

NOVADEL PHARMA INC  
 Form 424B4  
 February 15, 2011

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 Registration Statement No. 333-170066**

**PROSPECTUS**

**1,667 SHARES OF SERIES A CONVERTIBLE PREFERRED STOCK,  
 TOGETHER WITH SERIES A WARRANTS TO PURCHASE 16,670,000 SHARES OF  
 COMMON STOCK, SERIES B WARRANTS TO PURCHASE 16,670,000 SHARES OF  
 COMMON STOCK, SERIES C WARRANTS TO PURCHASE 16,670,000 SHARES OF  
 COMMON STOCK AND UP TO 40,000,000 SHARES OF COMMON STOCK UNDERLYING THE  
 CONVERTIBLE PREFERRED STOCK AND THE SERIES B WARRANTS**

We are offering 1,667 shares of our Series A Convertible Preferred Stock, convertible into our common stock, par value \$0.001 per share, together with Series A Warrants to purchase 16,670,000 shares of our common stock, Series B Warrants to purchase 16,670,000 shares of our common stock, Series C Warrants to purchase 16,670,000 shares of our common stock and up to 40,000,000 shares of common stock underlying the Series A Convertible Preferred Stock and the Series B Warrants to purchasers in this offering. The Series A Warrants, the Series B Warrants and the Series C Warrants are referred to herein as the warrants. The maximum number of shares of common stock underlying the convertible preferred stock and the warrants issued in this offering is up to 73,340,000; provided, however, we are not registering the 33,340,000 shares issuable upon exercise of the Series A and Series C Warrants. Each share of convertible preferred stock we sell will be accompanied by a Series A Warrant to purchase one (1) share of common stock for each share of common stock issuable upon conversion of the preferred stock, a Series B Warrant to purchase one (1) share of common stock for each share of common stock issuable upon conversion of the preferred stock, and a Series C Warrant to purchase one (1) share of common stock for each share of common stock issuable upon exercise of the Series B Warrants; provided that the Series C Warrants may only be exercised in the same proportion as the holder has exercised the Series B Warrants. The convertible preferred stock is convertible at any time at the option of the holder into shares of our common stock at a conversion ratio determined by dividing the stated value of the convertible preferred stock by a conversion price of \$0.10 per share. The Series B Warrants will be exercisable immediately and on or before the first year anniversary of their initial exercise date at an exercise price of \$0.10 per share of common stock. The Series A and Series C Warrants will be exercisable on or after the one year and one day anniversary following the issuance date and will be exercisable on or before the fifth year anniversary of their initial exercise date at an exercise price of \$0.15 per share of common stock. Each share of convertible preferred stock and the warrants will be sold at a price of \$1,000. The convertible preferred stock and warrants are immediately separable and will be issued separately.

Our common stock is presently quoted on the Over-the-Counter Bulletin Board under the symbol NVDL.OB We do not intend to apply for listing of the convertible preferred stock and warrants on any securities exchange or market. On February 10, 2011, the last reported sale price of our common stock as reported by the Over-the-Counter Bulletin Board was \$0.20 per share.

**INVESTING IN THE OFFERED SECURITIES INVOLVES RISKS, INCLUDING THOSE SET FORTH IN THE RISK FACTORS SECTION OF THIS PROSPECTUS BEGINNING ON PAGE 7.**

	<b>Per Share</b>	<b>Total</b>
Offering Price per Share	\$ 1,000	\$ 1,600,000

Placement Agent's Fees	\$ 60	\$ 96,000
Offering Proceeds before expenses	\$ 940	\$ 1,504,000

Roth Capital Partners has agreed to act as our exclusive placement agent in connection with this offering. The placement agent is not purchasing the securities offered by us, and is not required to sell any specific number or dollar amount of securities, 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 6% of the gross proceeds of the offering of securities by us, as well as "Placement Agent Warrants" to purchase shares of Common Stock of the Company equal to 2% of the aggregate number of shares of Common Stock issuable in the offering. The Placement Agent Warrants will be substantially on the same terms as the Series A Warrants offered hereby. We estimate the total expenses of this offering, excluding the placement agent fees, will be approximately \$100,000. 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 84 of this prospectus for more information on this offering and the placement agent arrangements. All costs associated with the registration will be borne by us.

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.**

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

Roth Capital Partners

The date of this prospectus is February 14, 2011.

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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
Zolpimist™	Zolpidem	Insomnia	FDA Approved	ECR Pharmaceuticals
<b>Product Candidates</b>				
Duromist™	Sildenafil	Erectile Dysfunction	Clinical development	
Zensana™	Ondansetron	Nausea/Vomiting	Clinical development	Hana Biosciences Par Pharmaceutical BioAlliance Pharma
NVD-201	Sumatriptan	Migraine headache	Clinical development	
NVD-301	Midazolam	Pre-Procedure Anxiety	Preclinical development	

**NitroMist®**

NitroMist, our oral spray formulation of nitroglycerin, has been approved by the 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 license and distribution agreement with Mist Acquisition, LLC, or Mist, to manufacture and commercialize NitroMist in North America. Mist is a subsidiary of Akrimax Pharmaceuticals, LLC. Under the terms of the agreement, we received an upfront payment of \$1,000,000, a milestone payment of \$500,000 in October 2010 and a milestone payment of \$500,000 in January 2011. We are also eligible to receive royalty payments of up to 17% of net sales. Mist began marketing NitroMist in the United States in January 2011.

**Zolpimist™**

Zolpimist, our oral spray formulation of zolpidem, has been approved by the FDA for short-term treatment of insomnia. Zolpidem is the active ingredient in Ambien®, a leading prescription medication for the treatment of insomnia, marketed by Sanofi-Aventis. In November 2009, we entered into an exclusive license and distribution agreement with ECR Pharmaceuticals Company, Inc., or ECR, to manufacture and commercialize Zolpimist in the

U.S. and Canada. ECR is a subsidiary of Hi-Tech Pharmacal Co., Inc. Under the terms of the agreement, we received an upfront payment of \$3,000,000. We are also eligible to receive royalty payments of up to 15% of net sales on branded products. ECR is expected to begin marketing Zolpimist in January 2011.

*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 September 30, 2010 we have cash and cash equivalents of \$1.4 million, negative working capital of \$3.3 million, and accumulated deficit of \$86.5 million. Based on our operating plan, we expect that our existing cash and cash equivalents will fund our operations only through March 31, 2011.

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

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

*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: 1,667 shares of our convertible preferred stock together with Series A Warrants to purchase 16,670,000 shares of our common stock, Series B Warrants to purchase 16,670,000 shares of our common stock and Series C Warrants to purchase 16,670,000 shares of our common stock and up to 40,000,000 shares of common stock underlying the convertible preferred stock and the Series B Warrants.

The maximum number of shares of common stock underlying the convertible preferred stock and the warrants issued in this offering is up to 73,340,000; provided, however, we are not registering the 33,340,000 shares issuable upon exercise of the Series A and Series C Warrants as described further under Description of the Securities Description of Warrants.

Each share of convertible preferred stock we sell will be accompanied by a Series A Warrant to purchase one (1) share of common stock for each share of common stock issuable upon conversion of the preferred stock, a Series B Warrant to purchase one (1) share of common stock for each share of common stock issuable upon conversion of the preferred stock, and a Series C Warrant to purchase one (1) share of common stock for each share of common stock issuable upon exercise of the Series B Warrants; provided that the Series C Warrants may only be exercised in the same proportion as the holder has exercised the Series B Warrants.

