NOVADEL PHARMA INC
Form 424B3
August 12, 2011

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

PROSPECTUS SUPPLEMENT NO. 2 DATED AUGUST 12, 2011
(To Prospectus Dated April 12, 2011)

NOVADEL PHARMA INC.

This is a supplement ("Prospectus Supplement No. 2") to our prospectus, dated April 12, 2011 (the "Prospectus"), relating to the offer and sale by certain selling securities holders of up to 7,583,335 shares of our common stock, par value $0.001 per share, issuable upon the exercise of five year warrants and six month warrants, each issued pursuant to the March 31, 2010 securities purchase agreement, referred to collectively herein as the Warrants.

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

Quarterly Report on Form 10-Q for Fiscal Quarter Ended June 30, 2011

On August 12, 2011, we filed with the Securities and Exchange Commission a quarterly report on Form 10-Q for the fiscal quarter ended June 30, 2011. The quarterly report, as filed (but without the exhibits filed with the Form 10-Q), is set forth below.

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

The Prospectus, together with Prospectus Supplement No. 1 and Prospectus Supplement No. 2, constitute the prospectus required to be delivered by Section 5(b) of the Securities Act of 1933, as amended, with respect to offers and sales of the securities as set forth in the Prospectus, as amended and supplemented. All references in the Prospectus to "this prospectus" are amended to read "this prospectus (as supplemented and amended)."

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

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

The date of this Prospectus Supplement No. 2 is dated August 12, 2011

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2011

or

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

For the transition period from to .

COMMISSION FILE NO. 001-32177

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

Delaware	22-2407152
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

1200 ROUTE 22 EAST, SUITE 2000, BRIDGEWATER, NEW JERSEY 08807

(Address of principal executive offices) (Zip Code)

(908) 203-4640
Registrant's telephone number, including area code

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ¨

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

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

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ¨ No x

As of August 4, 2011, the issuer had 134,690,615 shares of common stock, $0.001 par value, outstanding.

NovaDel Pharma Inc.

Form 10-Q
For the Quarterly Period Ended June 30, 2011

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

NovaDel Pharma Inc.

Condensed Balance Sheets

	June 30, 2011 (unaudited)	December 31, 2010 (Note 1)
Assets		
Current assets:		
Cash and cash equivalents	$ 865,000	$ 900,000
Receivables	—	744,000
Prepaid expenses and other current assets	153,000	346,000
Total current assets	1,018,000	1,990,000
Property and equipment, net	170,000	221,000
Other assets	7,000	7,000
Total assets	$ 1,195,000	$ 2,218,000
Liabilities and stockholders' deficiency		
Current liabilities:		
Accounts payable	$ 122,000	$ 356,000
Accrued expenses and other current liabilities	150,000	146,000
Derivative liability	3,779,000	611,000
Current portion of deferred revenue	259,000	3,259,000
Total current liabilities	4,310,000	4,372,000
Non-current portion of deferred revenue	6,560,000	3,689,000
Total liabilities	10,870,000	8,061,000
Commitments and contingencies		
Stockholders' deficiency:		
Preferred stock, $0.001 par value, 1,000,000 shares authorized, none issued and outstanding at June 30, 2011 and December 31, 2010, respectively	—	—
Common stock, $0.001 par value, 750,000,000 shares authorized, 133,590,615 and 98,681,029 shares issued at June 30, 2011 and December 31, 2010, respectively	134,000	99,000
Additional paid-in capital	83,226,000	79,496,000
Accumulated deficit	(93,029,000)	(85,432,000)
Treasury stock, at cost, 3,012 shares	(6,000)	(6,000)

Total stockholders' deficiency	(9,675,000)	(5,843,000)
Total liabilities and stockholders' deficiency	$ 1,195,000	$ 2,218,000

See accompanying notes.

NovaDel Pharma Inc.

Condensed Statements of Operations
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2011	2010	2011	2010
Revenue				
Royalties	$ 127,000	$ —	$ 127,000	$ —
Milestone fees	—	—	—	62,000
License fees	65,000	66,000	130,000	133,000
Total revenue	192,000	66,000	257,000	195,000
Operating expenses				
Research and development	412,000	559,000	1,032,000	1,006,000
General and administrative	703,000	813,000	1,385,000	1,787,000
Total operating expenses	1,115,000	1,372,000	2,417,000	2,793,000
Loss from operations	(923,000)	(1,306,000)	(2,160,000)	(2,598,000)
Other income (expense):				
Change in derivative liability	(2,427,000)	181,000	3,684,000	181,000
Change in conversion feature liability	(794,000)	—	27,000	—
Interest expense	(875,000)	(1,000)	(9,148,000)	(1,000)
Total other income (expense)	(4,096,000)	180,000	(5,437,000)	180,000
Net loss	$ (5,019,000)	$ (1,126,000)	$ (7,597,000)	$ (2,418,000)
Basic and diluted loss per common share	$ (0.04)	$ (0.01)	$ (0.07)	$ (0.03)
Weighted average common shares outstanding – basic and diluted	129,080,346	97,918,458	115,961,695	93,194,701

See accompanying notes.

NovaDel Pharma Inc.

