plan, referred to herein as the 2006 Plan, and thereafter, each non-employee Director will receive an annual grant of options to purchase 50,000 shares of our Common Stock upon re-election to the Board.

**Cash Compensation** -- Prior to October 15, 2009, each non-employee Director was paid an annual retainer fee of \$20,000 and \$2,000 for in-person and \$1,000 for telephonic meetings of the Board. The Lead Independent Director was paid a \$2,500 retainer for such role. In addition, each non-employee Director received certain additional annual retainers and meeting fees for chairing or serving as a member of the committees of the Board, with annual retainers as follows:

Chairman of the Audit Committee	\$ 7,500
Member of the Audit Committee	\$ 2,500
Chairman of the Compensation Committee	\$ 5,000
Member of the Compensation Committee	\$ 2,500
Chairman of the Corporate Governance and Nominating Committee	\$ 5,000
Member of the Corporate Governance and Nominating Committee	\$ 2,500

## Edgar Filing: NOVADEL PHARMA INC - Form S-1

In addition, each non-employee Director was paid \$1,000 for in-person and \$500 for telephonic committee meetings. The Board has agreed to permit each non-employee Director to elect to receive cash compensation in connection with their Board and committee retainers in the form of equity under the Plan. Such election will be made on an annual basis and valued at the time of grant. Equity grants will be received by such non-employee Directors when cash compensation payments are due.

On October 15, 2009, cash compensation for each non-employee Director was modified such that each non-employee Director will only receive an annual retainer of \$50,000 to be paid quarterly in installments of \$12,500. No additional non-employee Director cash compensation will be paid to the Company's non-employee Directors.

### **Compensation Committee Interlocks and Insider Participation**

From January 1, 2009 through October 15, 2009, the members of the Compensation Committee were Mr. Mark J. Baric, Mr. J. Jay Lobell and Dr. Charles Nemeroff. From October 15, 2009 through December 31, 2009, the members of the Compensation Committee were Dr. Charles Nemeroff, Mr. Mark J. Baric and Mr. Thomas J. Bonney. None of these individuals was at any time during fiscal year 2009 or at any other time an officer or employee of ours. No executive officer has served as a director or member of the Board of Directors or the Compensation Committee (or other committee serving an equivalent function) of any other entity while an executive officer of that other entity served as a director of or member of our Board of Directors or our Compensation Committee. Mr. Steven B. Ratoff, our Chairman of the Board, and our President and Chief Executive Officer participated in discussions and decisions regarding salaries and incentive compensation for all of our named executive officers, except he was excluded from discussions regarding his own salary and incentive stock compensation.

Edgar Filing: NOVADEL PHARMA INC - Form S-1

SECURITY OWNERSHIP OF DIRECTORS, MANAGEMENT AND CERTAIN BENEFICIAL OWNERS

*Stock Ownership of Directors and Management*

The following table sets forth information, as of October 14, 2010, regarding beneficial ownership of the Common Stock to the extent known to us, by (i) each person who is a director; (ii) each named executive officer in the Summary Compensation Table; and (iii) all directors and named executive officers as a group. Except as otherwise noted, each person has sole voting and investment power as to his or her shares.

<b>Title of Class</b>	<b>Name and Address or Number in Group<sup>(1)</sup></b>	<b>Amount and Nature of Beneficial Ownership<sup>(2)</sup></b>	<b>Percentage of Class</b>
Common Stock	Mark J. Baric	218,233 <sup>(3)</sup>	*
Common Stock	David H. Bergstrom, Ph.D.	1,609,167 <sup>(4)</sup>	1.61%
Common Stock	Thomas E. Bonney, CPA	278,100 <sup>(5)</sup>	*
Common Stock	Charles Nemeroff, M.D., Ph.D.	228,333 <sup>(6)</sup>	*
Common Stock	Steven B. Ratoff	3,695,039 <sup>(7)</sup>	3.67%
Common Stock	Michael E. Spicer, CPA	39,000 <sup>(8)</sup>	*
Common Stock	Deni M. Zodda, Ph.D.	15,625 <sup>(9)</sup>	*
Common Stock	Joseph Warusz		*
Common Stock	All Directors and Named Executive Officers as a group (8 persons)	6,083,497 <sup>(10)</sup>	5.91%

\* Less than 1%.

- (1) The address of all holders listed herein is c/o NovaDel Pharma Inc., 1200 Route 22 East, Suite 2000, Bridgewater, New Jersey 08807.
- (2) For each of the following persons, the numbers set forth in this column includes the number of shares of Common Stock immediately succeeding such person's name, which such person has the right to acquire within 60 days through the exercise of stock options:
- (3) Includes 9,900 shares of Common Stock owned of record and 208,333 shares of Common Stock subject to options which were exercisable as of October 14, 2010 or 60 days after such date. Excludes 41,667 shares of Common Stock underlying options, which become exercisable over time after such period.
- (4) Includes 240,000 shares of Common Stock owned of record and 1,369,167 shares of Common Stock subject to options which were exercisable as of October 14, 2010 or 60 days after such date. Excludes 680,833 shares, consisting of 630,833 shares of Common Stock underlying options and 50,000 shares of restricted stock units, which become exercisable or vest over time after such period.
- (5) Includes 25,300 shares of Common Stock owned of record and 252,800 shares of Common Stock subject to options which were exercisable as of October 14, 2010 or 60 days after such date. Excludes 41,667 shares of Common Stock underlying options, which become exercisable over time after such period.
- (6) Includes 15,000 shares of Common Stock owned of record and 213,333 shares of Common Stock subject to options which were exercisable as of October 14, 2010 or 60 days after such date. Excludes 44,167 shares of Common Stock underlying options, which become exercisable over time after such period.
- (7) Includes 1,260,000 shares of Common Stock owned of record, 38,727 shares of Common Stock subject to warrants which were exercisable as of October 14, 2010 or 60 days after such date and 2,396,312 shares of Common Stock subject to options which were exercisable as of October 14, 2010 or 60 days after such date. Excludes 1,433,333 shares, consisting of 1,133,333 shares of Common Stock underlying options and 300,000 shares of restricted stock units, which become exercisable or vest over time after such period.
- (8) Includes 39,000 shares of Common Stock owned of record.
- (9) Includes 15,625 shares of Common Stock subject to options which were exercisable as of October 14, 2010 or 60 days after such date.
- (10) Includes 1,589,200 shares of Common Stock owned of record, 38,727 shares of Common Stock subject to warrants which were exercisable as of October 14, 2010 or 60 days after such date and 4,455,570 shares of Common Stock subject to options which were exercisable as of October 14, 2010 or 60 days after such date. Excludes 2,241,667 shares, consisting of 1,891,667 shares of Common Stock underlying options and 350,000 shares of restricted stock units, which become exercisable or vest over time after such period.

*Stock Ownership of Certain Beneficial Owners*

The following table sets forth information, as of October 14, 2010, regarding beneficial ownership of the Common Stock to the extent known to us by each person known to be the beneficial owner of 5% or more of the Common Stock. Except as otherwise noted, each person has sole voting and investment power as to his or her shares.

<b>Title of Class</b>	<b>Name and Address or Number in Group</b>	<b>Amount and Nature of Beneficial Ownership</b>	<b>Percentage of Class</b>
Common Stock	ProQuest Investments, II, L.P. <sup>(1)</sup>	48,210,746 <sup>(2)</sup>	43.0%

- (1) The address for ProQuest Investments II, L.P., ProQuest Investments III, L.P. and ProQuest Investments II Advisors Fund, LP is 90 Nassau Street, 5<sup>th</sup> Floor, Princeton, NJ 08542.
- (2) The number of shares beneficially owned is (a) based on information disclosed on a report on Schedule 13D/A filed with the SEC on April 1, 2010 with respect to ownership as of March 31, 2010 and consists of (i) 10,792,899 shares of Common Stock, and warrants to purchase 6,343,916 shares of Common Stock held in the name of ProQuest Investments II, L.P., (ii) 23,417,138 shares of Common Stock, and warrants to purchase 9,074,381 shares of Common Stock held in the name of ProQuest Investments III, L.P., and (iii) 143,101 shares of Common Stock, and warrants to purchase 55,453 shares of Common Stock. ProQuest Associates III LLC ( Associates III ) is the General Partner of ProQuest Investments III, L.P. ProQuest Associates II LLC ( Associates II ) is the general partner of ProQuest Investments II, L.P. and of ProQuest Investments II Advisors Fund, L.P. Jay Moorin and Alain Schreiber, Managing Members of Associates III and Associates II, have voting, dispositive and investment power with respect to the securities. Each of Mr. Moorin and Mr. Schreiber disclaim beneficial ownership of such securities except to the extent of each such person's respective pecuniary interest in such securities, and (b) excludes warrants to purchase 1,616,142 shares of Common Stock held in the name of ProQuest Investments II, L.P. which expired on September 30, 2010.



**CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS**

To the best of management's knowledge, other than (i) compensation for services as named executive officers and Directors or (ii) as set forth below, there were no material transactions, or series of similar transactions, or any currently proposed transactions, or series of similar transactions, to which we were or were to be a party, in which the amount involved exceeds \$120,000 during fiscal 2009, and in which any Director or named executive officer, or any security holder who is known by us to own of record or beneficially more than 5% of any class of the Common Stock, or any member of the immediate family of any of the foregoing persons, has an interest.

On December 31, 2009, we entered into an amendment agreement with ProQuest Investments to convert the outstanding aggregate principal balance of all convertible notes and all liquidated damage notes, in each case, plus all accrued interest, in an aggregate amount equal to \$3,657,000 to 23,237,083 shares of the Company's common stock. Additionally on March 31, 2010, we announced a registered direct offering in which ProQuest Investments participated and received 4,848,485 shares of the Company's common stock and five-year warrants, Series A Warrants, to purchase 2,424,243 shares of common stock with an exercise price of \$0.25 per share and six-month warrants, Series B Warrants, to purchase 1,616,162 shares of common stock with an exercise price of \$0.25 per share. The Series B Warrants expired on September 30, 2010. As a result of the 2009 amendment agreement and the 2010 equity financing and as of October 14, 2010, ProQuest Investments beneficially owns 43.0% of our total outstanding common stock. As such, ProQuest Investments may be deemed to be our affiliate. Mr. Steven B. Ratoff, our President and Chief Executive Officer, has served as a venture partner with ProQuest Investments since December 2004, although he has no authority for investment decisions by ProQuest Investments.

The Audit Committee is responsible for reviewing, approving or ratifying all transactions between us and any related person. Related persons can include any of our directors or executive officers, certain of our stockholders, and any of their immediate family members. This obligation is set forth in our Audit Committee Charter. In evaluating related person transactions, the members of the Audit Committee apply the same standards of good faith and fiduciary duty they apply to their general responsibilities as a committee of the Board of the Directors and as individual directors. The Audit Committee will approve a related person transaction when, in its good faith judgment, the transaction is in the best interest of the Company. To identify related person transactions, each year, we require each of our directors, director nominees and executive officers to complete a disclosure questionnaire identifying any transactions with us in which the officer or director or their family members have an interest.

**PLAN OF DISTRIBUTION**

We are offering up to [ ] units, each consisting of [ ] share of common stock and warrants to purchase [ ] share of common stock for \$[ ] per unit with aggregate gross proceeds of \$[ ]. Pursuant to an engagement letter agreement, we engaged [ ] as our placement agent for this offering. [ ] is not purchasing or selling any units, nor are they required to arrange for the purchase and sale of any specific number or dollar amount of units, other than to use their best efforts to arrange for the sale of units by us. Therefore, we may not sell the entire amount of units being offered. Additionally, 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.

Upon the completion of the offering, we will pay the placement agent a cash transaction fee equal to [ ]% of the gross proceeds to us from the sale of the units in the offering.