Convertible Preferred Stock The convertible preferred stock is convertible at any time at the option of the holder into shares of our common stock at a conversion ratio determined by dividing the stated value of the convertible preferred stock by a conversion price of \$0.10 per share.

The convertible preferred stock is subject to automatic conversion, subject to the satisfaction of certain customary equity conditions, in four equal monthly installments commencing with March 17, 2011, into shares of our common stock, as further described in Description of the Securities Description of Preferred Stock. We may elect, at our option but subject to the satisfaction of certain conditions, to redeem the shares of convertible preferred stock in lieu of an automatic conversion occurring.

Series B Warrants      The Series B Warrants will be exercisable immediately and on or before the first year anniversary of their initial exercise date at an exercise price of \$0.10 per share of common stock. The exercise price is subject to adjustments as described in this prospectus.

Series A and Series C Warrants      The Series A and Series C Warrants will be exercisable on or after the one year and one day anniversary following the issuance date and will be exercisable on or before the fifth year anniversary of their initial exercise date at an exercise price of \$0.15 per share of common stock; provided that the Series C Warrants may only be exercised by the holders in the same proportion as the holders have already exercised their Series B Warrants. The exercise price is subject to adjustments as described in this prospectus.

We do not have a sufficient number of authorized shares to permit full exercise of the Series A and Series C Warrants. Thus, we may be unable to issue shares upon exercise thereof unless we obtain stockholder approval to effect an amendment to our certificate of incorporation to increase our authorized shares to an amount sufficient to permit full exercise of the Series A and Series C Warrants. See Description of the Securities Stockholder Approval; Other Covenants.

Common stock outstanding prior to the offering:      98,383,458 shares.

Common stock outstanding after the offering:      115,053,458 shares, assuming all of the convertible preferred stock are sold and are fully converted into shares of common stock.

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, subject to the limitations set forth in the Use of Proceeds section.

OTCBB Symbol:      NVDL.OB

Risk Factors:      See Risk Factors beginning on page 7 and the other information in this prospectus for a discussion of the factors you should consider before you decide to invest in the securities.

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

50,010,000  
shares of  
common  
stock  
issuable  
upon  
exercise of  
the warrants  
offered  
hereby;

333,400  
shares of  
common  
stock  
issuable  
upon  
exercise of

warrants  
issued to the  
placement  
agent in  
connection  
with this  
offering;

8,659,243  
shares of  
common  
stock  
issuable  
upon  
exercise of  
stock  
options  
outstanding  
as of  
September  
30, 2010  
under our  
stock option  
plans at a  
weighted  
average  
exercise  
price of  
\$0.73 per  
share;

24,170,004  
additional  
shares of  
common  
stock  
reserved for  
issuance  
under  
various  
outstanding  
warrant  
agreements  
as of  
September  
30, 2010, at  
a weighted  
average  
exercise  
price of  
\$0.67 per

share; and

10,651,257  
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.

	Nine months ended September 30,		Year ended December 31,		
	2010	2009	2009	2008	2007
	(unaudited)				
<b>Consolidated Statements of Operations Data</b>					
Total Revenues	\$ 261,000	\$ 356,000	\$ 422,000	\$ 361,000	\$ 469,000
Total Expenses	4,382,000	5,147,000	6,517,000	8,951,000	18,650,000
Loss from Operations	(4,121,000 )	(4,791,000 )	(6,095,000 )	(8,590,000 )	(18,180,000 )
Other Income (Expense), net	391,000	301,000	(385,000 )		(60,000 )
Interest Expense	1,000	717,000	2,160,000	1,868,000	
Interest Income	1,000	6,000	6,000	137,000	632,000
Income Tax Benefit			(1,057,000 )	(735,000 )	(650,000 )
Net Loss	\$ (3,730,000 )	\$ (5,201,000 )	\$ (7,577,000 )	\$ (9,586,000 )	\$ (16,960,000 )
Basic and Diluted Loss Per Common Share	\$ (0.04 )	\$ (0.09 )	\$ (0.12 )	\$ (0.16 )	\$ (0.25 )
Weighted Average Number of Shares of Common Stock Used in Computation of Basic and Diluted Loss	94,786,590	60,458,548	61,346,000	59,592,000	59,490,000

Per Share

	<b>September 30, 2010</b>	<b>December 31, 2009</b>
	<b>(unaudited)</b>	
<b>Balance Sheet Data:</b>		
Cash, cash equivalents, and short-term investments	\$ 1,409,000	\$ 2,663,000
Total Assets	2,059,000	4,453,000
Total Current Liabilities	5,096,000	4,588,000
Total Liabilities	9,099,000	8,794,000
Accumulated deficit	(86,496,000 )	(82,766,000 )
Total Stockholders Deficiency	(7,040,000 )	(4,341,000 )

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## 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 license and distribution agreement with privately-held Mist Acquisition, LLC to manufacture and commercialize NitroMist, our lingual spray version of nitroglycerine, a widely-prescribed and leading short-acting nitrate for the treatment of angina pectoris. Under the terms of the agreement, we received an upfront payment of \$1,000,000, a milestone payment of \$500,000 in October 2010 and a milestone payment of \$500,000 in January 2011. We are also eligible to receive royalty payments of up to seventeen percent (17%) of net sales.

On November 13, 2009, we entered into an exclusive license and distribution agreement with ECR Pharmaceuticals Company, Inc. to commercialize and manufacture our Zolpimist in the United States and Canada. Under the terms of the agreement, we received a \$3,000,000 licensing fee and will receive ongoing performance payments of up to 15% of net sales.

In addition, on December 31, 2009, we entered into an amendment agreement with ProQuest Investments L.P. and its affiliates, referred to herein as ProQuest, to convert the outstanding aggregate principal balance of all convertible notes and all liquidated damages notes, in each case, plus all accrued but unpaid interest, in an aggregate amount equal



to \$3,657,000 to 23,237,083 shares of our common stock as of December 31, 2009.

We have entered into a common stock purchase agreement with Seaside 88, LP, whereby Seaside 88, LP will purchase 500,000 shares of common stock in a series of closings occurring every

two weeks for a total of up to 26 closings, provided that the 3 day volume weighed average price prior to the scheduled closing is greater than or equal to the stated floor price of \$0.25 per share. We have received \$1,055,000 in gross proceeds for the closings that have occurred through December 31, 2009. Through March 26, 2010, we have received \$200,140 in gross proceeds for 2010. On March 26, 2010, we mutually agreed to terminate the common stock purchase agreement with Seaside 88, LP as of such date.

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

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

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

- further delay, scale-back or eliminate some or all of our research and product development programs;

- license third parties to develop and commercialize products or technologies that we would otherwise seek to develop and commercialize ourselves;

- attempt to sell our company;

- cease operations; or

declare  
bankruptcy.

We are seeking to raise additional capital in 2010 to fund our operations and future development. A capital raise could include the securing of funds through new strategic partnerships or collaborations, the sale of common stock or other equity securities or the issuance of debt. In the event we do not enter into a license agreement or other strategic transaction in which we receive an upfront fee or payment, or we do not undertake a financing of debt or equity securities, we may not have sufficient cash on hand to fund operations. We can give no assurances that we will be able to enter into a strategic transaction or raise any additional capital or if we do, that such additional capital will be sufficient to meet our needs, or on terms favorable to us.

Based on our operating plan, we expect that our existing cash and cash equivalents will fund our operations only through March 31, 2011.