Condensed Statement of Changes in Stockholders' Deficiency
(Unaudited)

	Common Stock		Additional	Accumulated	Treasury	Total Stockholders'
	Shares	Amount	Paid-In Capital	Deficit	Stock	Deficiency
Balance, December 31, 2010	98,681,029	$ 99,000	$ 79,496,000	$ (85,432,000)	$ (6,000)	$ (5,843,000)
Share-based compensation expense			127,000			127,000
Conversion of convertible preferred stock	30,987,052	31,000	3,188,000			3,219,000
Warrants exercised	3,973,406	4,000	372,000			376,000
Warrants issued			52,000			52,000
Restricted stock retired	(50,872)		(9,000)			(9,000)
Net loss for the six month period				(7,597,000)		(7,597,000)
Balance, June 30, 2011	133,590,615	$ 134,000	$ 83,226,000	$ (93,029,000)	$ (6,000)	$ (9,675,000)

See accompanying notes.

NovaDel Pharma Inc.

Condensed Statements of Cash Flows
(Unaudited)

	Six Months Ended June 30,	
	2011	2010
Operating activities		
Net loss	$ (7,597,000)	$ (2,418,000)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation expense	118,000	323,000
Depreciation and amortization	51,000	52,000
Change in derivative liability	(3,684,000)	(181,000)
Change in conversion feature liability	(27,000)	—
Interest expense	9,148,000	—
Changes in operating assets and liabilities:		
Receivables	744,000	—
Other assets	—	12,000
Prepaid expenses and other current assets	193,000	1,178,000
Accounts payable	(234,000)	134,000
Accrued expenses and other current liabilities	4,000	(30,000)
Deferred revenue	(129,000)	(133,000)
Net cash used in operating activities	(1,413,000)	(1,063,000)
Investing activities		
Return of lease deposits	—	17,000
Net cash provided by investing activities	—	17,000
Financing activities		
Net proceeds from exercise of warrants	141,000	—
Net proceeds from issuance of common stock and warrants	—	1,514,000
Net proceeds from issuance of convertible preferred stock and warrants	1,237,000	—
Payments of capital lease obligations	—	(14,000)
Net cash provided by financing activities	1,378,000	1,500,000
Net (decrease) increase in cash and cash equivalents	(35,000)	454,000
Cash and cash equivalents at beginning of period	900,000	2,663,000
Cash and cash equivalents at end of period	$ 865,000	$ 3,117,000

Supplemental disclosure of cash flow information		
Common stock issued from convertible preferred stock conversion	$ 3,219,000	—
Additional paid in capital for exercised warrants	$ 235,000	—
Placement agent warrants issued	$ 52,000	—
Derivative liability	—	$ 913,000
Cash paid for interest	—	$ 1,000

See accompanying notes.

NovaDel Pharma Inc.

Notes to Condensed Financial Statements
(Unaudited)

Note 1 – Basis of Presentation

The accompanying unaudited condensed financial statements of NovaDel Pharma Inc. have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") for interim financial information pursuant to the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and disclosures required by GAAP for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring accrual adjustments) considered necessary for a fair presentation have been included. Operating results for the three and six months ended June 30, 2011 are not necessarily indicative of the results that may be expected for other quarters or the year ending December 31, 2011. The December 31, 2010 condensed balance sheet was derived from audited financial statements but does not include all disclosures required by GAAP and included in the Form 10-K filing. For more complete information, these unaudited condensed financial statements and the notes thereto should be read in conjunction with the audited financial statements for the year ended December 31, 2010 included in our Form 10-K filed with the Securities and Exchange Commission. References in this report to "NovaDel," "Company," "we," "us," and "our" refer to NovaDel Pharma I

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

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

Note 2 – The Company

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

Note 3 – Liquidity and Going Concern

Our independent registered public accounting firm has included an explanatory paragraph in their report on our 2010 financial statements related to the uncertainty and substantial doubt of our ability to continue as a going concern.

As of June 30, 2011, we had cash and cash equivalents of $865,000, negative working capital of $3.3 million, and an accumulated deficit of $93.0 million. Based on our operating plan, we expect that our existing cash and cash equivalents will fund our operations only through September 30, 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. Our financial statements do not include any adjustments that may result from the outcome of this uncertainty. This basis of accounting contemplates the recovery of our assets and the satisfaction of liabilities in the normal course of business.

Our management plans to address the expected shortfall of working capital by securing additional funding through equity financings, strategic alternatives or similar transactions. There can be no assurance that we will be able to

obtain any sources of funding. If we are unsuccessful in securing funding from any of these sources, we will defer, reduce or eliminate certain planned expenditures.

Note 4 – Loss Per Share

Basic loss per share is calculated by dividing the net loss by the weighted average number of common shares outstanding for the period. Diluted loss per share is calculated by dividing the net loss by the weighted average number of common shares and common share equivalents outstanding for the period. For the purposes of this calculation, restricted stock, stock options and warrants are considered to be common share equivalents, and are determined using the treasury stock method. Common share equivalents are only included in the calculation of diluted loss per share when their effect is dilutive. Because we have incurred a net loss for all the periods presented, the effect of common share equivalents is anti-dilutive, and there is no difference between basic loss per share and diluted loss per share. As of June 30, 2011 and 2010, the number of restricted stock, stock options and warrants not included in the computation totaled 103.5 million and 36.5 million, respectively.