The placement agent may be deemed to be an underwriter within the meaning of Section 2(a)(11) of the Securities Act and any commissions received by it and any profit realized on the sale of the securities by them while acting as principal might be deemed to be underwriting discounts or commissions under the Securities Act. The placement agent would be required to comply with the requirements of the Securities Act of 1933, as amended, or the Securities Act, and the Securities Exchange Act of 1934, as amended, or the Exchange Act, including, without limitation, Rule 10b-5 and Regulation M under the Exchange Act. These rules and regulations may limit the timing of purchases and sales of shares of common stock and warrants to purchase shares of common stock by the placement agent. Under these rules and regulations, the placement agent may not (i) engage in any stabilization activity in connection with our securities; and (ii) bid for or purchase any of our securities or attempt to induce any person to purchase any of our securities, other than as permitted under the Exchange Act, until they have completed their participation in the distribution.

The placement agent agreement provides that we will indemnify the placement agent against specified liabilities, including liabilities under the Securities Act. We have been advised that, in the opinion of the Securities and Exchange Commission, indemnification for liabilities under the Securities Act is against public policy as expressed in the Securities Act and is therefore unenforceable. The placement agent agreement also provides that the agreement may be terminated by either party upon thirty (30) days prior written notice.

**Notice to Investors in the United Kingdom**

This prospectus is being distributed only to, and is only directed at (i) persons who are outside the United Kingdom, or (ii) investment professionals falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005 (the Order ) or (iii) high net worth entities, and other persons to whom it may lawfully be communicated, falling within Article 49(2)(a) to (e) of the Order, or (iv) persons to whom Article 33 of the Order applies (all such persons being referred to as relevant persons and each a relevant person ). Accordingly, by accepting delivery of this prospectus, the recipient warrants and acknowledges that it is such a relevant person and where Article 33 of the Order applies it acknowledges that it has previously been advised (a) that the protections conferred by the Financial Services and Markets Act 2000 (the Act ) will not apply to any communication in relation to the securities the subject of this prospectus; and (b) that the protections conferred by or under the Act may not apply to any investment activity that may be engaged in as a result of any such communication. The securities are only available to, and any invitation, offer, or agreement to subscribe, purchase or otherwise acquire such securities will be engaged in only with relevant persons. Any person who is not a relevant person should not act or rely on this prospectus or any of its contents.

This prospectus has not been approved by an authorized person in the United Kingdom. No person may communicate or cause to be communicated any invitation or inducement to engage in investment activity (within the meaning of Section 21(1) of the Act) received by it in connection with the issue or sale of the securities other than in circumstances in which Section 21(1) of the Act does not apply to us.

**European Economic Area**

In particular, this document does not constitute an approved prospectus in accordance with European Commission's Regulation on Prospectuses no. 809/2004 and no such prospectus is to be prepared and approved in connection with this offering. Accordingly, in relation to each Member State of the European Economic Area which has implemented the Prospectus Directive (being the Directive of the European Parliament and of the Council 2003/71/EC and including any relevant implementing measure in each Relevant Member State) (each, a Relevant Member State), with effect from and including the date on which the Prospectus Directive is implemented in that Relevant Member State (the Relevant Implementation Date) an offer of securities to the public may not be made in that Relevant Member State prior to the publication of a prospectus in relation to units which has been approved by the competent authority in that Relevant Member State or, where appropriate, approved in another Relevant Member State and notified to the competent authority in that Relevant Member State, all in accordance with the Prospectus Directive, except that it may, with effect from and including the Relative Implementation Date, make an offer of securities to the public in that Relevant Member State at any time:

to legal entities which are authorized or regulated to operate in the financial markets or, if not so authorized or regulated, whose corporate purpose is solely to invest in securities;

to any legal entity which has two or more of (1) an average of at least 250 employees during the last financial year; (2) a total balance sheet of more than 43,000,000 euros; and (3) an annual net turnover of more than 50,000,000 euros, as shown in the last annual or consolidated accounts; or

in any other circumstances which do not require the publication by the Issuer of a prospectus pursuant to Article 3 of the Prospectus Directive.

For the purposes of this provision, the expression an offer of securities to the public in relation to any shares in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and the securities to be offered so as to enable an investor to decide to purchase or subscribe the shares, as the same may be varied in that Member State by any measure implementing the Prospectus Directive in that Member State. For these purposes the units are securities.

**DESCRIPTION OF SECURITIES**

***Description of Capital Stock***

Under our certificate of incorporation, as amended to date, we are authorized to issue up to 200,000,000 shares of common stock, \$0.001 par value per share. At October 14, 2010, approximately 98,383,458 shares of common stock were issued and outstanding. The following description relating to our common stock, certificate of incorporation and bylaws are only summaries, and we encourage you to review complete copies of these documents. You can obtain copies of these documents by following the directions outlined in [Where You Can Find Additional Information](#) .

***Dividends, Voting Rights and Liquidation***

Each stockholder of record is entitled to one vote for each outstanding share of our common stock owned by that stockholder on every matter properly submitted to the stockholders for their vote. After satisfaction of the dividend rights of holders of any preferred stock, holders of common stock are entitled to any dividend declared by our board out of funds legally available for that purpose. After the payment of liquidation preferences to holders of any preferred stock, holders of common stock are entitled to receive, on a pro rata basis, all our remaining assets available for distribution to stockholders in the event of our liquidation, dissolution or winding up. Holders of common stock do not have any preemptive right to become subscribers or purchasers of additional shares of any class of our capital stock. The rights, preferences and privileges of holders of common stock are subject to, and may be injured by, the rights of the holders of shares of any series of preferred stock that we may designate and issue in the future.

***Description of Unit Warrants***

In connection with this offering, we will issue warrants to purchase up to [\_\_] shares of common stock. Each warrant entitles the holder to purchase one share of common stock at an exercise price of \$[\_\_] per share. After the expiration of the exercise period, unit warrant holders will have no further rights to exercise such unit warrants.

The unit warrants may be exercised only for full shares of common stock, and may be exercised on a cashless basis. If the registration statement covering the shares issuable upon exercise of the warrants contained in the units is no longer effective, the unit warrants will be issued with restrictive legends unless such shares are eligible for sale under Rule 144. We will not issue fractional shares of common stock or cash in lieu of fractional shares of common stock. Unit warrant holders do not have any voting or other rights as a stockholder of our company. The exercise price and the number of shares of common stock purchasable upon the exercise of each unit warrant are subject to adjustment upon the happening of certain events, such as stock dividends, distributions, and splits.

Certain institutional investors are prohibited, pursuant to their investment charter or other governing documents, from acquiring warrants. Accordingly, we and the placement agent may, upon request of any such investor in this offering, sell units to such investors that exclude the warrants, provided that the sale of units that exclude such warrants will be at a price per unit equal to \$[\_\_].

***Transfer Agent and Registrar***

American Stock Transfer and Trust Company is the transfer agent and registrar for our common stock.

***Delaware Law and Certain Certificate of Incorporation and By-Law Provisions***

The provisions of Delaware law and of our certificate of incorporation and by-laws discussed below could discourage or make it more difficult to accomplish a proxy contest or other change in our management or the acquisition of control by a holder of a substantial amount of our voting stock. It is possible that these provisions could make it more difficult to accomplish, or could deter, transactions that stockholders may otherwise consider to be in their best interests or the best interests of NovaDel.

***Business Combinations.*** We are subject to the provisions of Section 203 of the General Corporation Law of Delaware. Section 203 prohibits a publicly held Delaware

corporation from engaging in a business combination with an interested stockholder for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. A business combination includes mergers, asset sales and other transactions resulting in a financial benefit to the interested stockholder. Subject to specified exceptions, an interested stockholder is a person who, together with affiliates and associates, owns, or within three years did own, 15% or more of the corporation's voting stock.

**Limitation of Liability; Indemnification.** Our certificate of incorporation contains provisions permitted under the General Corporation Law of Delaware relating to the liability of directors. The provisions eliminate, to the extent legally permissible, a director's liability for monetary damages for a breach of fiduciary duty, except in circumstances involving wrongful acts, such as the breach of a director's duty of loyalty or acts or omissions that involve intentional misconduct or a knowing violation of law. The limitation of liability described above does not alter the liability of our directors and officers under federal securities laws. Furthermore, our certificate of incorporation contains provisions to indemnify our directors and officers to the fullest extent permitted by the General Corporation Law of Delaware. These provisions do not limit or eliminate our right or the right of any shareholder of ours to seek non-monetary relief, such as an injunction or rescission in the event of a breach by a director or an officer of his duty of care to us. We believe that these provisions assist us in attracting and retaining qualified individuals to serve as directors.

#### LEGAL MATTERS

Certain legal matters with respect to the validity of shares of our common stock being offered hereby will be passed on for us by Morgan, Lewis & Bockius LLP, Princeton, New Jersey.

#### EXPERTS

The balance sheets as of December 31, 2009 and 2008 and the related statements of operations, changes in stockholders' equity (deficiency) and cash flows for each of the three years in the period ended December 31, 2009 included in this prospectus and elsewhere in the registration statement have been audited by J. H. Cohn LLP, independent registered public accountants, as indicated in their report with respect thereto, which report includes an explanatory paragraph relating to NovaDel Pharma, Inc.'s ability to continue as a going concern and is included herein in reliance upon the authority of said firm as experts in giving said report.

#### WHERE YOU CAN FIND ADDITIONAL INFORMATION

We file annual, quarterly and special reports, proxy statements and other information with the SEC. You may read and copy any document we file at the SEC's public reference room at 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the public reference rooms. Many of the filings we make with the SEC are also available to the public from the SEC's Website at <http://www.sec.gov>. We make available free of charge our annual, quarterly and current reports, proxy statements and other information upon request. To request such materials, please send an e-mail to [cjohnson@novadel.com](mailto:cjohnson@novadel.com) or contact Craig Johnson, our Senior Vice President, Chief Financial Officer and Secretary, at 1200 Route 22 East, Suite 2000, Bridgewater, New Jersey 08807, or at (908) 203-4640. In addition, our common stock is listed for trading on the OTCBB under the symbol NVDL.OB. 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.

**NovaDel Pharma Inc.**

**INDEX TO DECEMBER 31, 2009 FINANCIAL STATEMENTS**

<u>Report of Independent Registered Public Accounting Firm</u>	F-2
<u>Balance Sheets</u>	F-3
<u>Statements of Operations</u>	F-4
<u>Statements of Changes in Stockholders' Equity (Deficiency)</u>	F-5
<u>Statements of Cash Flows</u>	F-6
<u>Notes to Financial Statements</u>	F-7
	F-1

---

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

The Stockholders and  
Board of Directors  
NovaDel Pharma Inc.

We have audited the accompanying balance sheets of NovaDel Pharma Inc. as of December 31, 2009 and 2008, and the related statements of operations, changes in stockholders' equity (deficiency) and cash flows for each of the three years in the period ended December 31, 2009. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of NovaDel Pharma Inc. as of December 31, 2009 and 2008 and its results of operations and cash flows for each of the three years in the period ended December 31, 2009, in conformity with accounting principles generally accepted in the United States of America.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has suffered recurring losses from operations and negative cash flows from operating activities that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ J.H. COHN LLP

---

Roseland, New Jersey  
March 31, 2010

**NOVADEL PHARMA INC.**  
**BALANCE SHEETS AS OF DECEMBER 31, 2009 AND 2008**

	<b>December 31, 2009</b>	<b>December 31, 2008</b>
	<u>                    </u>	<u>                    </u>
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 2,663,000	\$ 4,328,000
Assets held for sale		299,000
Deferred financing costs, net of accumulated amortization of \$238,000 and \$213,000, respectively		25,000
Prepaid expenses and other current assets	1,430,000	958,000
	<u>                    </u>	<u>                    </u>
Total Current Assets	4,093,000	5,610,000
Property and equipment, net	324,000	1,447,000
Other assets	36,000	259,000
	<u>                    </u>	<u>                    </u>
<b>TOTAL ASSETS</b>	<b>\$ 4,453,000</b>	<b>\$ 7,316,000</b>
	<u>                    </u>	<u>                    </u>
<b>LIABILITIES AND STOCKHOLDERS DEFICIENCY</b>		
Current Liabilities:		
Secured convertible notes payable, net of unamortized discount of zero and \$403,000, respectively	\$	\$ 3,597,000
Accounts payable	195,000	654,000
Accrued expenses and other current liabilities	117,000	924,000
Current portion of deferred revenue	4,266,000	266,000
Current portion of capital lease obligations	10,000	122,000
	<u>                    </u>	<u>                    </u>
Total Current Liabilities	4,588,000	5,563,000
Non-current portion of deferred revenue	4,202,000	4,468,000
Non-current portion of capital lease obligations	4,000	26,000
	<u>                    </u>	<u>                    </u>
Total Liabilities	8,794,000	10,057,000
	<u>                    </u>	<u>                    </u>
<b>COMMITMENTS AND CONTINGENCIES</b>		
<b>STOCKHOLDERS DEFICIENCY</b>		
Preferred stock, \$.001 par value:		
Authorized 1,000,000 shares, none issued		
Common stock, \$.001 par value:		
Authorized 200,000,000 shares, Issued 88,343,457 and 60,692,260 at December 31, 2009 and 2008, respectively	89,000	60,000
Additional paid-in capital	78,342,000	72,034,000
Accumulated deficit	(82,766,000)	(74,829,000)
Less: Treasury stock, at cost, 3,012 shares	(6,000)	(6,000)
	<u>                    </u>	<u>                    </u>
Total Stockholders Deficiency	(4,341,000)	(2,741,000)
	<u>                    </u>	<u>                    </u>
<b>TOTAL LIABILITIES AND STOCKHOLDERS DEFICIENCY</b>	<b>\$ 4,453,000</b>	<b>\$ 7,316,000</b>
	<u>                    </u>	<u>                    </u>



See accompanying notes to financial statements.