**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 third 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 licensee for NitroMist commercially launched the product in January 2011 and the licensee for Zolpimist is expected to commercially launch the product in January 2011. This limited history may not be adequate to enable one to fully assess our ability to develop our technologies and proposed products, obtain U.S. Food and Drug Administration, or FDA, approval and achieve market acceptance of our proposed products and respond to competition. The filing of a New Drug Application, or NDA, with the FDA is an important step in the approval process in the U.S. Acceptance for filing by the FDA does not mean that the NDA has been or will be approved, nor does it represent an evaluation of the adequacy of the data submitted. We cannot be certain as to when to anticipate commercializing and marketing any of our product candidates in development, if at all, and do not expect to generate sufficient revenues from proposed product sales to cover our expenses or achieve profitability in the near future.

We had an accumulated deficit as of September 30, 2010 of approximately \$86,496,000. We incurred losses in each of our last ten fiscal years, including net losses of approximately \$3,730,000 for the nine months ended September 30, 2010, \$7,577,000 for the year ended December 31, 2009, \$9,586,000 for the year ended December 31, 2008, and \$16,963,000 for the year ended December 31, 2007. Additionally, we have reported negative cash flows from operations of approximately \$2,771,000 for the nine months ended September 30, 2010, and negative cash flows from operations of \$1,578,000 for the year ended December 31, 2009, \$5,533,000 for the year ended December 31, 2008, and \$15,240,000 for the year ended December 31, 2007. We anticipate that, even with our limited research and development activities, we could incur substantial operating expenses in connection with continued research and development, clinical trials, testing and approval of our proposed products, administrative costs associated with operating as a SEC registrant, and expect these expenses will result in continuing and, perhaps, significant operating losses until such time, if ever, that we are able to achieve adequate product sales levels. Our ability to generate revenue and achieve profitability depends upon our ability, alone or with others, to complete the development of our product candidates, obtain the required regulatory approvals and manufacture, market and sell our product candidates.

**Our additional financing requirements could result in dilution to existing stockholders.**

The additional financings we require may be obtained through one or more transactions which effectively dilute the ownership interests of our existing stockholders. Given the recent downturn in the economy, we may not be able to secure such additional financing on terms acceptable to us, if



at all. We have the authority to issue additional shares of our common stock, as well as additional classes or series of ownership interests or debt obligations which may be convertible into any one or more classes or series of ownership interests. We are authorized to issue a total of 200,000,000 shares of common stock and 1,000,000 shares of preferred stock. Such securities may be issued without the approval or other consent of our stockholders.

**Our technology platform is based solely on our proprietary drug delivery technology. Our ongoing clinical trials for certain of our product candidates may be delayed, or fail, which will harm our business.**

Our strategy is to concentrate our product development activities primarily on pharmaceutical products for which there already are significant prescription sales, where the use of our proprietary, novel drug delivery technology could potentially enhance speed of onset of therapeutic effect, could potentially reduce side effects through a reduction of the amount of active drug substance required to produce a given therapeutic effect and improve patient convenience or compliance.

Companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials, even after obtaining promising results in earlier trials. Data obtained from tests are susceptible to varying interpretations which may delay, limit or prevent regulatory approval. In addition, companies may be unable to enroll patients quickly enough to meet expectations for completing clinical trials. The timing and completion of current and planned clinical trials of our product candidates depend on, among other factors, the rate at which patients are enrolled, which is a function of many factors, including:

the number  
of clinical  
sites;

the size of  
the patient  
population;

the  
proximity  
of patients  
to the  
clinical  
sites;

the  
eligibility  
criteria for  
the study;

the  
existence of  
competing  
clinical  
trials; and

the  
existence of  
alternative

available  
products.

Delays in patient enrollment in clinical trials may occur, which would likely result in increased costs, program delays or both.

**There are certain interlocking relationships and potential conflicts of interest.**

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

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

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

As of September 30, 2010, ProQuest, directly and indirectly, beneficially owns approximately 43% of our outstanding common stock (assuming full exercise of the warrants held by ProQuest). As such, ProQuest may be deemed to be our affiliate. Mr. Steven B. Ratoff, our Chairman, President, and Chief Executive Officer, has served as a venture partner with ProQuest since December 2004, although he has no authority for investment decisions by ProQuest.

**Our business and revenue is dependent on the successful development of our products.**

Revenue received from our product development efforts consists of payments by pharmaceutical companies for research and bioavailability studies, pilot clinical trials and similar milestone-related payments. Our future growth and profitability will be dependent upon our ability to successfully raise additional funds to complete the development of, obtain regulatory approvals for and license out or market our product candidates. Accordingly, our prospects must be considered in light of the risks, expenses and difficulties frequently encountered in connection with the establishment of a new business in a highly competitive industry, characterized by frequent new product introductions. We anticipate that we will incur substantial operating expenses in connection with the development, testing and approval of our product candidates and expect these expenses to result in continuing and significant operating losses until such time, if ever, that we are able to achieve adequate levels of sales or license revenues. We may not be able to raise additional financing, increase revenues significantly, or achieve profitable operations.

**Some of our product candidates are in early stages of clinical development and some are in preclinical testing, which may affect our ability or the time we require to obtain necessary regulatory approvals.**

Some of our product candidates are in early stages of clinical development, such as our Duromist product candidate, and some are in preclinical testing. These product candidates are continuously evaluated and assessed and are often subject to changes in formulation and technology. The regulatory requirements governing these types of products may be less well defined or more rigorous than for conventional products. As a result, we may experience delays with our preclinical and clinical testing, and a longer and more expensive regulatory process in connection with obtaining regulatory approvals of these types of product candidates as compared to others in our pipeline at later stages of development. These delays may negatively affect our business and operations.

We may not be able to successfully develop any one or more of our product candidates or develop such product candidates on a timely basis. Further, such product candidates may not be commercially accepted if developed. The inability to successfully complete development, or a determination by us, for financial or other reasons, not to undertake to complete development of any product candidates, particularly in instances in which we have made significant capital expenditures, could have a material adverse effect on our business and operations.

**We do not have commercially available products.**

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

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

**We do not have direct consumer marketing experience.**

We have no experience in marketing or distribution at the consumer level of our product candidates. Moreover, we do not have the financial or other resources to undertake extensive marketing and advertising activities. Accordingly, we



intend generally to rely on marketing

arrangements, including possible joint ventures or license or distribution arrangements with third-parties. Except for our agreements with Mist, ECR, BioAlliance, Par, Manhattan Pharmaceuticals, Velcera and Hana Biosciences, we have not entered into any significant agreements or arrangements with respect to the marketing of our product candidates. We may not be able to enter into any such agreements or similar arrangements in the future and we may not be able to successfully market our products. If we fail to enter into these agreements or if we or the third parties do not perform under such agreements, it could impair our ability to commercialize our products.

We have stated our intention to possibly market our own products in the future, although we have no such experience to date. Substantial investment will be required in order to build infrastructure and provide resources in support of marketing our own products, particularly the establishment of a marketing force. If we do not develop a marketing force of our own, then we will depend on arrangements with corporate partners or other entities for the marketing and sale of our remaining products. The establishment of our own marketing force, or a strategy to rely on third party marketing arrangements, could adversely affect our profit margins.