Note 5 – Convertible Preferred Stock

On February 14, 2011, we completed a public offering of 1,667 shares of our convertible preferred stock at a price of $1,000 per share, with an original issue discount of 4%, for gross proceeds of $1.6 million. The convertible preferred stock was convertible into 16,670,000 shares of common stock at a conversion price of $0.10 per share. The conversion price was also subject to adjustment if the Company issued equity securities (other than certain excluded securities) at a price per share less than the conversion price, such that the conversion price would equal the price per share of such equity securities. The convertible preferred stock was subject to automatic conversion, subject to the satisfaction of certain customary equity conditions, in four equal monthly installments commencing with March 17, 2011. The conversion price on each automatic conversion date was equal to the lower of (i) the conversion price then in effect or (ii) 85% of the average of the three lowest closing bid prices of the Company's common stock during the 20 trading day period prior to automatic conversion date. The Company could elect, at its option but subject to the satisfaction of certain conditions, to redeem the shares of convertible preferred stock in lieu of an automatic conversion occurring.

The estimated fair value of the convertible preferred stock and related conversion feature at issuance was $3,250,000. In accordance with FASB ASC 815 Derivatives and Hedging, the original fair value of the embedded conversion feature of $1,579,000 has been recorded as conversion feature liability. The original fair value was computed using the Black-Scholes model under the following assumptions: (1) expected life of .33 years; (2) volatility of 116%; (3) risk free interest of 2.26%, and (4) dividend rate of 0%. In addition, the Company is required to report the conversion liability at fair value and record the fluctuation to the fair value of the conversion feature liability to current operations.

As convertible preferred stock converted into common stock, the Company reduces the fair value of the conversion feature attributable to the convertible preferred shares converted and records the value as additional paid in capital. During the three months ended June 30, 2011, the Company derecognized the remaining $962,000 of the conversion feature liability in connection with the remaining shares that were converted.

The change in the fair value of the conversion feature liability resulted in losses of $794,000 for the three month period ended June 30, 2011 and a gain of $27,000 for the six month period ended June 30, 2011. The fair value of conversion feature outstanding at June 30, 2011 was $0 since all of the remaining shares were converted during the three month period ended June 30, 2011.

The investors also received Series PA Warrants, with a 5 year term from its initial exercise date, to purchase up to 16,670,000 shares of common stock at an exercise price of $0.15 per share; Series PB Warrants, with a 1 year term, to purchase up to 16,670,000 shares of common stock at an exercise price of $0.10 per share; and Series PC Warrants, with a 5 year term from its initial exercise date, to purchase up to 16,670,000 shares of common stock at an exercise price of $0.15 per share. The Series PC Warrants may be exercised by the investors only to the extent and in the same percentage that the investors exercise its Series PB Warrants. The Series PB Warrants are immediately exercisable, while the other warrants are only exercisable after June 8, 2012. As discussed in Note 6, the Company estimated the fair value of the Series PA, PB and PC Warrants on the grant date of February 14, 2011 to be $7,087,000.

The original fair value of the embedded conversion feature of $1,579,000, the original fair value of the warrants of $7,087,000 and the original issue discount of $67,000 were recorded as discounts to the convertible preferred stock. As a result, the value of the convertible preferred stock liability was reduced to zero. Discounts exceeding the fair value of the convertible preferred stock of $7,066,000 were recorded as interest expense. The discounts to the convertible preferred stock are accreted to interest expense as the convertible preferred stock is converted into common shares. The discount accreted to interest expense for the three month and six month periods ended June 30,

2011 was $701,000 and $1,667,000, respectively.

In addition, the Company incurred $415,000 of direct costs including warrants issued to our placement agent as part of their compensation for the transaction. The warrants allow for the purchase of up to 333,400 shares of our common stock at an exercise price of $0.15 per share, are only exercisable after June 8, 2012, and expire on June 8, 2017. The fair value of placement agent warrants were computed using the Black-Scholes model under the following assumptions: (1) expected life of 5 years; (2) volatility of 116%, (3) risk free interest of 2.26%, and (4) dividend rate of 0%. The fair value of the warrants was $52,000. The placement agent warrants do not contain provisions that would require liability classification in accordance with ASC 815 – Derivatives and Hedging. The direct costs are recorded as convertible preferred stock issuance costs in other assets. The convertible preferred stock issuance costs are amortized to interest expense as the convertible preferred stock is converted into common stock. Total costs amortized to interest expense for the three month and six month periods ended June 30, 2011 were $174,000 and $415,000, respectively.

Between April 1, 2011 and June 30, 2011, the remaining 701 shares of the convertible preferred stock were converted into 16,144,889 shares of common stock. As of June 30, 2011, no shares of convertible preferred stock were outstanding.

Note 6 – Derivative Liability

ASC 815 – Derivatives and Hedging provides guidance to determine what types of instruments, or embedded features in an instrument, are to be considered derivatives. This guidance can affect the accounting for warrants and other convertible instruments that contain provisions to protect holders from a decline in the stock price, or down-round provisions. Down-round provisions reduce the exercise price of a warrant or convertible instrument if a company either issues equity shares for a price that is lower than the exercise price of those instruments, or issues new warrants or convertible instruments that have a lower exercise price. We have determined that the following warrants contain such provisions and should be treated as derivative liabilities.