F-3

---

**NOVADEL PHARMA INC.**  
**STATEMENTS OF OPERATIONS FOR THE YEARS ENDED DECEMBER 31, 2009, 2008 AND 2007**

	Year Ended December 31,		
	2009	2008	2007
License Fees and Milestone Payments Earned	\$ 422,000	\$ 361,000	\$ 469,000
Research and Development Expenses	2,473,000	3,878,000	11,940,000
Consulting, Selling, General and Administrative Expenses	4,044,000	4,722,000	6,716,000
Loss on Assets Held for Sale		351,000	
Total Expenses	6,517,000	8,951,000	18,656,000
Loss From Operations	(6,095,000)	(8,590,000)	(18,187,000)
Other, net	(385,000)		(66,000)
Interest Expense	(2,160,000)	(1,868,000)	
Interest Income	6,000	137,000	632,000
Loss Before Income Tax Benefit	(8,634,000)	(10,321,000)	(17,621,000)
Income Tax Benefit	(1,057,000)	(735,000)	(658,000)
Net Loss	\$ (7,577,000)	\$ (9,586,000)	\$ (16,963,000)
Basic and Diluted Loss Per Common Share	\$ (0.12)	\$ (0.16)	\$ (0.29)
Weighted Average Number of Common Shares Used in Computation of Basic and Diluted Loss Per Common Share	61,346,000	59,592,000	59,497,000

See accompanying notes to financial statements.

**NOVADEL PHARMA INC.**  
**STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIENCY) FOR THE**  
**YEARS ENDED DECEMBER 31, 2009, 2008 AND 2007**

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Treasury Stock	Total Stockholders Equity (Deficiency)
	Shares	Amount					
BALANCE, December 31, 2006	58,358,818	\$ 58,000	\$ 66,860,000	\$ (48,280,000)	\$ (34,000)	\$ (6,000)	\$ 18,598,000
Share-based compensation expense			910,000				910,000
Stock issued in connection with private placement, net of costs	961,914	1,000	1,394,000				1,395,000
Stock issued for options and warrants exercised	271,528		200,000				200,000
Comprehensive income (loss):							
Unrealized loss on investment in marketable equity security					34,000		34,000
Net Loss				(16,963,000)			(16,963,000)
Total comprehensive loss							(16,929,000)
BALANCE, December 31, 2007	59,592,260	59,000	69,364,000	(65,243,000)		(6,000)	4,174,000
Share-based compensation expense			771,000				771,000
Restricted stock issued	1,100,000	1,000	(1,000)				
Warrants issued to investors and beneficial conversion feature embedded in convertible notes			1,900,000				1,900,000
Net loss				(9,586,000)			(9,586,000)
BALANCE, December 31, 2008	60,692,260	60,000	72,034,000	(74,829,000)		(6,000)	(2,741,000)
Share-based compensation expense			326,000				326,000
Cumulative effect for the adoption of ASC 815-40-15 relating to outstanding warrants indexed to the entity's own stock				(360,000)			(360,000)
Restricted stock cancelled	(575,000)						
Cashless exercise of warrants	489,114	1,000	(1,000)				
Issuance of common stock	27,737,083	28,000	5,983,000				6,011,000
Net loss				(7,577,000)			(7,577,000)
BALANCE, December 31, 2009	88,343,457	\$ 89,000	\$ 78,342,000	\$ (82,766,000)	\$	\$ (6,000)	\$ (4,341,000)

See accompanying notes to financial statements.

**NOVADEL PHARMA INC.**  
**STATEMENTS OF CASH FLOWS FOR THE YEARS ENDED**  
**DECEMBER 31, 2009, 2008 AND 2007**

	Year Ended December 31,		
	2009	2008	2007
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>			
Net loss	\$ (7,577,000)	\$ (9,586,000)	\$ (16,963,000)
Adjustments to reconcile net loss to net cash used in operating activities:			
Amortization of discount on short-term investments			(101,000)
Debt conversion to common stock expense	1,360,000		
Expiration of warrants	(360,000)		
Share-based compensation expense	326,000	771,000	910,000
Amortization of debt discount and deferred financing fees	428,000	1,711,000	
Loss on assets held for sale		351,000	
Loss on disposal of fixed assets	746,000	19,000	
Loss from return of investment in marketable security available-for-sale to issuer			140,000
Other than temporary impairment of investment in marketable equity security available-for-sale			360,000
Depreciation and amortization	369,000	506,000	685,000
Changes in operating assets and liabilities:			
Inventories			(99,000)
Prepaid expenses and other current assets	(472,000)	151,000	(574,000)
Other assets	223,000	110,000	(10,000)
Accounts payable	(459,000)	(978,000)	834,000
Accrued expenses and other current liabilities	104,000	(1,344,000)	206,000
Deferred revenue	3,734,000	2,756,000	(628,000)
<b>Net cash used in operating activities</b>	<b>(1,578,000)</b>	<b>(5,533,000)</b>	<b>(15,240,000)</b>
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>			
Purchases of property and equipment		(121,000)	(179,000)
Proceeds from sale of fixed assets	41,000		
Purchases of short-term and long-term investments			(9,737,000)
Maturities of short-term and long-term investments			13,528,000
<b>Net cash provided by (used in) investing activities</b>	<b>41,000</b>	<b>(121,000)</b>	<b>3,612,000</b>
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>			
Proceeds from issuance of common stock through private placements	1,007,000		1,395,000
Proceeds from issuance of convertible notes		4,000,000	
Deferred financing costs		(238,000)	
Proceeds from options and warrants exercised			200,000
Payments of convertible note obligation	(1,000,000)		
Payments of capital lease obligations	(135,000)	(164,000)	(169,000)
<b>Net cash provided by (used in) financing activities</b>	<b>(128,000)</b>	<b>3,598,000</b>	<b>1,426,000</b>
<b>NET DECREASE IN CASH AND CASH EQUIVALENTS</b>	<b>(1,665,000)</b>	<b>(2,056,000)</b>	<b>(10,202,000)</b>
<b>CASH AND CASH EQUIVALENTS, BEGINNING OF YEAR</b>	<b>4,328,000</b>	<b>6,384,000</b>	<b>16,586,000</b>
<b>CASH AND CASH EQUIVALENTS, END OF YEAR</b>	<b>\$ 2,663,000</b>	<b>\$ 4,328,000</b>	<b>\$ 6,384,000</b>
<b>SUPPLEMENTAL DISCLOSURE OF CASH PAID FOR INTEREST</b>	<b>\$ 10,000</b>	<b>\$ 28,000</b>	<b>\$ 37,000</b>

SUPPLEMENTAL DISCLOSURE OF NONCASH INVESTING AND FINANCING ACTIVITIES:			
Issuance of common stock for note conversion	\$ 3,000,000		
Issuance of common stock to convert penalties and interest	\$ 657,000		
Settlement of obligation with transfer of fixed assets	\$ 267,000		
Equipment acquired under capital lease obligations	\$		\$ 228,000

See accompanying notes to financial statements.

NOVADEL PHARMA INC.  
NOTES TO FINANCIAL STATEMENTS

**NOTE 1 - NATURE OF THE BUSINESS**

NovaDel Pharma Inc. (the Company) is a specialty pharmaceutical company developing oral spray formulations of a broad range of marketed pharmaceuticals. The Company's proprietary technology offers, in comparison to conventional oral dosage forms, the potential for faster absorption of drugs into the bloodstream leading to quicker onset of therapeutic effects and possibly reduced first pass liver metabolism, which may result in lower doses. Oral sprays eliminate the requirement for water or the need to swallow, potentially improving patient convenience and compliance. The Company's oral spray technology is focused on addressing unmet medical needs for a broad array of existing and future pharmaceutical products, with the most advanced oral spray candidates targeting angina, nausea, insomnia, migraine headaches and disorders of the central nervous system.

To date, we have entered into license agreements with (i) Mist Acquisition, LLC to manufacture and commercialize the NitroMist(R) lingual spray version of nitroglycerine, (ii) ECR Pharmaceuticals Company, Inc., to commercialize and manufacture ZolpiMist(TM) in the United States and Canada, (iii) Hana Biosciences, for the development and marketing rights in the U.S. and Canada for our ondansetron oral spray, (iv) Par Pharmaceuticals, Inc., or Par, for the marketing rights in the U.S. and Canada for NitroMist, (v) Manhattan Pharmaceuticals, in connection with propofol, (vi) Velcera, in connection with veterinary applications for currently marketed veterinary drugs and (vii) BioAlliance Pharma SA, for the European rights for ondansetron oral spray. In addition, we have entered into a sub-license agreement with Hana Biosciences and Par, pursuant to which Hana Biosciences granted a sublicense to Par to develop and commercialize Zensana.

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

Under the terms of the agreement, ECR paid the Company \$3 million 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.

On October 27, 2009, we and privately-held Mist Acquisition, LLC, or Mist, 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. Under terms of the agreement, Mist paid the Company a \$1,000,000 licensing fee upon execution of the agreement, and will pay milestone payments totaling an additional \$1,000,000 over twelve months, and ongoing performance payments of seventeen percent (17%) of net sales.

Through a separate license agreement with Mist, Akrimax Pharmaceuticals, LLC will receive the exclusive right to manufacture, distribute, market and sell NitroMist® in the United States, Canada and Mexico. 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.

On May 19, 2008, the Company and BioAlliance Pharma SA or BioAlliance, entered into an agreement where BioAlliance acquired the European rights for NovaDel's Ondansetron oral spray. Under the terms of the agreement, BioAlliance paid NovaDel a license fee of \$3,000,000 upon closing. The Company is eligible for additional milestone payments totaling approximately \$24 million (an approval milestone of \$5 million and sales-related milestone payments of approximately \$19 million) as well as a royalty on net sales. BioAlliance and the Company anticipate collaborating in the completion of development activities for Europe, with BioAlliance responsible for regulatory and pricing approvals and then commercialization throughout Europe. The Company 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).

In July 2007, the Company entered into a Product Development and Commercialization Sublicense Agreement (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, the Company and Hana Biosciences amended and restated their existing License and Development Agreement, as amended, relating to the development and commercialization of Zensana (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. The Company retains its 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 the Company until such time as Hana Biosciences had recovered one-half of its costs and expenses incurred in developing Zensana from sales of Zensana and the Company agreed to surrender for cancellation all 73,121 shares of the Hana Biosciences common stock acquired by the Company in connection with execution of the original License Agreement. Also in July 2007, the Company and Par agreed to terminate the agreement relating to NitroMist.