**We must comply with current Good Manufacturing Practices.**

The manufacture of our pharmaceutical products under development will be subject to current Good Manufacturing Practices, or cGMP, prescribed by the FDA, pre-approval inspections by the FDA or comparable foreign authorities, or both, before commercial manufacture of any such products and periodic cGMP compliance inspections thereafter by the FDA. We, or any of our third party manufacturers, may not be able to comply with cGMP or satisfy pre- or post-approval inspections by the FDA or comparable foreign authorities in connection with the manufacture of our product candidates. Failure or delay by us or any such manufacturer to comply with cGMP or satisfy pre- or post-approval inspections would have a material adverse effect on our business and operations.

**We are dependent on our suppliers.**

We believe that the active ingredients used in the manufacture of our product candidates are presently available from numerous suppliers located in the U.S., Europe, India and Japan. We believe that certain raw materials, including inactive ingredients, are available from a limited number of suppliers and that certain packaging materials intended for use in connection with our spray products currently are available only from sole source suppliers. Although we do not believe we will encounter difficulties in obtaining the inactive ingredients or packaging materials necessary for the manufacture of our product candidates, we may not be able to enter into satisfactory agreements or arrangements for the purchase of commercial quantities of such materials.

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

With respect to other suppliers, we operate primarily on a purchase order basis beyond which there is no contract memorializing our purchasing arrangements. The inability to enter into agreements or otherwise arrange for adequate or timely supplies of principal raw materials and the possible inability to secure alternative sources of raw material supplies, or the failure of DPT Laboratories, or Rechon Life Sciences to comply with their supply obligations to us, could have a material adverse effect on our ability to arrange for the manufacture of formulated products. In addition, development and regulatory approval of our products are dependent upon our ability to procure active ingredients and certain packaging materials from FDA-approved sources. Since the FDA approval process requires manufacturers to specify their proposed suppliers of active ingredients and certain packaging materials in their applications, FDA approval of a supplemental application to use a new supplier would be required if active ingredients or such packaging materials were no longer available from the originally specified supplier, which may result in manufacturing delays. If we do not maintain important manufacturing relationships, we may fail to find a replacement manufacturer or to develop our own manufacturing capabilities. If we cannot do so, it could delay or impair our ability to obtain regulatory approval for our products and substantially increase our costs or deplete any profit margins. If we do find replacement manufacturers, we may



not be able to enter into agreements with them on terms and conditions favorable to us and, there could be a substantial delay before a new facility could be qualified and registered with the FDA and foreign regulatory authorities.

**Failure to achieve and maintain effective internal controls in accordance with Section 404 of the Sarbanes-Oxley Act of 2002 could have a material adverse effect on our business and operating results. In addition, current and potential stockholders could lose confidence in our financial reporting, which could have a material adverse effect on our stock price.**

Effective internal controls are necessary for us to provide reliable financial reports and effectively prevent fraud. If we cannot provide reliable financial reports or prevent fraud, our operating results and financial condition could be harmed.

We are required to document and test our internal control procedures in order to satisfy the requirements of Section 404 of the Sarbanes-Oxley Act of 2002, which requires annual management assessments of the effectiveness of our internal controls over financial reporting. During the course of our testing we may identify deficiencies which we may not be able to remediate in time to meet the deadline imposed by the Sarbanes-Oxley Act of 2002 for compliance with the requirements of Section 404. In addition, if we fail to maintain the adequacy of our internal controls, as such standards are modified, supplemented or amended from time to time, we may not be able to ensure that we can conclude on an ongoing basis that we have effective internal controls over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act of 2002. Failure to achieve and maintain an effective internal control environment could also cause investors to lose confidence in our reported financial information, which could have a material adverse effect on the price of our common stock.

**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 our Medicaid drug rebates to states, once the provision is effective. The new law also imposes a significant annual fee on companies that manufacture or import branded prescription drug products (beginning in 2010). Substantial new provisions affecting compliance also have been added, which may require modification of business practices with health care practitioners.

The reforms imposed by the new law will significantly impact the pharmaceutical industry; however, the full effects of PPACA cannot be known until these provisions are implemented and the Centers for Medicare & Medicaid Services and other federal and state agencies issue applicable regulations or guidance. Moreover, in the coming years, additional change could be made to governmental healthcare programs that could significantly impact the success of our current and future products, and we could be adversely affected by current and future health care reforms.

**Our strategy includes entering into collaboration agreements with third parties for certain of our product candidates and we may require additional collaboration agreements. If we fail to enter into these agreements or if we or the third parties do not perform under such agreement, it could impair our ability to commercialize our proposed products.**

Our strategy for the completion of the required development and clinical testing of certain of our product candidates and for the manufacturing, marketing and commercialization of such product candidates includes entering into collaboration arrangements with pharmaceutical companies to market, commercialize and distribute the products.

Through September 30, 2010, we entered into strategic license agreements with: (i) Hana Biosciences, for the development and marketing rights in the U.S. and Canada which was subsequently sublicensed to Par for our ondansetron oral spray Zensana, (ii) Manhattan Pharmaceuticals, in connection with propofol, (iii) Velcera, in connection with veterinary applications



for currently marketed veterinary drugs, (iv) BioAlliance Pharma SA, for the European rights for ondansetron oral spray Zensana, (v) Mist Acquisition, LLC, for the manufacturing and commercialization rights in the United States, Canada and Mexico for our lingual spray version of nitroglycerine, NitroMist, and (vi) ECR Pharmaceuticals Company, for the manufacturing and commercialization rights in the United States and Canada for our oral spray formulation of zolpidem tartrate, Zolpimist.

Our success depends upon obtaining additional collaboration partners and maintaining our relationships with our current partners. In addition, we may depend on our partners' expertise and dedication of sufficient resources to develop and commercialize proposed products. For example, in November 2008, Par announced that it had completed bioequivalence studies on Zensana with mixed results and, as a result, it had ceased development of the product. Since such time, we have had numerous meetings and discussions with both Par and Hana regarding the development of Zensana. We cannot assure you that Par or Hana will perform under our license agreements.

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

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

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

defend our  
patents and  
otherwise  
prevent  
others from  
infringing  
on our  
proprietary  
rights;

protect our  
trade  
secrets; and

operate  
without  
infringing  
upon the  
proprietary  
rights of

others, both  
in the U.S.  
and in other  
countries.

The patent position of firms relying upon biotechnology is highly uncertain and involves complex legal and factual questions for which important legal principles are unresolved. To date, the U.S. Patent and Trademark Office, or USPTO, has not adopted a consistent policy regarding the breadth of claims that the USPTO allows in biotechnology patents or the degree of protection that these types of patents afford. As a result, there are risks that we may not develop or obtain rights to products or processes that are or may seem to be patentable.

Section 505(b)(2) of the 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 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 quoted on the Over-the-Counter Bulletin Board, the liquidity of our common stock may be impaired.**

On December 24, 2009, we announced that our common stock was accepted for quotation on the Over-the-Counter Bulletin Board, or OTCBB. Our new ticker symbol on OTCBB is NVDL.OB. We filed a Form 25 on December 14, 2009, voluntarily withdrawing our listing and registration from NYSE Amex LLC. The final day of trading on NYSE Amex LLC was December 23, 2009.

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

**We are influenced by current stockholders, officers and directors.**

Our directors, executive officers and principal stockholders and certain of our affiliates have the ability to influence the election of our directors and most other stockholder actions. As of September 30, 2010, management and our affiliates currently beneficially own, including shares they have the right to acquire, approximately 44% of the common stock on a fully-diluted basis. This determination of affiliate status is not necessarily a conclusive determination for other purposes. Specifically, ProQuest has the ability to exert significant influence over matters submitted to our stockholders for approval. Such positions may discourage or prevent any proposed takeover of us, including transactions in which our stockholders might otherwise receive a premium for their shares over the then current market prices. Our directors, executive officers and principal stockholders may influence corporate actions, including influencing elections of directors and significant corporate events.