Warrant	Exercise Price	Number of Warrants	Expiration Date	Fair Value June 30, 2011
Series A	$ 0.04	28,159,369	March, 31, 2015	$ 1,665,000
Series PA	$ 0.15	16,670,000	June 8, 2017	898,000
Series PB	$ 0.10	16,670,000	Feb 14, 2012	318,000
Series PC	$ 0.15	16,670,000	June 8, 2017	898,000
Total				$ 3,779,000

The Company estimated the fair value of the Series PA, PB and PC Warrants on the grant date of February 14, 2011 to be $7,087,000. As discussed in Note 5, the Company immediately recognized the value of the warrants that exceeded the fair value of the convertible preferred stock as interest expense and recorded a corresponding derivative liability. As of June 30, 2011, the fair value of the warrants deemed to be derivatives was $3,779,000, as compared to the December 31, 2010 fair value of $611,000, resulting in a reduction in the derivative liability and a corresponding recognition of $3,684,000 in gain in the change in derivative liability for the six months ended June 30, 2011. In addition, the derivative liability was reduced related to warrant exercises by $235,000 with a corresponding increase in additional paid-in capital.

On May 31, 2011, the Company amended the Series PA and PC Warrants issued in February 2011 to extend the initial exercise date of such warrants to the date that is one year and one day from the effective date of the Company’s Post-Effective Amendment No. 2 to the Registration Statement on Form S-1. As a result, the initial exercise date of

the Series PA and PC Warrants was amended from February 14, 2012 to June 8, 2012. Since the Series PA and PC Warrants are exercisable for a period of five years from the initial exercise date, the expiration date of the Series PA and PC Warrants automatically adjusted to June 8, 2017 in connection with such amendment. The accounting impact associated with this modification was evaluated in accordance with ASC 815 – Derivatives and Hedges and it was determined that no accounting charge was needed.

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

The Company values its financial assets and liabilities on a recurring basis and effective January 1, 2009 certain nonfinancial assets and nonfinancial liabilities on a nonrecurring basis based on the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. In order to increase consistency and comparability in fair value measurements, a fair value hierarchy that prioritizes observable and unobservable inputs is used to measure fair value into three broad levels, which are described below:

Level 1:	Quoted prices (unadjusted) in active markets that are accessible at the measurement date for identical assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.
Level 2:	Observable inputs other than Level 1 prices such as quoted prices for similar assets or liabilities; quoted prices in inactive markets; or model-derived valuations in which all significant inputs are observable or can be derived principally from or corroborated with observable market data.
Level 3:	Unobservable inputs are used when little or no market data is available. The fair value hierarchy gives the lowest priority to Level 3 inputs.

In determining fair value, the Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible as well as considers counterparty credit risk in its assessment of fair value.

Financial liabilities carried at fair value on a recurring basis at June 30, 2011 and December 31, 2010 are classified in the tables below in one of the three categories described above:

	June 30, 2011			
	Level 1	Level 2	Level 3	Total
Derivative liability	—	$ 3,779,000	—	$ 3,779,000

	December 31, 2010			
	Level 1	Level 2	Level 3	Total
Derivative liability	—	$ 611,000	—	$ 611,000

The assumptions used in the June 30, 2011 fair value measurement of warrants are as follows:

	Series A	Series PA & PC	Series PB
Discount Rate	1.58%	1.58%	1.58%
Volatility	124%	124%	124%
Expected Term	3.75 years	5 years	0.63 years
Dividend Yield	0%	0%	0%

The assumptions used in the February 14, 2011 fair value measurement of warrants are as follows:

	Series PA & PC	Series PB
Discount Rate	2.26%	2.26%
Volatility	116%	116%
Expected Term	5 years	1 year
Dividend Yield	0%	0%

Note 7 – Revenue from Licensing Agreements

Royalty payments are recognized on sale of the related product, provided the royalty amounts are fixed and determinable, and collection of the related receivable is probable.

As of June 30, 2011, the Company has the following deferred revenue from licensing agreements:

	Total	Current	Non Current
Hi-Tech Pharmacal Co., Inc.	$ 3,000,000	$ —	$ 3,000,000
BioAlliance Pharma SA	2,519,000	154,000	2,365,000
Velcera, Inc.	992,000	75,000	917,000
Other	308,000	30,000	278,000
Totals	$ 6,819,000	$ 259,000	$ 6,560,000

Hi-Tech Pharmacal Co., Inc. – In November 2009, we entered into an exclusive license and distribution agreement with Hi-Tech Pharmacal Co., Inc., through its wholly owned subsidiary ECR Pharmaceuticals Company, Inc., to commercialize and manufacture Zolpimist® in the United States and Canada. Under the terms of the agreement, we received an upfront payment of $3,000,000. The upfront payment has been included in deferred revenue, and the remaining contractual deliverable is not expected in the next twelve months.

BioAlliance Pharma SA – In May 2008, we entered into an exclusive license and supply agreement with BioAlliance Pharma SA to develop and commercialize Zensana in Europe. Under the terms of the agreement, we received an upfront fee of $3,000,000. The upfront fee has been included in deferred revenue, and it is being recognized as revenue over the nineteen and one half-year term of the agreement.

Velcera, Inc. – In June 2004, we entered into an exclusive worldwide license agreement with Velcera, Inc. to develop and commercialize our patented oral spray drug delivery technology for animals. Under the terms of the agreement, we received an upfront license fee of $1,500,000 in September 2004. The upfront license fee has been included in deferred revenue, and it is being recognized as revenue over the twenty year term of the agreement.