On November 18, 2004, the Company entered into a manufacturing and supply agreement with INyX whereby INyX manufactures and supplies NitroMist. For a five-year period that began November 18, 2004, INyX was to be the exclusive provider of the nitroglycerin lingual spray to the Company substantially worldwide. Pursuant to the terms and conditions of the agreement, it would be INyX's responsibility to manufacture, package and supply NitroMist in such territories. Thereafter, INyX would have a non-exclusive right to manufacture such spray for an additional five years. In July 2007, INyX announced it filed for protection under the Chapter 11 bankruptcy laws. The Company was informed by the trustees for INyX in June 2008 that the facility in Puerto Rico where manufacturing operations for NitroMist were conducted would be ceasing operations as of the end of July 2008. As a result, the Company selected an alternative contract manufacturing company, DPT Laboratories Inc (DPT), and is in the process of transferring manufacturing operations for NitroMist to DPT.

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

The Company has reported a net loss of \$7,577,000 \$9,586,000 and \$16,963,000, and negative cash flows from operating activities of \$1,578,000, \$5,533,000 and \$15,240,000, for the years ended December 31, 2009, 2008 and 2007, respectively. As of December 31, 2009, the Company had negative working capital of \$495,000 and cash and cash equivalents of \$2,663,000. Until and unless the Company's operations generate significant revenues and cash flow, we will attempt to continue to fund operations from cash on hand and through the sources of capital described below. The Company's long-term liquidity is contingent upon achieving sales and positive cash flows from operating activities, and/or obtaining additional financing. The most likely sources of financing include private placements of the Company's equity or debt securities or bridge loans to the Company from third-party lenders, license payments from current and future partners, and royalty payments from sales of approved product candidates by partners. The Company can give no assurances that any additional capital that it is able to obtain will be sufficient to meet its needs, or on terms favorable to it.

Since the fourth quarter 2007 and continuing throughout 2009, we have significantly reduced clinical development activities on our product candidate pipeline, such that we have limited our expenditures primarily to those required to support our two approved products NitroMist and Zolpimist and minor expenditures to support formulation development activities for certain other products, as we did not believe that we had sufficient cash to sustain such activities. Despite this reduction in expenditures for clinical activities, the Company requires capital to sustain its existing organization until such time as clinical activities can be resumed. The Company received \$1,055,000 in gross proceeds for common stock purchased by Seaside 88, LP during the year ended December 31, 2009. During the fourth quarter of 2009, the Company also entered into licensing and distribution agreements with ECR Pharmaceuticals Company, Inc. and Mist Acquisition, LLC, as a result of which it received non-refundable license fees of \$4,000,000.

## Edgar Filing: NOVADEL PHARMA INC - Form S-1

The Company will seek to raise additional capital in 2010 to fund our operations and future development activities through new strategic partnerships or collaborations, the sale of common stock or other equity securities or the issuance of debt. In the event we do not enter into a license agreement or other strategic transaction in which we receive an upfront fee or payment, or we do not undertake a financing of debt or equity securities, we may not have sufficient cash on hand to fund operations. We can give no assurances that we will be able to enter into a strategic transaction or raise any additional capital or, if we do, that such additional capital will be sufficient to meet our needs, or on terms favorable to us. If we are unable to raise additional capital, and we do not use our existing working capital to fund our development plans, we will have sufficient cash on hand to fund operating costs through the fourth quarter 2010.

Our audited financial statements for the year ended December 31, 2009, were prepared under the assumption that we will continue our operations as a going concern. We were incorporated in 1982, and have a history of losses. As a result, our independent registered public accounting firm in their audit report has expressed substantial doubt about our ability to continue as a going concern. Continued operations are dependent on our ability to complete equity or debt formation activities or to generate profitable operations. Such capital formation activities may not be available or may not be available on reasonable terms. Our financial statements do not include any adjustments that may result from the outcome of this uncertainty. If we cannot continue as a viable entity, our stockholders may lose some or all of their investment in the Company.

On May 14, 2008, we received notice from the NYSE Amex LLC (formally known as the American Stock Exchange) indicating that we are not in compliance with certain of the NYSE Amex LLC continued listing standards. Specifically, the NYSE Amex LLC has notified us that we are not in compliance with Section 1003(a)(iii) of the NYSE Amex LLC Company Guide with stockholders' equity of less than \$6,000,000 and losses from continuing operations and net losses in our five most recent fiscal years, and Section 1003(a)(iv) of the NYSE Amex LLC Company Guide in that we have sustained losses which are so substantial in relation to our overall operations or our existing financial resources, or our financial condition has become so impaired that it appears questionable, in the opinion of the NYSE Amex LLC, as to whether we will be able to continue operations and/or meet our obligations as they mature. On December 2, 2009, we formally notified NYSE Amex LLC of our intent to voluntarily withdraw our listing and registration. On December 14, 2009, we filed Form 25 voluntarily withdrawing our listing and registration from NYSE Amex LLC ( AMEX ). The final day of trading on AMEX was December 23, 2009. On December 24, 2009, we announced that our common stock will begin trading on the Over-the-Counter Bulletin Board ( OTCBB ) under its new ticker symbol on OTCBB as NVDL.OB

### **NOTE 3 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

**REVENUE RECOGNITION** The Company receives revenue from license agreements and consulting services. Upfront license agreement payments are initially deferred and subsequently amortized into revenue over the contractual period. Milestone payments related to license agreements are recognized as revenue when earned. Consulting revenues from contract clinical research are recognized in the period in which the services are rendered, provided that collection is reasonably assured.

**CASH EQUIVALENTS AND INVESTMENTS** - Cash equivalents include certificates of deposit and money market instruments with original maturities of three months or less when purchased. At times, such investments may be in excess of the Federal Deposit Insurance Corporation (FDIC) insurance limit.

**FINANCIAL INSTRUMENTS** Financial instruments include cash and cash equivalents and accounts payable. The amounts reported for financial instruments are considered to be reasonable approximations of their fair values.

**PROPERTY AND EQUIPMENT** - Property and equipment, including leasehold improvements, are stated at cost. The Company provides for depreciation and amortization using the straight-line method, based upon estimated useful lives of five to ten years or the lease term, if shorter.

**RESEARCH AND DEVELOPMENT COSTS** - Research and development costs are expensed as incurred.

**INCOME TAXES** - Deferred tax assets and liabilities are recognized for the future tax consequences attributable to temporary differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Temporary differences between financial statement and



## Edgar Filing: NOVADEL PHARMA INC - Form S-1

income tax reporting result primarily from net operating losses. As a result of these temporary differences, the Company has recorded a deferred tax asset with an offsetting valuation allowance for the same amount. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. Valuation allowances are established when it is considered more likely than not that some portion or all of the deferred tax asset will not be realized.

**DEFINED CONTRIBUTION RETIREMENT PLANS** - During January 2004, the Company established a 401(k) retirement plan that is available to all employees and requires matching contributions by the Company. During the years ended December 31, 2009, 2008 and 2007, the Company contributed approximately \$38,000, \$69,000 and \$95,000, respectively.

**VALUATION OF LONG-LIVED ASSETS** We assess the impairment of long-lived assets whenever events or changes in circumstances indicate that the carrying value may not be recoverable. Our long-lived assets as of December 31, 2009 and 2008 were represented by property and equipment, as we have no intangible assets on our balance sheet. Factors we consider important which could trigger an impairment review include the following:

significant underperformance relative to expected historical or projected future operating results;

significant changes in the manner of our use of the acquired assets or the strategy for our overall business;

significant negative industry or economic trends; and

significant decrease in the market value of the assets.

The impairment test is based upon a comparison of the estimated undiscounted cash flows to the carrying value of the long-lived assets. If we determine that the carrying value of long-lived assets may not be recoverable based upon the existence of one or more of the above indicators of impairment, we measure any impairment based on projected discounted cash flows. The cash flow estimates used to determine the impairment, if any, contain management's best estimate using appropriate assumptions and projections at that time. Net long-lived property and equipment as of December 31, 2009 and 2008 was \$324,000 and \$1,447,000, respectively. We reviewed our long-lived property and equipment as of December 31, 2009, and have determined that their estimated fair value exceeds the carrying amount of such assets; therefore, we have not recognized an impairment loss for our long-lived property and equipment.

**USE OF ESTIMATES** The accompanying financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America. This requires our management to make estimates about the future resolution of existing uncertainties that affect the reported amounts of assets, liabilities, revenues and expenses which in the normal course of business are subsequently adjusted to actual results. Actual results could differ from such estimates. In preparing these financial statements, management has made its best estimates and judgments of the amounts and disclosures included in the financial statements giving due regard to materiality.

**LOSS PER SHARE** The Company's basic loss per common share is computed as net loss divided by the weighted average number of common shares outstanding for the period. Diluted net loss per common share is the same as basic net loss per common share, since potentially dilutive securities from the assumed exercise of all outstanding options and warrants would have an antidilutive effect because the Company incurred a net loss during each period presented. As of December 31, 2009, 2008 and 2007, there were 28.1 million, 48.0 million, and 35.1 million common shares, respectively, issuable upon exercise of options and warrants, and the vesting of non-vested restricted common stock.

**STOCK-BASED COMPENSATION** - The Company calculates the fair value of stock-based compensation using the Black-Scholes method. Stock-based compensation costs are recorded as earned for all unvested stock options outstanding. The charge is being recognized in research and development and consulting, general and administrative expenses over the remaining service period after the adoption date based on the original estimate of fair value of the options as of the grant date. The Company recorded share-based

compensation of approximately \$326,000, \$771,000 and \$910,000 for the years ended December 31, 2009, 2008 and 2007, respectively. The Company will continue to incur share-based compensation charges in future periods. As of December 31, 2009, unamortized stock-based compensation expense of \$880,000 remains to be recognized, which is comprised of \$482,000 related to non performance-based stock options to be recognized over a weighted average period of 0.7 years, \$104,000 related to restricted stock to be recognized over a weighted average period of 1.1 years, and \$294,000 related to performance-based stock options which vest upon reaching certain milestones. Expenses related to the performance-based stock options will be recognized if and when the Company determines that it is probable that the milestone will be reached.

**NEW ACCOUNTING PRONOUNCEMENTS** In June 2009, the FASB issued FASB ASC 105, Generally Accepted Accounting Principles ( GAAP ), which establishes the FASB Accounting Standards Codification as the sole source of authoritative generally accepted accounting principles. Pursuant to the provisions of FASB ASC 105, the Company has updated references to GAAP in its financial statements issued for the period ended December 31, 2009. The adoption of FASB ASC 105 did not impact the Company's financial position or results of operations.

In April 2009, the FASB issued guidance now codified as FASB ASC Topic 825, Financial Instruments, which amends previous Topic 825 guidance to require disclosures about fair value of financial instruments in interim as well as annual financial statements. The adoption did not have a material impact on our results from operations or on our financial condition. Financial instruments include cash and cash equivalents, short-term investments, and accounts payable. The amounts reported for financial instruments are considered to be reasonable approximations of their fair values.

#### **NOTE 4 CONVERTIBLE NOTES**

On May 6, 2008, the Company entered into a binding Securities Purchase Agreement by and among ProQuest Investments II, L.P., ProQuest Investments II Advisors Fund, L.P., and ProQuest Investments III, L.P., referred to herein as the Purchasers, as amended pursuant to Amendment No. 1 to the Securities Purchase Agreement, dated May 28, 2008, by and among the Company and the Purchasers, to sell up to \$4,000,000 of secured convertible promissory notes, referred to herein as the convertible notes, and accompanying warrants to such Purchasers, referred to herein as the 2008 Financing. Mr. Steven Ratoff, the Company's Chairman, Interim President, Chief Executive Officer and Interim Chief Financial Officer, is a private investor in, and since December 2004 has served as a venture partner with, ProQuest Investments.

On May 30, 2008, the Company closed the initial portion of the transaction, referred to herein as the Initial Closing, for \$1,475,000, representing no more than 5,000,000 shares of the common stock underlying the convertible notes, upon receipt of approval from the NYSE Amex LLC, and satisfaction of customary closing conditions. The 5,000,000 shares, along with the prior securities owned by the Purchasers, represented 19.8% of the Company's outstanding common stock upon execution of the Securities Purchase Agreement. At its Annual Stockholders' Meeting on September 8, 2008, the Company sought and received stockholder approval to fund additional amounts such that the total commitment, inclusive of the amount at the Initial Closing, equaled up to \$4,000,000, referred to herein as the Subsequent Closing and together with the Initial Closing, the Closings. On October 17, 2008, the Company closed the Subsequent Closing, for gross proceeds of \$2,525,000.