**The market price of our stock and our earnings may be adversely affected by market volatility.**

The market price of our common stock, like that of many other development stage pharmaceutical or biotechnology companies, has been and is likely to continue to be volatile. In addition to general economic, political and market conditions, the price and trading volume of our common stock could fluctuate widely in response to many factors, including:

- announcements of the results of clinical trials by us or our competitors;

adverse  
reactions to  
products;

governmental  
approvals,  
delays in  
expected  
governmental  
approvals or  
withdrawals of  
any prior  
governmental  
approvals or  
public or  
regulatory  
agency  
concerns  
regarding the  
safety or  
effectiveness of  
our products;

changes in the  
U.S. or foreign  
regulatory  
policy during  
the period of  
product  
development;

developments  
in patent or  
other  
proprietary  
rights, including  
any third party  
challenges of  
our intellectual  
property rights;

announcements  
of technological  
innovations by  
us or our  
competitors;

announcements  
of new products  
or new  
contracts by us  
or our  
competitors;

actual or  
anticipated  
variations in  
our operating  
results due to  
the level of  
development  
expenses and  
other factors;

changes in  
financial  
estimates by  
securities  
analysts and  
whether our  
earnings meet  
or exceed the  
estimates;

conditions and  
trends in the  
pharmaceutical  
and other  
industries;

new accounting  
standards; and

the occurrence  
of any of the  
risks set forth  
in these Risk  
Factors and  
other reports,  
including this  
prospectus and  
other filings  
filed with the  
Securities and  
Exchange  
Commission  
from time to

time.

Our common stock is currently 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 nine-month period ended September 30, 2010, the closing price of our common stock has ranged from \$0.15 to \$0.29. We expect the price of our common stock to remain volatile. The average daily trading volume in our common stock varies significantly. Our relatively low volume and low number of transactions per day may affect the ability of our stockholders to sell their shares in the public market at prevailing prices and a more active market may never develop.

In the past, following periods of volatility in the market price of the securities of companies in our industry, securities class action litigation has often been instituted against companies in our industry. If we face securities litigation in the future, even if without merit or unsuccessful, it would result in substantial costs and a diversion of management attention and resources, which would negatively impact our business.

**Because the average daily trading volume of our common stock is low, the ability to sell our shares in the secondary trading market may be limited.**

Because the average daily trading volume of our common stock is low, the liquidity of our common stock may be impaired. As a result, prices for shares of our common stock may be lower than might otherwise prevail if the average daily trading volume of our common stock was higher. The average daily trading volume of our common stock may be low relative to the stocks of exchange-listed companies, which could limit investors' ability to sell shares in the secondary trading market.

**We likely will issue additional equity securities, which will dilute current stockholders' share ownership.**

We likely will issue additional equity securities to raise capital and through the exercise of options and warrants that are outstanding or may be outstanding. These additional issuances will dilute current stockholders' share ownership.

**Penny stock regulations may impose certain restrictions on marketability of our securities.**

The SEC has adopted regulations which generally define a penny stock to be any equity security that has a market price of less than \$5.00 per share or an exercise price of less than \$5.00 per share, subject to certain exceptions. As a result, our common stock is subject to rules that impose additional sales practice requirements on broker dealers who sell such securities to persons other than established customers and accredited investors (generally those with assets in excess of \$1,000,000 or annual income exceeding \$200,000, or \$300,000 together with their spouse). For transactions covered by such rules, the broker dealer must make a special suitability determination for the purchase of such securities and have received the purchaser's written consent to the transaction prior to the purchase. Additionally, for any transaction involving a penny stock, unless exempt, the rules require the delivery, prior to the transaction, of a risk disclosure document mandated by the SEC relating to the penny stock market. The broker dealer must also disclose the commission payable to both the broker dealer and the registered representative, current quotations for the securities and, if the broker dealer is the sole market maker, the broker dealer must disclose this fact and the broker dealer's presumed control over the market. Finally, monthly statements must

be sent disclosing recent price information for the penny stock held in the account and information on the limited market in penny stocks. Broker-dealers must wait two business days after providing buyers with disclosure materials regarding a security before effecting a transaction in such security. Consequently, the penny stock rules restrict the ability of broker dealers to sell our securities and affect the ability of investors to sell our securities in the secondary market and the price at which such purchasers can sell any such securities, thereby affecting the liquidity of the market for our common stock.

Stockholders should be aware that, according to the SEC, the market for penny stocks has suffered in recent years from patterns of fraud and abuse. Such patterns include:

- control of the market for the security by one or more broker-dealers that are often related to the promoter or issuer;

- manipulation of prices through prearranged matching of purchases and sales and false and misleading press releases;

- boiler room practices involving high pressure sales tactics and unrealistic price projections by inexperienced sales persons;

- excessive and undisclosed bid-ask differentials and markups by selling broker-dealers; and

the wholesale  
dumping of the  
same securities  
by promoters  
and  
broker-dealers  
after prices  
have been  
manipulated to  
a desired level,  
along with the  
inevitable  
collapse of  
those prices  
with  
consequent  
investor losses.

Our management is aware of the abuses that have occurred historically in the penny stock market.

**Additional authorized shares of our common stock and preferred stock available for issuance may adversely affect the market.**

We are authorized to issue a total of 200,000,000 shares of common stock and 1,000,000 shares of preferred stock. Such securities may be issued without the approval or other consent of our stockholders. As of September 30, 2010, there were 98,383,458 shares of common stock issued and outstanding. However, the total number of shares of our common stock issued and outstanding does not include shares reserved in anticipation of the exercise of options or warrants. As of September 30, 2010, we had outstanding stock options and warrants to purchase approximately 32.8 million shares of common stock, the exercise prices of which range between \$0.17 per share and \$3.18 per share, and we have reserved shares of our common stock for issuance in connection with the potential exercise thereof. As a result, as of September 30, 2010, 370,000 and 10,121,000 shares remain available for issuance under the 1998 Stock Option Plan and the 2006 Equity Incentive Plan, respectively.

To the extent such options or warrants are exercised, the holders of our common stock will experience further dilution.

In addition, in the event that any future financing should be in the form of, be convertible into or exchangeable for, equity securities, and upon the exercise of options and warrants, investors may experience additional dilution.

See Risk Factors Our Additional Financing Requirements Could Result In Dilution To Existing Stockholders included herein. The exercise of the outstanding derivative securities will reduce the percentage of common stock held by our stockholders in relation to our aggregate outstanding capital stock. Further, the terms on which we could obtain additional capital during the life of the derivative securities may be adversely affected, and it should be expected that the holders of the derivative securities would exercise them at a time when we would be able to obtain equity capital on terms more favorable than those provided for by such derivative securities. As a result, any issuance of additional shares of our common stock may cause our current stockholders to suffer significant dilution which may adversely affect the market.

In addition to the above referenced shares of our common stock which may be issued without stockholder approval, we have 1,000,000 shares of authorized preferred stock, the terms of which may be fixed by our Board. We presently have no issued and outstanding shares of preferred stock



and while we have no present plans to issue any shares of preferred stock, our Board has the authority, without stockholder approval, to create and issue one or more series of such preferred stock and to determine the voting, dividend and other rights of holders of such preferred stock. The issuance of any of such series of preferred stock may have an adverse effect on the holders of our common stock.