Note 8 – Stock Based Compensation

The Company recorded share-based compensation expense of $55,000 and $127,000 for the three and six months ended June 30, 2011, and $118,000 and $323,000 for the three and six months ended June 30, 2010. We will continue to incur share-based compensation charges in future periods. As of June 30, 2011, unamortized share-based compensation expense of $256,000 remains to be recognized, which is comprised of $90,000 related to non-performance based stock options to be recognized over a weighted average period of .46 years, and $166,000 related to performance-based stock options which vest upon reaching certain milestones. Expenses related to the performance-based stock options will be recognized if and when the Company determines that it is probable that the milestone will be reached. No options were exercised during the six month periods ended June 30, 2011 or June 30, 2010.

During the six months ended June 30, 2011 and 2010, employees and non-employee directors of the Company were granted stock options under our 2006 Stock Option Plan per the table below:

Period Ended	Grants Issued	Weighted Average Exercise Price	Weighted Average Fair Value
June 30, 2011	150,000	$ 0.06	$ 0.04
June 30, 2010	900,000	$ 0.19	$ 0.13

Note 9 – Related Party Transactions

In September 2006, the Board of Directors appointed Steven B. Ratoff as Chairman of the Board. In connection with Mr. Ratoff's appointment as Chairman of the Board, the Board entered into a consulting arrangement to compensate Mr. Ratoff for his efforts. This arrangement ended in December 2009. In January 2010, our Board of Directors appointed Steven B. Ratoff as President and Chief Executive Officer. Effective as of August 1, 2011, Mr. Ratoff also serves as our Chief Financial Officer, after the resignation of Craig Johnson, our former Chief Financial Officer.

Mr. Ratoff has served as a venture partner with ProQuest Investments, or ProQuest, since December 2004. Mr. Ratoff has no authority for investment decisions made by ProQuest. As of June 30, 2011, ProQuest owns 34.7 million common shares, or 26%, of our common stock.

Note 10 – Recent Accounting Pronouncements

The FASB has issued Accounting Standards Update (ASU) No. 2011-04, Fair Value Measurement (Topic 820): Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRS. This ASU represents the converged guidance of the FASB and the IASB (the Boards) on fair value measurement. The collective efforts of the Boards and their staffs, reflected in ASU 2011-04, have resulted in common requirements for measuring fair value and for disclosing information about fair value measurements, including a consistent meaning of the term “fair value.” The Boards have concluded the common requirements will result in greater comparability of fair value measurements presented and disclosed in financial statements prepared in accordance with U.S. GAAP and IFRS. The amendments to the FASB Accounting Standards Codification™ (Codification) in this ASU are to be applied prospectively. The amendments are effective during interim and annual periods beginning after December 15, 2011. The Company is in the process of assessing whether the adoption of this ASU will have an impact on its financial statements.

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

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

Overview

Company Overview

NovaDel Pharma Inc. is a specialty pharmaceutical company that develops oral spray formulations of marketed pharmaceutical products. Our patented oral spray drug delivery technology seeks to improve the efficacy, safety, patient compliance, and patient convenience for a broad range of prescription medications. Our products and product candidates are as follows:

	Active Ingredient	Indications	Stage of Development	Partner
Products				
NitroMist®	Nitroglycerin	Angina Pectoris	Market	Akrimax Pharmaceuticals
Zolpimist®	Zolpidem	Insomnia	Market	Hi-Tech Pharmacal
Product Candidates				
Duromist®	Sildenafil	Erectile Dysfunction	Clinical development	—
ZensanaTM	Ondansetron	Nausea/Vomiting	Clinical development	Talon Therapeutics Par Pharmaceutical BioAlliance Pharma Kwang Dong Pharma
NVD-201	Sumatriptan	Migraine headache	Clinical development	—
NVD-301	Midazolam	Pre-Procedure Anxiety	Preclinical development	—

NitroMist®

NitroMist is our oral spray formulation of nitroglycerin. It 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. NitroMist is marketed by Akrimax Pharmaceuticals LLC in the U.S. Akrimax Pharmaceuticals began marketing NitroMist in January 2011. We are eligible to receive royalty payments of up to 17% of net sales. In the second quarter of 2011, we received royalty payments totaling $127,000.

Zolpimist®

Zolpimist is our oral spray formulation of zolpidem. It 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. Zolpimist is marketed by Hi-Tech Pharmacal Co., Inc., through its wholly owned subsidiary ECR Pharmaceuticals Company, Inc., in the U.S. ECR Pharmaceuticals began marketing Zolpimist in February 2011. We are eligible to receive royalty payments of up to 15% of net sales. However, for an initial period of time, we will not receive royalty payments until a specified amount of net sales are generated.

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 version of sildenafil may afford faster onset of therapeutic action, and may allow for a lower dose compared to tablets.