In the Initial Closing, the Company issued the convertible notes, which convert into its common stock at a fixed price of \$0.295 per share subject to certain adjustments, and five-year warrants to purchase 3,000,000 shares of its common stock, with an exercise price of \$0.369 per share. The maturity date of the convertible notes issued in the Initial Closing was November 30, 2008.

In the Subsequent Closing, the Company issued the convertible notes, which convert into 10,744,681 shares of its common stock at a fixed price of \$0.235 per share subject to certain adjustments, and five-year warrants to purchase 6,446,809 shares of its common stock, with an exercise price of \$0.294 per share. The maturity date of the convertible notes issued in the Subsequent Closing was April 17, 2009.

The convertible notes accrue interest on their outstanding principal balances at an annual rate of 10%. All unpaid principal, together with any accrued but unpaid interest and other amounts payable under the convertible notes, shall be due and payable upon the earliest to occur of (i) when such amounts are declared due and payable by the Purchasers on or after the date that is 180 days after the date of issuance; or (ii)

## Edgar Filing: NOVADEL PHARMA INC - Form S-1

upon the occurrence of any change of control event. At the option of the Purchasers, interest may be paid in cash or in common stock of the Company. If the Company pays interest in common stock, the stock will be valued at the related conversion price for such convertible note. Therefore, on November 30, 2008, with respect to the Initial Closing and on April 17, 2009, with respect to the Subsequent Closing, the noteholders had the ability to either convert the convertible notes issued in such closing into shares of common stock or demand payment of the outstanding principal balance, plus accrued and unpaid interest at a rate of 10% per annum.

At its option, the Company had the ability to redeem without penalty or premium a portion of, or all of, the principal owed under the convertible notes by providing the Purchasers with at least 5 days written notice; provided that the Purchasers shall retain conversion rights in respect of the convertible notes for such period of 5 days after the Company has given such notice. Each prepayment shall be accompanied by the payment of accrued and unpaid interest on the amount being prepaid, through the date of the prepayment. On April 29, 2009, the Company remitted \$1.0 million to ProQuest Investments and related entities against the \$4.0 million of convertible notes issued during 2008.

On December 31, 2009, the Company announced an amendment agreement with ProQuest Investments L.P. and its affiliates (collectively, ProQuest ) to convert the outstanding aggregate principal balance of all convertible notes and all liquidated damages notes, in each case, plus all accrued interest, in an aggregate amount equal to \$3,657,000 to 23,237,083 shares of the Company's common stock as of December 31, 2009.

The Company filed an initial registration statement with the Securities Exchange Commission ( SEC ) to register the resale of common stock issuable in connection with the Initial Closing (excluding interest shares), referred to herein as the initial registrable shares, on June 26, 2008, which registration statement became effective as of July 16, 2008. These registration rights will cease once the initial registrable shares are eligible for sale by the Purchasers without restriction under Rule 144. Upon certain events, the Company has agreed to pay as liquidated damages an amount equal to 1.0% of the aggregate purchase price paid by the Purchasers for any convertible notes then held by the Purchasers, but these payments may not exceed 10% of the aggregate purchase price paid by the Purchasers.

The Company has entered into agreements with the holders of our common stock that require 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, the Company may be subject to liability to pay liquidated damages.

With respect to the subsequent closing of the 2008 private placement, we agreed to file a registration statement with the SEC to register the resale of 17,978,724 shares of common stock issuable pursuant to the 2008 private placement, referred to herein as the subsequent registrable shares, within 30 days of the related closing. Also, we agreed to respond to all SEC comment letters as promptly as reasonably possible and to use our best efforts to have the registration statement declared effective within 90 days of the related closing. However, we were unable to register 9,044,649 of the subsequent registrable shares in accordance with the rules and regulations of the SEC.

Therefore, we have filed the registration statement with the SEC to register the resale of 8,934,075 subsequent registrable shares issuable pursuant to the 2008 private placement. In connection with our reduction of subsequent registrable shares being registered on the registration statement, in January 2009 we had agreed with the purchasers to pay, as liquidated damages, an amount equal to 1.0% of the aggregate purchase price paid by the purchasers for the shares that were not able to register for resale under the registration statement. Such liquidated damages equaled \$12,703 for each 30 day period during which the shares remain unregistered, beginning on February 15, 2009 and ending on the date on which such subsequent registrable shares are registered. However, these payments could not exceed 10% of the aggregate purchase price paid by the purchasers, or \$127,030, which the Company had recorded as a liability. The registration statement for the 8,934,075 shares did not become effective until May 5, 2009.

Consequently, the Company renegotiated the registration penalty with the purchasers due to the delay in registering the 8,934,075 shares. As a result, the Company agreed to pay the purchasers a registration

## Edgar Filing: NOVADEL PHARMA INC - Form S-1

penalty for the full amount of shares (17,978,924) for the period beginning on January 19, 2009 and ending on May 5, 2009. This resulted in an increase in the registration penalty of \$44,770, for a maximum registration penalty of \$171,800. The liquidated damages will be paid in the form of a non-convertible promissory note, which accrues interest at a rate of 10% per annum and all interest and principal will become due and payable upon the earlier to occur of (i) the maturity date, which is twelve months following the date of issuance or (ii) a change of control (as defined in the liquidated damages note). As of December 31, 2009, the Company had issued \$172,000 in non-convertible promissory notes to the purchasers. As part of the Company's December 31, 2009 announcement entering into an amendment agreement with ProQuest to convert the outstanding aggregate principal balance of all convertible notes, the liquidated damages notes were also converted into shares of the Company's common stock as of December 31, 2009.

The Purchasers represented that they are accredited investors and agreed that the securities issued in the 2008 Financing bear a restrictive legend against resale without registration under the Securities Act. The convertible notes and warrants were sold pursuant to the exemption from registration afforded by Section 4(2) of the Securities Act and Regulation D thereunder.

The value of the warrants issued to the investors was calculated relative to the total amount of the debt offering. The relative fair value of the warrants issued to the investors in the Initial Closing was determined to be \$467,000, or 31.7% of the total offering. This was determined using the Black Scholes Model and the following key assumptions were used; a discount rate of 3.41%, volatility of 80.26%, 5 year expected term, and dividend yield of 0%.

The relative fair value of the warrants issued in the Initial Closing (equaling \$467,000), along with the effective beneficial conversion feature of the debt in the Initial Closing of \$743,000 (calculated as the difference between the conversion price specified in the Securities Purchase Agreement and the calculated intrinsic value of the conversion feature) total \$1,210,000 and are not in excess of the face value of the debt. The Company is using the straight-line method to amortize the debt discount and beneficial conversion feature through the maturity dates of the convertible notes, which result does not differ materially from the effective interest rate method. For the year ended December 31, 2009, the Company has recorded additional interest expense of \$403,000, related to the amortization of the debt discount for the Initial Closing.

The balance of the convertible debt as of December 31, 2009 is summarized as follows:	
Face amount	\$ 3,000,000
Total debt discount and beneficial conversion feature	1,900,000
Amortization of debt discount and beneficial conversion feature	1,900,000
Net unamortized debt discount and beneficial conversion feature	-
Debt Conversion	3,000,000
Net debt recorded at December 31, 2009	\$ -

Related to the issuance of the Initial Closing and the Subsequent Closing, the Company paid debt finance costs totaling \$238,000, which were capitalized as deferred financing costs. These costs were amortized into interest expense using the straight-line method, which result does not differ materially from the effective interest rate method. For the year ended December 31, 2009, the Company had recorded expense of approximately \$25,000 related to the amortization of the deferred financing costs. Related to the amended agreement and conversion of the outstanding aggregate principal balance of all convertible notes

## Edgar Filing: NOVADEL PHARMA INC - Form S-1

and all liquidated damages notes, in each case, plus all accrued interest, the Company recorded additional interest expense of approximately \$1,360,000.

Related to the debt conversion agreement with ProQuest of \$3,657,000 to 23,237,083 shares of the Company's common stock, \$0.001 par value per share, the conversion consists of the following:

Initial Closing	\$ 1,475,000
Subsequent Closing	2,525,000
	4,000,000
Total Proceeds	4,000,000
Less principal payment	1,000,000
	3,000,000
Net Amount Outstanding	3,000,000
Liquidated Damages	172,000
Accrued Interest	485,000
	3,657,000
Conversion at December 31, 2009	\$ 3,657,000

In addition to the convertible notes and liquidated damages notes, ProQuest received 9,446,809 warrants with exercise prices of 125% of the related note conversion price. As consideration for converting all of the notes, the Company agreed to set a conversion price of \$0.1574 per share for the notes and to reduce the exercise price of the warrants to \$0.1888 per share, which resulted in an approximate \$170,000 charge to interest expense for the year ended December 31, 2009.

The Company accounted for the conversion of notes in accordance with FASB ASC 470, *Debt with Conversion and Other Options*. Accordingly, the Company recognized a loss equal to the fair value of all securities and other consideration transferred in the transaction in excess of the fair value of the consideration issuable in accordance with the original conversion terms. The fair value of the consideration in accordance with the original terms was approximately \$3,657,000. The Company determined the fair value of the consideration transferred, along with the effective beneficial conversion feature of the debt, was approximately \$1,200,000 greater than the fair value of the notes and related interest on December 31, 2009. Thus, the Company recorded this expense as interest expense on the Company's Statement of Operations for the year ended December 31, 2009.

The Company accounted for this modification in accordance with FASB ASC 718 *Compensation-Stock Compensation*. Accordingly, the Company calculated the total fair value of the original warrants to purchase common stock immediately prior to the modification, as well as, the fair value of the warrants to purchase common stock in accordance with the modification and recorded the incremental fair value as expense in the Company's Statement of Operations for the year ended December 31, 2009. The fair value was determined using the Black-Scholes Model and the following ranges of key assumptions were used:

Discount Rate	1.7%
Volatility	157 - 163%
Expected Term	0.9 - 1.99 years
Dividend Yield	0%

F-14

## Edgar Filing: NOVADEL PHARMA INC - Form S-1

In addition, the Agreement also provides that warrants to purchase 220,726 shares of the Common Stock issued previously to ProQuest in past transactions will be retired and the exercise price of all other warrants held by ProQuest, which consist of warrants to purchase 1,986,536 shares of the Common Stock, will be reduced to \$0.1888 per share. The Company accounted for this modification in accordance with FASB ASC 718 *Compensation-Stock Compensation*. Accordingly, the Company calculated the total fair value of the original warrants to purchase common stock immediately prior to the modification, as well as, the fair value of the warrants to purchase common stock in accordance with the modification and recorded the incremental fair value as expense in the Company's Statement of Operations for the year ended December 31, 2009. The fair value was determined using the Black-Scholes Model and the following ranges of key assumptions were used:

Discount Rate	1.7%
Volatility	134 - 199%
Expected Term	0.9 - 1.99 years
Dividend Yield	0%

As a result of these modifications, the Company recorded approximately an additional \$1.69 million as interest expense on the Company's Statement of Operations for the year ended December 31, 2009. Upon conversion of all of the outstanding notes in accordance with the Agreement, the security interest granted to ProQuest in prior securitizations shall extinguish and be of no further force or effect. As a result of the Agreement, ProQuest's equity ownership in the Company will consist of (i) 29,504,653 shares of the Common Stock and (ii) warrants to purchase 11,433,345 shares of the Common Stock at an exercise price of \$0.1888 per share.