**Shares eligible for future sale may adversely affect the market.**

From time to time, certain of our stockholders may be eligible to sell all or some of their shares of our common stock by means of ordinary brokerage transactions in the open market pursuant to Rule 144, promulgated under the Securities Act of 1933, as amended, subject to certain limitations. In general, pursuant to Rule 144, a stockholder (or stockholders whose shares are aggregated) who has satisfied a six-month holding period may, under certain circumstances, sell within any three month period a number of securities which does not exceed the greater of 1% of the then outstanding shares of common stock or the average weekly trading volume of the class during the four calendar weeks prior to such sale. Rule 144 also permits, under certain circumstances, the sale of securities, without any limitation, by our stockholders that are non-affiliates that have satisfied a one-year holding period. Any substantial sale of our common stock pursuant to Rule 144 or pursuant to any resale prospectus may have a material adverse effect on the market price of our common stock.

**Limitation on director and officer liability.**

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

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

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

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

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

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

Since May 2005, we have entered into private placements and registered direct offerings whereby we sell large quantities of our common stock to investors. For example, on March 31, 2010, we sold 9,100,001 shares of our



common stock at a price of \$0.165 per share to certain investors in a

registered direct offering. The investors also received warrants to purchase 7,583,335 shares of common stock with an exercise price of \$0.25 per share

These holders of the shares may sell such shares, if such shares are registered or pursuant to an exemption from registration, at any price and at any time, as determined by such holders in their sole discretion without limitation. Any sales of large quantities of our common stock could reduce the price of our common stock. If any such holders sell such shares in large quantities, our common stock price may decrease and the public market for our common stock may otherwise be adversely affected because of the additional shares available in the market.

We cannot assure you of the prices at which our common stock will trade in the future, and such prices may continue to fluctuate significantly. Prices for our common stock will be determined in the marketplace and may be influenced by many factors, including the following:

The depth  
and  
liquidity of  
the markets  
for our  
common  
stock;

Investor  
perception  
of us and  
the industry  
in which  
we  
participate;  
and

General  
economic  
and market  
conditions.

As of September 30, 2010, we have 98,383,458 shares of common stock issued and outstanding and approximately 32.8 million shares of common stock issuable upon the exercise of outstanding stock options and warrants. In the event we wish to offer and sell shares of our common stock in excess of the 200,000,000 shares of common stock currently authorized by our certificate of incorporation, we will first need to receive stockholder approval. Such stockholder approval has the potential to adversely affect the timing of any potential transactions.

**We may incur significant costs from class action litigation due to our expected stock volatility.**

In the past, following periods of large price declines in the public market price of a company's stock, holders of that stock occasionally have instituted securities class action litigation against the company that issued the stock. If any of our stockholders were to bring this type of lawsuit against us, even if the lawsuit is without merit, we could incur substantial costs defending the lawsuit. The lawsuit also could divert the time and attention of our management, which would hurt our business. Any adverse determination in litigation could also subject us to significant liabilities.

**The uncertainty created by current economic conditions and possible terrorist attacks and military responses thereto could have a material adverse effect on our ability to sell our products, and procure needed financing.**

Current conditions in the domestic and global economies continue to present challenges. We expect that the future direction of the overall domestic and global economies will have a significant impact on our overall performance. Fiscal, monetary and regulatory policies worldwide will continue to influence the business climate in which we operate. If these actions are not successful in spurring continued economic growth, we expect that our business will be negatively impacted, as customers will be less likely to buy our products, if and when we commercialize our products. In addition, the potential for future terrorist attacks or war as a result thereof has created worldwide uncertainties that make it very difficult to estimate how the world economy will perform going forward.

**Our inability to manage the future growth that we are attempting to achieve could severely harm our business.**

We believe that, given the right business opportunities, we may expand our operations rapidly and significantly. If rapid growth were to occur, it could place a significant strain on our management, operational and financial resources. To manage any significant growth of our operations, we will be required to undertake the following successfully:

We will need to improve our operational and financial systems, procedures and controls to support our expected growth and any inability to do so will adversely impact our ability to grow our business. Our current and planned systems, procedures and controls may not be adequate to support our future operations and expected growth. Delays or problems associated with any improvement or expansion

of our  
operational  
systems and  
controls  
could  
adversely  
impact our  
relationships  
with  
customers  
and harm our  
reputation  
and brand.

We will need to attract and retain qualified personnel, and any failure to do so may impair our ability to offer new products or grow our business. Our success will depend on our ability to attract, retain and motivate managerial, technical, marketing, and administrative personnel. Competition for such employees is intense, and we may be unable to successfully attract, integrate or retain sufficiently qualified personnel.

If we are unable to hire, train, retain or manage the necessary personnel, we may be unable to successfully introduce new products or otherwise implement our business strategy. If we are unable to manage growth effectively, our business, results of operations and financial condition could be materially adversely affected.

**We may be obligated, under certain circumstances, to pay liquidated damages to holders of our common stock.**

We have entered into agreements with the holders of our common stock that requires us to continuously maintain as effective, a registration statement covering the underlying shares of common stock. Such registration statements were declared effective on 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, subject to the limitations set forth in the Use of Proceeds section of this prospectus. We intend to use the net proceeds to further clinical development of Duromist and our other product candidates, and for working capital and other general corporate purposes. Our judgment may not result in positive returns on your investment and you will not have an opportunity to evaluate the economic, financial, or other information upon which we base our decisions.

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

You will incur immediate and substantial dilution as a result of this offering. After giving effect to the sale by us of 1,667 shares of convertible preferred stock and accompanying warrants and after deducting the placement agent fees and estimated offering expenses payable by us, investors in this offering can expect an immediate dilution of \$0.01 per share, assuming no exercise of the warrants. Investors exercising their warrants may experience additional dilution.

**There is no public market for the convertible preferred stock or the warrants being offered in this offering.**

There is no established public trading market for the convertible preferred stock or the warrants being offered in this offering, and we do not expect a market to develop. In addition, we do not intend to apply for listing the convertible preferred stock or the warrants on any securities exchange. Without an active market, the liquidity of the convertible preferred stock and the warrants will be limited.

**We are required to hold a stockholders meeting no later than July 31, 2011 to vote on a proposal related to this offering, and if we fail to obtain such approval, we are required to continue to pursue such approval on a periodic basis.**

We have agreed to hold a stockholders meeting no later than July 31, 2011 to approve an increase in the authorized shares of our common stock to permit the full exercise of the Series A and Series C Warrants. If we are unable to obtain the requested stockholder approval, we will be prohibited from issuing and selling any shares of our common stock for a price per share that is less than the exercise price of the Series A 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, 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 \$1,404,000 in net proceeds from the sale of securities in this offering if all of the convertible preferred stock and warrants offered hereby are sold 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. Without limiting the foregoing, none of such proceeds shall be used, directly or indirectly, (i) for the satisfaction of any debt of the Company or any of its subsidiaries, other than payment of trade payables incurred after the date hereof in the ordinary course of business of the Company and its subsidiaries and consistent with prior practices, (ii) for the redemption of any securities of the Company, other than any of the securities in this offering, or (iii) with respect to any litigation involving the Company or any of its subsidiaries, including, without limitation, (x) any settlement thereof or (y) the payment of any costs or expenses related thereto.