In October 2010, we completed a non-IND pilot pharmacokinetic, or PK, clinical trial comparing Duromist to Viagra. The 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 data from the clinical trial demonstrated that the 20 mg dose (two sprays) of Duromist is bioequivalent to the 25 mg Viagra tablet with respect to systemic exposure, or AUC0-inf. The mean AUC0-inf for the 10 mg dose (one spray) was approximately 40% of the 25 mg Viagra tablet, as expected. The mean AUC0-inf for the 30 mg dose (three sprays) was approximately 40% higher than the 25 mg Viagra tablet, about 20% higher than expected. The increased systemic exposure observed with the 20 and 30 mg oral spray doses, as compared to the 25 mg Viagra tablet, is suggestive of absorption of sildenafil via the oral transmucosal route. The 20 mg dose demonstrated a slightly lower maximum measured plasma concentration, or Cmax, than that of the 25 mg Viagra tablet. The time point at Cmax, or Tmax, for the 20 mg 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.

In February 2011, we had a pre-IND meeting with the FDA. At that meeting we discussed the requirements for opening an IND, as well as the clinical and nonclinical development plan for a new drug application, or NDA, for Duromist. In June 2011, we opened the IND, and for the remainder of 2011 and in 2012, we plan to complete the required clinical and nonclinical work, and file a NDA. In order to carry out this plan we will need to secure additional funding or obtain a development partner.

ZensanaTM

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. We have partnered with Talon Therapeutics, Inc. and Par Pharmaceutical, Inc. for the development and commercialization of Zensana in the U.S. and Canada. Under these agreements, we are eligible to receive milestone payments and royalty payments. However, in November 2008, Par Pharmaceutical, Inc. announced it had completed bioequivalency studies on Zensana with mixed results, and that it had ceased development of the product.

We have also partnered with BioAlliance Pharma SA and Kwang Dong Pharmaceuticals for the development and commercialization of Zensana in Europe and South Korea, respectively. Under these agreements, we are eligible to receive milestone payments and royalty payments. However, product development in Europe and South Korea 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 PK clinical trials evaluating multiple doses of NVD-201 given to healthy adults. We have also completed a pilot efficacy clinical trial of NVD-201. We believe the results from these trials demonstrate NVD-201 is safe and effective in relieving migraine headaches at a dose lower than sumatriptan tablets. In order to pursue further clinical development of this product candidate, 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 prescription medication 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 in the relief of 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 of this product candidate, we will need to secure project financing, equity financing or a development partner.

Veterinary

Our veterinary initiatives are being carried out by our partner, Velcera, Inc., or Velcera. In June 2009, Velcera announced it had entered into a global licensing agreement with a multinational animal health company to develop a pain management product for canines. Under our agreement with Velcera, we are eligible to receive milestone payments and royalty payments.

Going Concern and Management's Plan

Our independent registered public accounting firm has included an explanatory paragraph in their report on our 2010 financial statements related to the uncertainty and substantial doubt of our ability to continue as a going concern.

As of June 30, 2011, we had cash and cash equivalents of $865,000, negative working capital of $3.3 million, and an accumulated deficit of $93.0 million. Based on our operating plan, we expect that our existing cash and cash equivalents will fund our operations only through September 30, 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. Our financial statements do not include any adjustments that may result from the outcome of this uncertainty. This basis of accounting contemplates the recovery of our assets and the satisfaction of liabilities in the normal course of business.

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

Results of Operations

Fluctuations in Operating Results

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

Comparison of the Six Months ended June 30, 2011 and 2010

Revenue earned for the six months ended June 30, 2011 was $257,000 as compared to $195,000 for the six months ended June 30, 2010. The increase was due to a $127,000 royalty received for NitroMist® in the second quarter of 2011 offset by a decrease in milestone fees. In 2011, we did not receive any milestone payments. In 2010, we received a milestone payment of $62,000 from Velcera.

Total operating expenses for the first six months decreased by $376,000, or 13%, from $2,793,000 in 2010 to $2,417,000 in 2011.

Research and development expenses increased by $26,000, or 3%, from $1,006,000 for the six months ended June 30, 2010 to $1,032,000 for the same period in 2011. Research and development expense primarily consists of costs to manufacture our product candidates, fees to contract research organizations for preclinical studies and clinical trials, fees to professional service providers for regulatory and other product development services, allocated salaries and benefits, and allocated facility and administrative costs.

General and administrative expenses decreased by $402,000, or 22%, from $1,787,000 for the six months ended June 30, 2010 to $1,385,000 for the same period in 2011. General and administrative expenses consist primarily of salaries and related expenses for executive, finance and administrative personnel, professional fees, facility costs, and other corporate expenses. The decrease is primarily attributable to reduced professional fees reflecting reduced usage of outside financial services and lower legal costs. Reductions in personnel costs, due to a decrease in headcount, as well as reduced facility costs, due to the relocation of our offices also contributed to lower expenses.

Change in derivative liability for the six months ended June 30, 2011 was $3,684,000, all of which was non-cash income. The derivative liability is related to warrants issued in conjunction with our convertible preferred stock offering in February 2011 and our common stock offering in March 2010. The income reflects a decline in the fair value of the underlying warrants as of June 30, 2011 and is attributed primarily to a decline in the stock price as of June 30, 2011 from prior valuation dates. For the six months ended June 30, 2010, the change in derivative liability was $181,000 and related to our common stock offering in March 2010.