### NOTE 5 ASSETS HELD FOR SALE

As of December 31, 2009, the Company reclassified assets with a net book value of \$299,000, which on December 31, 2008 had been reported as assets held for sale to fixed assets which will be used in the production of its Duromist product line. For the year ended December 31, 2007, the Company owned inventory of \$131,000 related to the production of its NitroMist product line, which inventory was disposed of during the year ended December 31, 2008. During the year ended December 31, 2008, the Company wrote off \$129,000 in inventory and \$183,000 of the net property, plant and equipment, as a result of transferring manufacturing operations for NitroMist from its contract manufacturer in Manati, Puerto Rico, to its new contract manufacturer in Texas. The total amount of the inventory and equipment disposal, inclusive of \$39,000 for the costs of such disposal, was recognized as a loss on disposal of assets held for sale of \$351,000. In addition, the Company invested an additional \$121,000 during the year ended December 31, 2008 for tooling to support product development activities located at the facility of its contract manufacturer for spray valves in England.

### NOTE 6 - PROPERTY AND EQUIPMENT

Property and equipment are summarized as follows:

	December 31, 2009	December 31, 2008
Equipment	\$ 514,000	\$ 2,164,000
Furniture and fixtures		455,000
Leasehold improvements		1,432,000
	514,000	4,051,000
Less: Accumulated depreciation and amortization	190,000	2,604,000
	\$ 324,000	\$ 1,447,000

Property and equipment as of December 31, 2009 has been significantly reduced versus December 31, 2008. The net reduction in fixed assets of \$1,123,000 is the result of assets being disposed of during the

## Edgar Filing: NOVADEL PHARMA INC - Form S-1

fiscal year due to the Company relocating to much smaller office space. Depreciation expense for December 31, 2009, 2008 and 2007 was \$369,000, \$506,000 and \$685,000, respectively.

As of December 31, 2009 and 2008, the Company had total gross fixed assets of \$34,000 and \$513,000, with an accumulated depreciation of \$17,000 and \$93,000, respectively, recorded under a capital lease.

The Company reviews long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. An asset is considered to be impaired when the sum of the undiscounted future net cash flows expected to result from the use of the asset and its eventual disposition is less than its carrying amount. The amount of impairment loss, if any, is measured as the difference between the carrying amount of the asset and its estimated fair value. The Company has reviewed its long-lived property and equipment as of December 31, 2009, and has determined that their estimated fair value exceeds the carrying amount of such assets; therefore, the Company has not recognized an impairment loss for its long-lived property and equipment.

### NOTE 7 - RELATED PARTY TRANSACTIONS

**PRIVATE PLACEMENTS** On May 6, 2008, the Company entered into a binding Securities Purchase Agreement with ProQuest Investments (see Note 8), as amended, to sell up to \$4,000,000 of secured convertible promissory notes and accompanying warrants to ProQuest Investments. On December 31, 2009, the Company announced entering into an amendment agreement with ProQuest Investments L.P. and its affiliates (collectively, ProQuest ) to convert the outstanding aggregate principal balance of all convertible notes and all liquidated damages notes, in each case, plus all accrued interest, in an aggregate amount equal to \$3,657,000 to 23,237,083 shares of the Company's common stock as of December 31, 2009. As such, ProQuest Investments may be deemed to be our affiliate. Mr. Steven B. Ratoff, our President and Chief Executive Officer, has served as a venture partner with ProQuest Investments since December 2004, although he has no authority for investment decisions by ProQuest Investments.

In September 2006, the Company's Board of Directors appointed Steven B. Ratoff as Chairman of the Board. In connection with Mr. Ratoff's appointment as Chairman of the Board, the Board entered into a consulting arrangement to compensate Mr. Ratoff for his efforts. This arrangement is on a month-to-month basis and compensates Mr. Ratoff at a rate of \$17,500 per month. Pursuant to this consulting arrangement, the Company paid Mr. Ratoff approximately \$210,000 for each of the years ended December 31, 2009 and 2008; and approximately \$207,000 for the year ended December 31, 2007. In March 2007, Mr. Ratoff's monthly compensation was reduced to \$10,000 to reflect his decreased day-to-day time involvement at the Company, and in June, 2007, Mr. Ratoff's monthly compensation was increased to \$17,500 per month to reflect his appointment as the Company's Interim President and Chief Executive Officer. In January 2010, the Company's Board of Directors appointed Steven B. Ratoff as President and Chief Executive Officer effective January 1, 2010. Mr. Ratoff will continue to serve as Interim Chief Financial Officer.

In September 2007, in connection with his resignation, Dr. Egberts (the Company's former Chief Executive Officer) and the Company entered into a Separation, Consulting and General Release Agreement (the Agreement ). Pursuant to the Agreement, the Company paid Dr. Egberts approximately \$223,000 and \$140,000 for the years ended December 31, 2008 and 2007, respectively.

### NOTE 8 - STOCKHOLDERS' EQUITY (DEFICIENCY)

On May 6, 2008, the Company entered into a binding Securities Purchase Agreement by and among ProQuest Investments II, L.P., ProQuest Investments II Advisors Fund, L.P., and ProQuest Investments III, L.P., referred to herein as the Purchasers, as amended pursuant to Amendment No. 1 to the Securities Purchase Agreement, dated May 28, 2008, by and among the Company and the Purchasers, to sell up to \$4,000,000 of secured convertible promissory notes, referred to herein as the convertible notes, and accompanying warrants to such Purchasers, referred to herein as the 2008 Financing. On May 30, 2008, the Company closed the initial portion of the transaction, referred to herein as the Initial Closing, for \$1,475,000, representing 5,000,000 shares of the common stock underlying the convertible notes. On October 17, 2008, the Company closed the Subsequent Closing, for gross proceeds of \$2,525,000, representing 10,744,681 shares of the common stock underlying the convertible notes (see Note 4).

On December 31, 2009, the Company announced an amendment agreement with ProQuest Investments L.P. and its affiliates (collectively, ProQuest ) to convert the outstanding aggregate principal balance of

## Edgar Filing: NOVADEL PHARMA INC - Form S-1

all convertible notes and all liquidated damages notes, in each case, plus all accrued interest, in an aggregate amount equal to \$3,657,000 to 23,237,083 shares of the Company's common stock as of December 31, 2009.

On June 26, 2009, the Company entered into a common stock purchase agreement with Seaside 88, LP. As of December 31, 2009, the Company issued 4,500,000 shares of the common stock and received gross proceeds of \$1,055,000.

The Company has entered into registration rights agreements with certain holders of our common stock that require us to continuously maintain an effective registration statement covering the underlying shares of common stock. Such registration statements have been declared effective and must continuously remain effective for a specified term. If we fail to continuously maintain such registration statements as effective throughout the specified terms, the Company may be subject to liability to pay liquidated damages.

**PREFERRED STOCK** - The Company's Certificate of Incorporation authorizes the issuance of up to 1,000,000 shares of Preferred Stock. None of the Preferred Stock has been designated or issued through December 31, 2009. The Board is authorized to issue shares of Preferred Stock from time to time in one or more series and to establish and designate any such series and to fix the number of shares and the relative conversion and voting rights, and terms of redemption and liquidation.

### **NOTE 9 - COMMITMENTS AND CONTINGENCIES**

**EMPLOYMENT AGREEMENTS** - At December 31, 2009, the Company had an employment agreement with one officer of the Company providing for an aggregate salary of \$300,000 in each of the years ending December 31, 2009 and 2010, excluding potential Company matching contributions to the officer's 401(k) plan for 2009. Effective January 1, 2010, the Company matching contributions to the 401(k) plan was discontinued. Effective January 1, 2010, the Company entered into an employment agreement with the newly appointed President and Chief Executive Officer providing an aggregate salary of \$350,000 for the year ending December 31, 2010.

The remaining terms of the officer's employment agreement are outlined below. Generally, in the event an officer is terminated prior to the end of such agreement, the officer is entitled to severance payments equal to the officer's salary for the shorter of twelve months or the remaining term of the officer's employment agreement.

The employment agreements with Dr. Bergstrom expire in December 2010 and Mr. Ratoff's agreement has no defined expiration date.

In September 2007, in connection with his resignation, Dr. Egberts and the Company entered into a Separation, Consulting and General Release Agreement, pursuant to which the Company agreed to pay Dr. Egberts fees for services at a rate of \$363,000 per annum through July 25, 2008. At December 31, 2009, the Company had no further obligations to Dr. Egberts under the Agreement.

All of the foregoing employment agreements provide for the potential issuance of bonuses based on certain factors. Such agreements also provide for the grant of options to purchase shares of the Company's common stock.

**LICENSE AND DEVELOPMENT AGREEMENTS** - In April 2003, the Company entered into a license and development agreement with Manhattan Pharmaceuticals for the worldwide, exclusive rights to the Company's proprietary oral spray technology to deliver propofol for pre-procedural sedation. The terms of the agreement call for certain milestone and other payments, the first \$125,000 of which was partially received during June 2003. In November 2003, the Company received \$375,000 from Manhattan Pharmaceuticals for license fees. The Company has included these license fees in deferred revenue and is recognizing these license fees over the 20-year term of the license.

In June 2004, the Company entered into a 20-year worldwide exclusive license agreement with Velcera, a veterinary company. The license agreement is for the exclusive rights to the Company's proprietary oral spray technology in animals. In September 2004, the Company received \$1,500,000 from Velcera as an upfront payment in connection with the commercialization agreement. The upfront payment has been included in deferred revenue and will be recognized in income over the 20-year term of the agreement. In addition, the Company received an equity stake of 529,500 shares of common stock, approximately 15% at



## Edgar Filing: NOVADEL PHARMA INC - Form S-1

the time the shares were issued, in Velcera which did not have a material value. The Company may receive additional milestone payments and royalty payments over the 20-year term of the agreement. During the year ended December 31, 2007, the Company invoiced Velcera \$125,000 for contractual milestones that were reached.

In July 2004, the Company entered into a licensing agreement with Par for the exclusive right to market, sell and distribute nitroglycerin lingual spray in the U.S. and Canada. The Company has received \$250,000 in upfront and milestone payments and may receive additional fees and royalty payments over the 10-year term of the license. The upfront payment has been included in deferred revenue and will be recognized in income over the 10-year term of the agreement. In July 2007, the Company and Par agreed to terminate the agreement relating to NitroMist .

In October 2004, the Company entered into a license and development agreement pursuant to which the Company granted to Hana Biosciences an exclusive license to develop and market the Company's oral spray version of ondansetron in the U.S. and Canada. Pursuant to the terms of the agreement, in exchange for \$1,000,000, Hana Biosciences purchased 400,000 shares of the Company's common stock at a per share price equal to \$2.50, a premium of \$.91 per share or \$364,000 over the then market value of the Company's common stock. The Company accounted for this premium as deferred revenue related to the license. In connection with the agreement, Hana Biosciences issued to the Company \$500,000 worth of common stock of Hana Biosciences (73,121 shares based on a market value of \$6.84 per share). The proceeds received from Hana Biosciences attributable to the premium are included in deferred revenue and are being recognized over the 20-year term of the agreement. The Company may receive additional license fees and royalties over the 20-year term of the agreement.

In July 2007, the Company entered into a 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, the Company and Hana Biosciences amended and restated their existing license agreement, as amended, relating to the development and commercialization of Zensana 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. The Company retains its 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 the Company until such time as Hana Biosciences had recovered one-half of its costs and expenses incurred in developing Zensana from sales of Zensana and the Company agreed to surrender for cancellation all 73,121 shares of the Hana Biosciences common stock acquired by the Company in connection with execution of the original License Agreement.

On May 19, 2008, the Company and BioAlliance Pharma SA or BioAlliance, entered into an agreement where BioAlliance acquired the European rights for NovaDel's Ondansetron oral spray. Under the terms of the agreement, BioAlliance paid NovaDel a license fee of \$3,000,000 upon closing. The Company is 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 the Company anticipate collaborating in the completion of development activities for Europe, with BioAlliance responsible for regulatory and pricing approvals and then commercialization throughout Europe. The Company 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).

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

Under the terms of the agreement, ECR paid the Company \$3 million 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.

## Edgar Filing: NOVADEL PHARMA INC - Form S-1

On October 27, 2009, the Company and privately-held Mist 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. Under terms of the agreement, Mist paid the Company a \$1,000,000 licensing fee upon execution of the agreement, and will pay milestone payments totaling an additional \$1,000,000 over twelve months, and ongoing performance payments of seventeen percent (17%) of net sales.