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 September 30, 2010:

on an actual  
basis; and

on an as  
adjusted  
basis to  
reflect our  
sale of  
1,667  
shares of  
convertible  
preferred  
stock, less  
the  
placement  
agent fees  
and  
estimated  
offering  
expenses  
payable by  
us.

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 September 30, 2010</b>	
	<b>Actual</b>	<b>As Adjusted</b>
	<b>(Unaudited)</b>	<b>(Unaudited)</b>
<b>Stockholders' Deficiency:</b>		
Preferred stock: \$0.001 par value; Authorized 1,000,000 shares, none issued at September 30, 2010, Issued 1,667 shares of Series A Convertible Preferred Stock at September 30, 2010, as adjusted	\$	\$
Common stock: \$0.001 par value; Authorized 200,000,000 shares, Issued 98,383,458 at September 30, 2010	99,000	99,000
Additional paid-in capital	79,363,000	80,767,000
Accumulated deficit	(86,496,000 )	(86,496,000 )
Treasury stock	(6,000 )	(6,000 )
<b>Total Stockholders' Deficiency</b>	<b>\$ (7,040,000 )</b>	<b>\$ (5,636,000 )</b>

The number of shares in the table above excludes:

50,010,000  
shares of  
common  
stock  
issuable  
upon  
exercise of  
the warrants  
offered  
hereby;

333,400  
shares of  
common  
stock  
issuable  
upon  
exercise of  
warrants  
issued to the  
placement  
agent in  
connection  
with this  
offering;

8,659,243  
shares of  
common  
stock  
issuable  
upon  
exercise of  
stock  
options  
outstanding  
as of  
September  
30, 2010  
under our  
stock option  
plans at a  
weighted  
average  
exercise  
price of  
\$0.73 per  
share;

24,170,004  
additional  
shares of  
common  
stock  
reserved for  
issuance  
under  
various  
outstanding  
warrant  
agreements  
as of  
September  
30, 2010, at  
a weighted  
average  
exercise  
price of  
\$0.67 per  
share; and

10,651,257  
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 invest in the securities being offered by this prospectus, you will suffer immediate and substantial dilution in the net tangible book value per share of common stock. Our net tangible book value as of September 30, 2010 was approximately \$(7,040,000), or approximately \$(0.07) 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 September 30, 2010.

Dilution in net tangible book value per share represents the difference between the effective price per share of common stock underlying the convertible preferred stock paid by purchasers in this offering and the net tangible book value per share of our common stock immediately after this offering. Without taking into account any other changes in the net tangible book value after September 30, 2010, other than to give effect to our receipt of the estimated proceeds from the sale of 1,667 shares of convertible preferred stock and accompanying warrants to purchase shares of our

common stock in this offering at an offering price of \$1,000, or 16,670,000 shares of common stock issuable upon conversion of the convertible preferred stock at an effective acquisition price of \$0.10, per share of common stock, less the placement agent's fees and our estimated offering expenses, but

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before deducting our dividend and related payment obligations, our net tangible book value as of September 30, 2010, after giving effect to the items above, would have been approximately \$(5,636,000), or approximately \$(0.05) per share of common stock. This represents an immediate increase of \$0.02 in net tangible book value per share to our existing stockholders and an immediate dilution of \$0.15 per share to purchasers of securities in this offering. The following table illustrates this per share dilution:

Public offering price per share	\$ 0.10
Net tangible book value per share as of September 30, 2010	\$ (0.07 )
Increase in net tangible book value per share attributable to new investors	\$ 0.02
Adjusted net tangible book value per share as of September 30, 2010, after giving effect to the offering	\$ (0.05 )
Dilution per share to new investors in the offering	\$ 0.15

Investors exercising their warrants may experience additional dilution.

The above discussion and tables do not include the following:

50,010,000  
shares of  
common  
stock  
issuable  
upon  
exercise of  
the warrants  
offered  
hereby;

333,400  
shares of  
common  
stock  
issuable  
upon  
exercise of  
warrants  
issued to the  
placement  
agent in  
connection  
with this  
offering;

8,659,243  
shares of  
common  
stock  
issuable

upon  
exercise of  
stock  
options  
outstanding  
as of  
September  
30, 2010  
under our  
stock option  
plans at a  
weighted  
average  
exercise  
price of  
\$0.73 per  
share;

24,170,004  
additional  
shares of  
common  
stock  
reserved for  
issuance  
under  
various  
outstanding  
warrant  
agreements  
as of  
September  
30, 2010, at  
a weighted  
average  
exercise  
price of  
\$0.67 per  
share; and

10,651,257  
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	
Zensana™	Ondansetron	Nausea/Vomiting	Clinical development	Hana Biosciences Par Pharmaceuticals BioAlliance Pharma
NVD-201	Sumatriptan	Migraine headache	Clinical development	
NVD-301	Midazolam	Pre-Procedure Anxiety	Preclinical development	



## **Our Approved Products**

### ***NitroMist®***

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

### ***Zolpimist™***

Zolpimist, our oral spray formulation of zolpidem, has been approved by the FDA for short-term treatment of insomnia. Zolpidem is the active ingredient in Ambien®, a leading prescription medication for the treatment of insomnia, marketed by Sanofi-Aventis. In November 2009, we entered into an exclusive license and distribution agreement with ECR Pharmaceuticals Company, Inc., or ECR, to manufacture and commercialize Zolpimist in the U.S. and Canada. ECR is a subsidiary of Hi-Tech Pharmacal Co., Inc. Under the terms of the agreement, we received an upfront payment of \$3,000,000. We are also eligible to receive royalty payments of up to 15% of net sales on branded products. ECR is expected to begin marketing Zolpimist in January 2011.

## **Our Product Candidates**

### ***Duromist™***

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

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

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

The preliminary data from the trial demonstrated that the 20 mg dose (two sprays) of Duromist is bioequivalent to the 25 mg Viagra tablet with respect to systemic exposure ( $AUC_{0-\text{inf}}$ ). The mean  $AUC_{0-\text{inf}}$  for the 10 mg dose (one spray) was approximately 40% of the 25 mg Viagra tablet, as expected. The mean  $AUC_{0-\text{inf}}$  for the 30 mg dose (three sprays) was approximately 40% higher than the 25 mg Viagra tablet, which is about 20% higher than expected. The increased systemic exposure observed with the 20 and 30 mg oral spray doses compared to the 25 mg Viagra tablet is suggestive of absorption of sildenafil via the oral transmucosal route.

A slightly lower maximum measured plasma concentration ( $C_{\max}$ ) than that of the 25 mg Viagra tablet was observed with the 20 mg oral spray dose. The  $T_{\max}$  (or time point at  $C_{\max}$ ) for the 20 mg oral spray dose was essentially the same as the 25 mg Viagra tablet (1.10 and 1.04 hours,

respectively). Duromist demonstrated an excellent safety profile and was well tolerated in the pilot PK study.

### ***Zensana™***

Zensana is our oral spray formulation of ondansetron. Ondansetron is the active ingredient in Zofran®, a leading prescription medication for the treatment of chemotherapy-induced nausea and vomiting, marketed by GlaxoSmithKline, or GSK. In October 2004, we entered into an exclusive license and development agreement with Hana Biosciences, Inc., or Hana Biosciences, to develop and market Zensana in the U.S. and Canada. In July 2007, we entered into a product development and commercialization sublicense agreement with Hana Biosciences and Par Pharmaceutical, Inc., or Par, pursuant to which Hana Biosciences granted a sublicense to Par to develop and commercialize Zensana. Also at that time, we entered into an amended and restated license and development agreement with Hana Biosciences. Par is responsible for all development, regulatory, manufacturing and commercialization activities of Zensana in the United States and Canada. Par had previously announced that it expected to complete clinical development on the revised formulation of Zensana during 2008, and expected to submit a new NDA for Zensana by the end of 2008. However, in November 2008, Par announced that it had completed bioequivalency studies on Zensana with mixed results, and had ceased development of the product.