Interest expense for the six months ended June 30, 2011 was $9,148,000 and related to our convertible preferred stock offering. Discounts exceeding the fair value of the convertible preferred stock of $7,066,000 were recorded as interest expense and primarily represent the original fair value of the warrants. The discounts to the convertible preferred stock are accreted to interest expense as the convertible preferred stock is converted into common shares. The discount accreted to interest expense for the six months ended June 30, 2011 was $1,667,000. Additionally, the convertible preferred stock issuance costs are amortized to interest expense as the convertible preferred stock is converted into common stock. Total costs amortized to interest expense for the six months ended June 30, 2011 were $415,000.

The resulting net loss for the six months ended June 30, 2011 was $7,597,000 as compared to $2,418,000 for the six months ended June 30, 2010.

Comparison of the Three Months ended June 30, 2011 and 2010

Revenue earned for the three months ended June 30, 2011 was $192,000 as compared to $66,000 for the three months ended June 30, 2010. The increase was due to a $127,000 royalty received for NitroMist in the second quarter of 2011.

Total operating expenses for the three months ended June 30, 2011 decreased by $257,000, or 19%, from $1,372,000 in 2010 to $1,115,000 in 2011.

Research and development expenses decreased by $147,000, or 26%, from $559,000 for the three months ended June 30, 2010 to $412,000 for the same period in 2011. Research and development expense primarily consists of costs to manufacture our product candidates, fees to contract research organizations for preclinical studies and clinical trials, fees to professional service providers for regulatory and other product development services, allocated salaries and benefits, and allocated facility and administrative costs. The decrease is attributable to cost containment measures in an effort to preserve cash.

General and administrative expenses decreased by $110,000, or 14%, from $813,000 for the three months ended June 30, 2010 to $703,000 for the same period in 2011. General and administrative expenses consist primarily of salaries and related expenses for executive, finance and administrative personnel, professional fees, facility costs, and other corporate expenses. The decrease is primarily attributable to reduced professional fees reflecting reduced usage of outside financial services and lower legal costs. Reductions in personnel costs, due to a decrease in headcount, as well as reduced facility costs, due to the relocation of our offices also contributed to lower expenses.

Change in derivative liability for the three months ended June 30, 2011 was $2,427,000, all of which was non-cash expense. The derivative liability is related to warrants issued in conjunction with our convertible preferred stock offering in February 2011 and our common stock offering in March 2010. The expense reflects an increase in the fair value of the underlying warrants as of June 30, 2011 as compared to the fair value at March 31, 2011, and is attributed primarily to an increase in the stock price between those periods. For the three months ended June 30, 2010, the change in derivative liability was $181,000 and related to our common stock offering in March 2010.

Interest expense for the three months ended June 30, 2011 was $875,000 and related to our convertible preferred stock offering. The discounts to the convertible preferred stock are accreted to interest expense as the convertible preferred stock is converted into common shares. The discount accreted to interest expense for the three months ended June 30, 2011 was $701,000. Additionally, the convertible preferred stock issuance costs are amortized to interest expense as the convertible preferred stock is converted into common stock. Total costs amortized to interest expense for the three months ended June 30, 2011 were $174,000.

The resulting net loss for the three months ended June 30, 2011 was $5,019,000 as compared to $1,126,000 for the three months ended June 30, 2010.

Liquidity and Capital Resources

From inception through June 30, 2011, we have incurred a cumulative net loss of $93.0 million. We have financed our operations primarily through public and private offerings of securities, revenue from strategic partnership agreements, and proceeds from loans and capital contributions from our principal stockholders.

Our cash used in operating activities was $1,413,000 and $1,063,000 for the six months ended June 30, 2011 and 2010, respectively. The increase in cash used was primarily due to the $1,057,000 received from the sale of net operating losses in first quarter 2010 which sale did not reoccur in 2011. This was partially offset by non-cash charges associated with our February 2011 convertible preferred stock offering, the collection of $744,000 in receivables and an increase in accrued expenses in the first quarter of 2011. Net cash flows provided by financing activities were $1,378,000 for the six months ended June 30, 2011, and resulted from $1,237,000 in net proceeds received relating to issuance of convertible preferred stock and warrants in the first quarter 2011 and $141,000 in proceeds from warrant exercises in the second quarter of 2011.

As of June 30, 2011, we had cash and cash equivalents of $865,000, negative working capital of $3.3 million, and an accumulated deficit of $93.0 million. Based on our operating plan, we expect that our existing cash and cash equivalents will fund our operations only through September 30, 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. Our financial statements do not include any adjustments that may result from the outcome of this uncertainty. This basis of accounting contemplates the recovery of our assets and the satisfaction of liabilities in the normal course of business.

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

Critical Accounting Policies and Estimates

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

results may differ from these estimates under different assumptions or conditions.

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

Revenue Recognition

We receive revenue from our license agreements. Upfront non-refundable license fees are recognized as earned, or they are deferred and subsequently recognized into revenue on a straight-line basis over the contracted or estimated period of performance, which is typically the contractual term. Milestone payments are recognized on achievement of the milestone, unless the amounts received are creditable against royalties or we have on-going performance obligations. Royalty payments are recognized on sale of the related product, provided the royalty amounts are fixed and determinable, and collection of the related receivable is probable.