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.

**CAPITAL LEASE OBLIGATIONS** As of December 31, 2009, the Company has aggregate capital lease obligations of \$14,000, of which \$10,000 and \$4,000 are scheduled to be paid in the years ending December 31, 2010 and 2011, respectively.

**OPERATING LEASES** - In March 2003, the Company entered into a 10-year lease for office, laboratory, manufacturing and warehouse space. During the first five years of the lease, the annual rent was approximately \$332,000 plus a proportionate share of real estate taxes and common area charges. Beginning in the sixth year and continuing through the tenth year of the lease, the annual rent was approximately \$366,000 plus a proportionate share of real estate taxes and common areas. Effective July 1, 2009, the Company executed a lease amendment modifying certain terms to the existing lease. The amendment converts the lease term to month to month with a provision to terminate upon thirty days written notice. During the years ended December 31, 2009, 2008, and 2007, the Company paid rent of approximately \$257,000, \$453,000, and \$443,000, respectively.

In January 2010, the Company terminated the March 2003 lease effective January 31, 2010 and relocated its corporate office to Bridgewater, NJ upon signing a one-year lease effective February 1, 2010.

Future minimum rental payments subsequent to December 31, 2009 are as follows:

<b>Years Ending December 31,</b>	
2010	\$ 39,000
2011	3,500
	<hr/>
	\$ 42,500
	<hr/>

### **NOTE 10 OTHER, NET**

For the year ended December 31, 2007, the Company recorded a charge of \$500,000 to account for the return of stock of Hana Biosciences shares. This amount was offset by \$434,000 benefit recognized to write off the remaining deferred revenue related to the shares received from Hana Biosciences resulting in a net \$66,000 expense for Other, net.

For the year ended December 31, 2009 the Company recorded income relating to the reversal of the warrant liability initially recorded upon the Company's adoption of ASC 815-40-15 in the amount of \$360,000. This amount was offset with a loss on disposition of fixed assets in the amount of \$745,000 resulting in a net \$385,000 expense for Other, net.

**NOTE 11 ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES**

Accrued expenses and other current liabilities are comprised of the following at December 31, 2009 and 2008:

	<b>December 31, 2009</b>	<b>December 31, 2008</b>
Professional fees	\$ 31,000	\$ 60,000
Accrued compensation		40,000
Accrued interest expense		126,000
Non-registration penalty		127,000
Product development costs		437,000
Insurance premiums	84,000	129,000
Other	2,000	5,000
	<b>\$ 117,000</b>	<b>\$ 924,000</b>

**NOTE 12 - INCOME TAXES**

The significant components of the Company's net deferred tax assets are summarized as follows:

	<b>December 31, 2009</b>	<b>December 31, 2008</b>
Stock-based compensation	\$ 374,000	\$ 272,000
Net operating loss ( NOL ) carryforwards	23,035,000	22,542,000
Deferred revenue	3,387,000	1,894,000
Property and equipment	(27,000)	(166,000)
Research and development credit	1,568,000	1,350,000
Capital loss carryforwards	200,000	200,000
Accrued expenses and other reserves		216,000
	<b>28,537,000</b>	<b>26,308,000</b>
Total gross deferred tax assets	28,537,000	26,308,000
Valuation allowance	(28,537,000)	(26,308,000)
	<b>\$</b>	<b>\$</b>
Net deferred tax assets	<b>\$</b>	<b>\$</b>

At December 31, 2009, the Company had Federal and state net operating loss carryforwards for financial reporting and income tax purposes of approximately \$ 64.7 million and \$16.4 million, respectively, which can be used to offset current and future Federal and state taxable income, if any, through 2029 and 2016, respectively. In addition, the Company has federal and state research and development tax credits of \$ 1.0 million and \$0.5 million, respectively, which will expire beginning 2020 and 2013, respectively. A valuation allowance is provided when it is more likely than not that some portion or all of the deferred tax assets will not be realized. The Company has provided valuation allowances to offset its deferred tax assets due to the significant uncertainties related to its ability to generate future taxable income. The net increases in the total valuation allowance for the years ended December 31, 2009 and 2008 were \$2.2 million and \$1.9 million, respectively.

The tax benefits recognized in the years ended December 31, 2009, 2008 and 2007 of \$1,057,000, \$735,000 and \$658,000, respectively, relate solely to the sale of certain of the Company's state net operating loss carryforwards.

## Edgar Filing: NOVADEL PHARMA INC - Form S-1

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

	Years Ended		
	December 31, 2009	December 31, 2008	December 31, 2007
Federal tax at statutory rate	(34.0%)	(34.0%)	(34.0%)
State income tax	3.4%	(6.0%)	(6.0%)
Other	(1.2%)	2.0%	0.2%
Sale of net operating losses	(8.1%)	(7.1%)	(3.7%)
Amortization of convertible debt discount	1.6%	5.4%	
Cancelled stock option		5.7%	
Expired Federal NOL	0.3%	1.1%	
Increase in valuation allowance	25.8%	25.8%	39.8%
	(12.2%)	(7.1%)	(3.7%)
<b>Totals</b>	<b>(12.2%)</b>	<b>(7.1%)</b>	<b>(3.7%)</b>

The Tax Reform Act of 1986 (the "Act") provides for a limitation on the annual use of NOL carryforwards (following certain ownership changes, as defined by the Act), which could significantly limit the Company's ability to utilize these carryforwards. The Company has experienced various ownership changes, as defined by the Act, as a result of past financings and may experience others in connection with future financings. Accordingly, the Company's ability to utilize the aforementioned Federal operating loss carryforwards will be limited. The Company is in the process of determining the impact of ownership changes that have occurred, as defined by the Act. Additionally, because U.S. tax laws limit the time during which these carryforwards may be applied against future taxes, the Company may not be able to take full advantage of these attributes for Federal income tax purposes.

**SALE OF NET OPERATING LOSS CARRYFORWARDS:** The State of New Jersey has enacted legislation permitting certain corporations located in New Jersey to sell state tax loss carryforwards and state research and development credits, or net operating loss carryforwards, in order to obtain tax benefits. The Company recorded an income tax benefit of \$1,057,000, \$732,000, and \$658,000 for the years ended December 31, 2009, 2008 and 2007, respectively, from the sale of its New Jersey net operating loss carryforwards. If still available under New Jersey law, the Company may attempt to sell its remaining New Jersey net operating loss carryforwards of \$16.4 million as of December 31, 2009. The Company cannot estimate, however, what percentage of its saleable net operating loss carryforwards New Jersey will permit it to sell, how much money will be received in connection with the sale, if the Company will be able to find a buyer for its net operating loss carryforwards or if such funds will be available in a timely manner or at all.

## Edgar Filing: NOVADEL PHARMA INC - Form S-1

The Company files income tax returns in the U.S. Federal jurisdiction and in the State of New Jersey. With certain exceptions, the Company is no longer subject to U.S. Federal and state income tax examinations by tax authorities for years prior to 2004. However, NOL and tax credits generated from those prior years could still be adjusted upon audit. The Company adopted ASC 740-10 (Formerly FIN 48) Accounting for Uncertainty in Income Taxes an interpretation of ASC 740 (Formerly FASB statement No. 109) on January 1, 2007 with no material impact to the financial statements.

The Company had no unrecognized tax benefits at December 31, 2009 that would affect the annual effective tax rate. Further, the Company is unaware of any positions for which it is reasonably possible that the total amounts of unrecognized tax benefits will significantly increase or decrease within the next twelve months.

### **NOTE 13 - STOCK OPTIONS AND WARRANTS**

At December 31, 2009, the Company had two plans which allow for the issuance of stock options and other awards: the 1998 Stock Option Plan and the 2006 Equity Incentive Plan (the Plans ). On January 17, 2006, the stockholders of the Company, upon recommendation of the Board of Directors of the Company, approved the NovaDel Pharma Inc. 2006 Equity Incentive Plan (the 2006 Plan ). The 2006 Plan authorizes the grant of several types of stock-based awards, including stock options, stock appreciation rights and stock (including restricted stock). The number of shares of common stock originally reserved for issuance under the 2006 Plan was 6 million shares. These Plans are administered by the Compensation Committee of the Board of Directors. Incentive Stock Options ( ISOs ) may be granted to employees and officers of the Company and non-qualified options may be granted to consultants, directors, employees and officers of the Company. Options to purchase the Company s common stock may not be granted at a price less than the fair market value of the common stock at the date of grant and will expire not more than 10 years from the date of grant, and vesting is determined by the Compensation Committee of the Board of Directors. ISOs granted to a 10% or more stockholder may not be for less than 110% of fair market value or for a term of more than five years. As of December 31, 2009, there were approximately 0.9 million shares available for issuance under the Plans (see Note 14).

The Company selected the Black-Scholes method of valuation for share-based compensation effective August 1, 2005. Compensation costs are recorded as earned for all unvested stock options outstanding at the beginning of the first quarter of 2005 and for all options granted after the date of adoption. The charge is being recognized in research and development and consulting, selling, general and administrative expenses over the remaining service period after the adoption date based on the original estimate of fair value of the options as of the grant date.

Edgar Filing: NOVADEL PHARMA INC - Form S-1

Information with respect to stock option activity for the years ended December 31, 2009, 2008 and 2007 is as follows:

Options	Shares (000)	Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Terms (Years)	Aggregate Intrinsic Value (\$000)
Outstanding at January 1, 2007	8,775	\$ 1.68		
Grants	3,239	1.67		
Exercises	(268)	.75		
Forfeitures/Cancellations	(3,317)	1.72		
Outstanding at December 31, 2007	8,429	\$ 1.69	5.9	\$
Exercisable at December 31, 2007	5,549	\$ 1.75	5.0	\$
Outstanding at January 1, 2008	8,429	1.69		
Grants	338	.24		
Exercises				
Forfeitures/Cancellations	(3,300)	1.72		
Outstanding at December 31, 2008	5,467	\$ 1.59	5.4	\$
Vested and expected to vest at December 31, 2008	5,349	\$ 1.59	5.4	
Exercisable at December 31, 2008	3,102	\$ 1.74	4.2	\$
Outstanding at January 1, 2009	5,467	1.59		
Grants	5,103	.25		
Exercises				
Forfeitures/Cancellations	(2,291)	1.41		
Outstanding at December 31, 2009	8,279	\$ 0.81	4.1	
Vested and expected to vest at December 31, 2009	8,073	\$ 0.82	4.1	
Exercisable at December 31, 2009	4,148	\$ 1.16	3.2	\$

The Company recorded share-based compensation for options using the fair value method of approximately \$326,000 for the year ended December 31, 2009, \$771,000 for the year ended December 31, 2008,



## Edgar Filing: NOVADEL PHARMA INC - Form S-1

\$910,000 for the year ended December 31, 2007, which amounts are included in the Company's net loss for each period.

On February 6, 2008, the Company's Board of Directors, upon the recommendation of the Compensation Committee, approved grants of 750,000 shares of restricted common stock to the executive officers of the Company and an additional 350,000 shares of restricted common stock to other employees of the Company. The restricted stock was awarded from the 1998 Stock Option Plan. The restrictions on the restricted stock shall lapse over a three-year period, subject to reduction as follows: (1) in the event of a \$5 million non-dilutive financing by the Company on or before December 31, 2008, the three-year restriction shall be accelerated such that the restrictions on the restricted stock shall lapse over a two-and-one-half year period; (2) in the event of an additional \$5 million (or \$10 million in the aggregate) non-dilutive financing by the Company on or before December 31, 2008, the three-year restriction shall be accelerated such that the restrictions on the restricted stock shall lapse over a two-year period; and (3) in the event of a \$20 million (or \$20 million in the aggregate) non-dilutive financing by the Company, the restrictions shall immediately lapse. Additionally, the Board, upon the recommendation of the Compensation Committee, agreed that, in the case of the Company's Chief Executive Officer, an additional 200,000 shares of restricted stock shall be granted as follows: (1) upon achieving a \$5 million non-dilutive financing by the Company on or before December 31, 2008, an additional 100,000 shares of restricted stock shall be granted; and (2) upon achieving an additional \$5 million (or \$10 million in the aggregate) in non-dilutive financing by the Company on or before December 31, 2008, an additional 100,000 shares of restricted stock shall be granted. The restrictions on such additional shares shall lapse over a three-year period. The events triggering the aforementioned issuance of restricted common stock did not occur on or before December 31, 2008.