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

### ***NVD-201***

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

### ***NVD-301***

NVD-301 is our oral spray formulation of midazolam. Midazolam is a leading benzodiazepine used for sedation during diagnostic, therapeutic and endoscopic procedures. We believe that NVD-301 has the potential to be an easy-to-use, rapid onset product useful to relieve the pre-procedure anxiety suffered by many patients prior to undergoing a wide variety of procedures performed in hospitals, imaging centers, 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 license and distribution agreement to manufacture and commercialize NitroMist®, our lingual spray version of nitroglycerine, a widely-prescribed and leading short-acting nitrate for the treatment of angina pectoris, in the United States, Canada and Mexico. Under terms of the agreement, we received an upfront payment of \$1,000,000, a milestone payment of \$500,000 in October 2010 and a milestone payment of \$500,000 in January 2011. We are also eligible to receive royalty 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.

***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 an upfront payment of \$3,000,000. We are also eligible to receive royalty payments of up to 15% on net sales. ECR will assume responsibility for manufacturing and marketing the product in the United States and Canada.

***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 nine months ended September 30, 2010 and twelve months ended December 31, 2009, we recognized \$115,386 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 (Malmo, 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, 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, benzodiazepines, 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 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 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 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 ANDA

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 February 3, 2011, we had 4 employees, all of whom were full-time employees.

### 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	46	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	49	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, 46. 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 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. 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, 49. 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.

### **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.

<b>Fiscal Quarter Ended</b>	<b>High</b>	<b>Low</b>
<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
December 31, 2010	0.27	0.14
<b>2011 Fiscal Year:</b>		
Through February 10, 2011	\$ 0.23	0.16

On February 10, 2011, the last reported sale price of our common stock on the OTCBB was \$0.20 per share. On January 6, 2011, there were 61 holders of record and approximately 2,868 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 nine months ended September 30, 2010 and 2009, the years ended December 31, 2009, 2008 and 2007, and the Balance Sheet data as of September 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.

<b>STATEMENT OF OPERATIONS DATA:</b>	<b>Nine Months Ended September 30,</b>	
	<b>2010 (unaudited)</b>	<b>2009 (unaudited)</b>
Total Revenues	\$ 261,000	\$ 356,000
Total Expenses	4,382,000	5,147,000
Loss from Operations	(4,121,000 )	(4,791,000 )
Other Income, net	391,000	301,000
Interest Expense	1,000	717,000
Interest Income	1,000	6,000
Income Tax Benefit		
Net Loss	\$ (3,730,000 )	\$ (5,201,000 )
Basic and Diluted Loss Per Common Share	\$ (0.04 )	\$ (0.09 )
Weighted Average Number of Shares of Common Stock Used in Computation of Basic and Diluted Loss Per Share	94,786,590	60,458,548

<b>STATEMENT OF OPERATIONS DATA:</b>	<b>Years Ended December 31,</b>				<b>Five Months Ended December 31,</b>
	<b>2009</b>	<b>2008</b>	<b>2007</b>	<b>2006 (unaudited)</b>	
Total Revenues	\$ 422,000	\$ 361,000	\$ 469,000	\$ 3,280,000	\$ 2,200,000
Total Expenses	6,517,000	8,951,000	18,656,000	13,544,000	6,517,000

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Loss from Operations	(6,095,000 )	(8,590,000 )	(18,187,000 )	(10,264,000 )	(4,000,000 )
Other, net	(385,000 )		(66,000 )		
Interest Expense	2,160,000	1,868,000			
Interest Income	6,000	137,000	632,000	337,000	
Income Tax Benefit	(1,057,000 )	(735,000 )	(658,000 )	(467,000 )	(1,000,000 )
Net Loss	\$ (7,577,000 )	\$ (9,586,000 )	\$ (16,963,000 )	\$ (9,460,000 )	\$ (3,000,000 )
Basic and Diluted Loss Per Common Share	\$ (0.12 )	\$ (0.16 )	\$ (0.29 )	\$ (0.20 )	\$ (0.10 )
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	49,000,000

BALANCE SHEET DATA:	Nine Months Ended September 30, 2010 (unaudited)		December 31, 2007		
	2009	2008	2007	2006	2005
Cash, cash equivalents, and short-term investments	\$ 1,409,000	\$ 2,663,000	\$ 4,328,000	\$ 6,384,000	\$ 20,000,000
Total Assets	2,059,000	4,453,000	7,316,000	10,363,000	24,000,000
Total Current Liabilities	5,096,000	4,588,000	5,563,000	4,211,000	3,000,000
Total Liabilities	9,099,000	8,794,000	10,057,000	6,189,000	5,000,000
Accumulated Deficit	(86,496,000 )	(82,766,000 )	(74,829,000 )	(65,243,000 )	(48,000,000 )
Total Stockholders Equity (Deficiency)	\$ (7,040,000 )	\$ (4,341,000 )	\$ (2,741,000 )	\$ 4,174,000	\$ 18,000,000

## 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.

		<b>Sep 30 2010</b>	<b>Jun 30 2010</b>	<b>Mar 31 2010</b>
Total revenues	\$	66,000	\$ 66,000	\$ 129,000
Net loss	\$	(1,312,000 )	\$ (1,126,000 )	\$ (1,421,000 )
Net loss per basic common share:	\$	(0.01 )	\$ (0.01 )	\$ (0.01 )
Net loss per diluted common share:	\$	(0.01 )	\$ (0.01 )	\$ (0.01 )
Shares used in computing basic per common share amounts:		97,918,000	97,918,000	88,372,000
Shares used in computing diluted per common share amounts:		97,918,000	97,918,000	88,372,000
	<b>Dec 31 2009</b>	<b>Sep 30 2009</b>	<b>June 30 2009</b>	<b>Mar 31 2009</b>
Total revenues	\$ 66,000	\$ 223,000	\$ 67,000	\$ 66,000
Net loss	\$ (2,376,000 )	\$ (1,361,000 )	\$ (1,701,000 )	\$ (2,139,000 )
Net loss per basic common share:	\$ (0.04 )	\$ (0.02 )	\$ (0.03 )	\$ (0.04 )
Net loss per diluted common share:	\$ (0.04 )	\$ (0.02 )	\$ (0.03 )	\$ (0.04 )
Shares used in computing basic per common share amounts:	65,282,000	61,386,000	60,081,000	59,892,000
Shares used in computing diluted per common share amounts:	65,282,000	61,386,000	60,081,000	59,892,000
	<b>Dec 31 2008</b>	<b>Sep 30 2008</b>	<b>June 30 2008</b>	<b>Mar 31 2008</b>
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 )
	\$ (0.03 )	\$ (0.04 )	\$ (0.05 )	\$ (0.03 )

Net loss per diluted  
common share:

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><i>Approved Products</i></b>				
NitroMist®	Nitroglycerin	Angina Pectoris	FDA Approved	Mist Acquisition
Zolpimist™	Zolpidem	Insomnia	FDA Approved	