During the year ended December 31, 2009, the Company additionally granted 5,102,500 additional stock options. The exercise price of such options ranged from \$0.17 per share to \$0.34 per share.

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

	<b>Year Ended</b>		
	<b>2009</b>	<b>2008</b>	<b>2007</b>
Expected volatility	85%	83%	63%
Dividend yield	0%	0%	0%
Expected term until exercise (years)	2.6	3.7	4.9
Risk-free interest rate	1.8%	2.3%	4.8%

Expected volatility is based on historical volatility of the Company's common stock. The expected term of options is estimated based on the average of the vesting period and contractual term of the option. The risk-free rate is based on U.S. Treasury yields for securities in effect at the time of grant with terms approximating the expected term until exercise of the option. In addition, the fair value of stock options granted is recognized as expense over the service period, net of estimated forfeitures. The Company is utilizing a 5% forfeiture rate, which it believes is a reasonable assumption to estimate forfeitures. However, the estimation of forfeitures requires significant judgment, and to the extent actual results or updated estimates differ from our current estimates, the effects of such resulting adjustment will be recorded in the period estimates are revised. The weighted average grant date fair value of options granted was \$0.25, \$0.15, and \$0.93 during the years ended December 31, 2009, 2008 and 2007. The total intrinsic value of options exercised was \$0, \$172,000 and \$398,000 during the years ended December 31, 2009, 2008 and 2007, respectively. There were no options exercised during the year ended December 31, 2009.

At December 31, 2009, there were approximately 581,000 non-plan options reserved for issuance.



## Edgar Filing: NOVADEL PHARMA INC - Form S-1

A summary of the status of the Company's non-vested restricted common stock as of December 31, 2009 and changes during the twelve months ended December 31, 2009 is presented below:

Non-Vested Restricted Common Stock	Shares (000)	Weighted Average Grant- Date Fair Value
January 1, 2009	1,133	\$ 0.51
Vested	(33)	\$ 1.71
Forfeited	(575)	\$ 0.47
Granted		
December 31, 2009	525	\$ 0.47

The following table summarizes information related to warrants outstanding at December 31, 2009:

Price Range	Number of Warrants Outstanding and Exercisable 000 s	Remaining Contractual Life (Years)
0.01		
\$ 0.99 1.00	11,854	3.1
\$ 1.99	7,966	1.5
Total	19,820	

### NOTE 14 SUBSEQUENT EVENTS

#### Seaside Closings

Under the common stock purchase agreement with Seaside 88, LP, the Company has received \$200,140 in gross proceeds for the closings that have occurred after December 31, 2009 through March 31, 2010. On March 26, 2010, the Company and Seaside 88, LP mutually agreed to terminate the common stock purchase agreement which was entered into in 2009.

On March 31, 2010, the Company announced it will receive approximately \$1.5 million in gross proceeds in a registered direct offering (the Offering) of 9,100,001 shares of common stock, par value \$0.001 per share (the Common Shares), at a price of \$0.165 per share. The investors received five-year warrants (the Series A Warrants) to purchase 4,550,001 shares of common stock with an exercise price of \$0.25 per share and six-month warrants (the Series B Warrants, together with the Common Shares and the Series A Warrants, the Securities) to purchase 3,033,334 shares of common stock at an exercise price of \$0.25 per share. As of March 31, 2010, the Company recorded net proceeds of \$551,000 and a note receivable of \$800,000 which was subsequently received on April 15, 2010, relating to 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 the Company sold the Common Shares pursuant to an effective registration statement.

Edgar Filing: NOVADEL PHARMA INC - Form S-1

**NOTE 15 QUARTERLY RESULTS OF OPERATIONS (UNAUDITED)**

Unaudited quarterly financial data for the years ended December 31, 2009, 2008 and 2007 as follows:

	Three Months Ended				Year Ended
	March 31, 2009	June 30, 2009	September 30, 2009	December 31, 2009	December 31, 2009
Total Revenues	\$ 66,000	\$ 67,000	\$ 223,000	\$ 66,000	\$ 422,000
Total Expenses	2,084,000	1,560,000	1,503,000	1,370,000	6,517,000
Loss from Operations	(2,018,000)	(1,493,000)	(1,280,000)	(1,304,000)	(6,095,000)
Other, net	360,000	(59,000)		(686,000)	(385,000)
Interest Expense	486,000	150,000	81,000	1,443,000	2,160,000
Interest Income	5,000	1,000			6,000
Income Tax Benefit				1,057,000	1,057,000
<b>Net Loss</b>	<b>\$ (2,139,000)</b>	<b>\$ (1,701,000)</b>	<b>\$ (1,361,000)</b>	<b>\$ (2,376,000)</b>	<b>\$ (7,577,000)</b>
Basic and Diluted Loss Per Common Share	\$ (0.04)	\$ (0.03)	\$ (0.02)	\$ (0.04)	\$ (0.12)
Weighted Average Number of Shares of Common Stock Used in Computation of Basic and Diluted Loss Per Common Share	59,892,000	60,081,000	61,386,000	65,282,000	61,346,000
	Three Months Ended				Year Ended
	March 31, 2008	June 30, 2008	September 30, 2008	December 31, 2008	December 31, 2008
Total Revenues	\$ 103,000	\$ 51,000	\$ 104,000	\$ 103,000	\$ 361,000
Total Expenses	2,110,000	2,987,000	1,878,000	1,976,000	8,951,000
Loss from Operations	(2,007,000)	(2,936,000)	(1,774,000)	(1,873,000)	(8,590,000)
Interest Expense		294,000	750,000	824,000	1,868,000
Interest Income	35,000	28,000	21,000	53,000	137,000
Income Tax Benefit				735,000	735,000
<b>Net Loss</b>	<b>\$ (1,972,000)</b>	<b>\$ (3,202,000)</b>	<b>\$ (2,503,000)</b>	<b>\$ (1,909,000)</b>	<b>\$ (9,586,000)</b>
Basic and Diluted Loss Per Common Share	\$ (0.03)	\$ (0.05)	\$ (0.04)	\$ (0.03)	\$ (0.16)
Weighted Average Number of Shares of Common Stock Used in Computation of Basic and Diluted Loss Per Common Share	59,592,000	59,592,000	59,592,000	59,592,000	59,592,000

	Three Months Ended				Year Ended
	March 31, 2007	June 30, 2007	September 30, 2007	December 31, 2007	December 31, 2007
Total Revenues	\$ 40,000	\$ 165,000	\$ 206,000	\$ 58,000	\$ 469,000
Total Expenses	5,334,000	5,676,000	3,037,000	4,609,000	18,656,000
Loss from Operations	(5,294,000)	(5,511,000)	(2,831,000)	(4,551,000)	(18,187,000)
Other Income/(Loss)	(360,000)		294,000	(66,000)	
Interest Income	230,000	187,000	127,000	88,000	632,000
Income Tax Benefit				658,000	658,000
<b>Net Loss</b>	<b>\$ (5,424,000)</b>	<b>\$ (5,324,000)</b>	<b>\$ (2,410,000)</b>	<b>\$ (3,805,000)</b>	<b>\$ (16,963,000)</b>
Basic and Diluted Loss Per Common Share	\$ (0.09)	\$ (0.09)	\$ (0.04)	\$ (0.06)	\$ (0.29)
Weighted Average Number of Shares of Common Stock Used in Computation of Basic and Diluted Loss Per Common Share	59,264,000	59,537,000	59,591,000	59,592,000	59,497,000
The sum of the quarters may not equal the full year basic and diluted loss per share since each period is calculated separately.					

**NovaDel Pharma Inc.**

**INDEX TO UNAUDITED JUNE 30, 2010 FINANCIAL STATEMENTS**

<u>Balance Sheets</u>	F-29
<u>Statements of Operations</u>	F-30
<u>Statements of Changes in Stockholders Deficiency</u>	F-31
<u>Statements of Cash Flows</u>	F-32
<u>Notes to Financial Statements</u>	F-33
	F-28

---

**NOVADEL PHARMA INC.**  
**CONDENSED BALANCE SHEETS**  
**AS OF JUNE 30, 2010 (UNAUDITED) AND DECEMBER 31, 2009**

	<b>June 30, 2010</b>	<b>December 31, 2009</b>
	<u>(unaudited)</u>	<u>(Note 1)</u>
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 3,117,000	\$ 2,663,000
Prepaid expenses and other current assets	252,000	1,430,000
	<u>3,369,000</u>	<u>4,093,000</u>
Total Current Assets	3,369,000	4,093,000
Property and equipment, net	272,000	324,000
Other assets	7,000	36,000
	<u>279,000</u>	<u>360,000</u>
Total Assets	<u>\$ 3,648,000</u>	<u>\$ 4,453,000</u>
<b>LIABILITIES AND STOCKHOLDERS DEFICIENCY</b>		
Current Liabilities:		
Accounts payable	\$ 329,000	\$ 195,000
Accrued expenses and other current liabilities	87,000	117,000
Derivative liability	732,000	
Current portion of deferred revenue	4,266,000	4,266,000
Current portion of capital lease obligations		10,000
	<u>5,414,000</u>	<u>4,588,000</u>
Total Current Liabilities	5,414,000	4,588,000
Non-current portion of deferred revenue	4,069,000	4,202,000
Non-current portion of capital lease obligations		4,000
	<u>4,069,000</u>	<u>4,206,000</u>
Total Liabilities	<u>9,483,000</u>	<u>8,794,000</u>
Commitments and contingencies		
<b>STOCKHOLDERS DEFICIENCY</b>		
Preferred stock, \$.001 par value:		
Authorized 1,000,000 shares, none issued		
Common stock, \$.001 par value:		
Authorized 200,000,000 shares, Issued 98,383,458 and 88,343,457 shares at June 30, 2010 and December 31, 2009, respectively	99,000	89,000
Additional paid-in capital	79,256,000	78,342,000
Accumulated deficit	(85,184,000)	(82,766,000)
Less: treasury stock, at cost, 3,012 shares	(6,000)	(6,000)
	<u>(5,835,000)</u>	<u>(4,341,000)</u>
Total Stockholders Deficiency	(5,835,000)	(4,341,000)
Total Liabilities and Stockholders Deficiency	<u>\$ 3,648,000</u>	<u>\$ 4,453,000</u>

See accompanying notes to condensed financial statements.



**NOVADEL PHARMA INC.**  
**CONDENSED STATEMENTS OF OPERATIONS**  
**FOR THE THREE AND SIX MONTHS ENDED**  
**JUNE 30, 2010 AND JUNE 30, 2009**  
**(UNAUDITED)**

	<b>Three Months Ended June 30,</b>		<b>Six Months Ended June 30,</b>	
	<b>2010</b>	<b>2009</b>	<b>2010</b>	<b>2009</b>
License fees and milestone fees earned	\$ 66,000	\$ 67,000	\$ 195,000	\$ 133,000
Research and development expenses	559,000	624,000	1,006,000	1,450,000
General and administrative expenses	813,000	936,000	1,787,000	2,194,000
Total expenses	1,372,000	1,560,000	2,793,000	3,644,000
Loss from operations	(1,306,000)	(1,493,000)	(2,598,000)	(3,511,000)
Other income / (expense):				
Derivative liability valuation adjustment	181,000		181,000	360,000
Loss on sale of fixed assets		(59,000)		(59,000)
Interest expense	(1,000)	(150,000)	(1,000)	(636,000)
Interest income		1,000		6,000
Net loss	\$ (1,126,000)	\$ (1,701,000)	\$ (2,418,000)	\$ (3,840,000)
Basic and diluted loss per common share	\$ (0.01)	\$ (0.03)	\$ (0.03)	\$ (0.06)
Weighted average common shares outstanding basic and diluted	97,918,458	60,081,374	93,194,701	