Accrued Expenses

We are required to estimate accrued expenses as part of preparing our financial statements. This process involves identifying services which have been performed on our behalf, and estimating the level of service performed and the associated cost incurred for such service as of each balance sheet date in our financial statements. Examples of services for which we must estimate accrued expenses include contract service fees paid to contract manufacturers in conjunction with the production of clinical drug supplies and to contract research organizations in connection with our preclinical studies and clinical trials. In connection with such service fees, our estimates are most affected by our understanding of the status and timing of services provided. The majority of our service providers invoice us in arrears for services performed. In the event that we do not identify certain costs which have been incurred, or we under- or over-estimate the level of services performed or the costs of such services in a given period, our reported expenses for such period would be too low or too high. The date on which certain services commence, the level of services performed on or before a given date, and the cost of such services are often determined based on subjective judgments. We make these judgments based upon the facts and circumstances known to us. Through the date of this filing, we have been able to reasonably estimate these costs; however, if we increase the level of services performed on our behalf, it will become increasingly more difficult for us to estimate these costs, which could result in our reported expenses for future periods being too high or too low.

Stock-Based Compensation

We grant equity based awards under stock-based compensation plans. We estimate the fair value of stock options granted using the Black-Scholes option valuation model. This fair value is then amortized over the requisite service periods of the awards. The Black-Scholes option valuation model requires the input of subjective assumptions, including the option’s expected life, price volatility of the underlying stock, risk free interest rate, and expected dividend rate. As stock-based compensation expense is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Forfeitures are estimated based on historical experience. Changes in assumptions used under the Black-Scholes option valuation model could materially affect our net loss and net loss per share.

Derivative Financial Instruments

We recognize all derivative financial instruments as assets or liabilities in the financial statements and measure them at fair value with changes in fair value reflected as current period income or loss unless the derivatives qualify as hedges. As a result, certain warrants are now accounted for as derivatives.

Recent Accounting Pronouncements

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

Off-Balance Sheet Arrangements

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk

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

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures or controls and other procedures that are designed to ensure that the information required to be disclosed by us in the reports that we file or submit under the Securities Exchange Act of 1934, or Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission, or SEC, rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in the reports that a company files or submits under the Exchange Act is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate to allow timely decisions regarding required disclosure.

We carried out an evaluation, under the supervision and with the participation of our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) and Rule 15d-15(e) of the Exchange Act) as of June 30, 2011. Based on this evaluation, our principal executive officer and principal financial officer concluded that as of June 30, 2011, our disclosure controls and procedures were effective at providing reasonable assurance that the information required to be disclosed by us in reports filed under the Exchange Act is (i) recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms; and (ii) accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate, to allow timely decisions regarding disclosure.

Changes in Internal Controls Over Financial Reporting

During the quarter ended June 30, 2011, there were no changes in our internal control over financial reporting (as defined in Rule 13a-15(f) and Rule 15d-15(f) under the Exchange Act) that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1A. Risk Factors

This report contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those discussed in this report. Factors that could cause or contribute to these differences include, but are not limited to, those discussed below, elsewhere in this report, and in any documents incorporated in this report by reference.

Risks Related to Our Business

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

Our audited financial statements as of and for the year ended December 31, 2010 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 2010 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.

Since 2007, we significantly reduced expenditures on our approved products and our product candidate pipeline. During the quarter ended June 30, 2011, we utilized capital primarily to progress development for our product candidate Duromist. During the remainder of 2011, we intend to use additional capital to complete the clinical trials for Duromist and file a New Drug Application for product approval. 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.

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 2011 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.

As of June 30, 2011, we had $865,000 in cash and cash equivalents. Based on our operating plan, we expect that our existing cash and cash equivalents will fund our operations only through September 30, 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. 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.

We have incurred losses since inception and we may continue to incur losses for the foreseeable future. Royalty revenues for products which we license out are dependent upon the commercialization efforts of our partners, including the sales and marketing efforts of Akrimax relating to NitroMist and HiTech Pharmacal relating to Zolpimist.

We had an accumulated deficit as of June 30, 2011 of approximately $93.0 million and we incurred losses in each of our last three fiscal years, including net losses of approximately $2,666,000 for the year ended December 31, 2010, $7,577,000 for the year ended December 31, 2009 and $9,586,000 for the year ended December 31, 2008. Additionally, we have reported negative cash flows from operations of $3,280,000 for the year ended December 31, 2010, $1,578,000 for the year ended December 31, 2009 and $5,533,000 for the year ended December 31, 2008. 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 product candidates, and administrative costs associated with operating as a SEC registrant. We 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 receive royalty revenue from the sale of our products and achieve profitability is dependent on a number of factors, including our ability to complete the development of our product candidates, obtain the required regulatory approvals and the successful commercialization of our product candidates by us or commercial partners. Our licensees for NitroMist and Zolpimist commercially launched these products in January 2011. We have not generated significant royalty revenue from the commercial sale of NitroMist and Zolpimist, and do not expect to generate significant royalty revenue from the sale of these approved products in the future. In addition, we cannot be certain as to when to anticipate commercializing and marketing any of our other product candidates in development, if at all, and cannot be certain whether we will generate any royalty revenue from the sale of these product candidates in the future.

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 to secure additional 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 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.

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

Our future growth and profitability will be dependent upon our ability 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.

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 direct consumer marketing experience.

We have no experience in the marketing or distribution of pharmaceutical products at the consumer level. 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, license or distribution arrangements with third-parties. Except for our agreements with Kwang Dong, Akrimax, HiTech Pharmacal, BioAlliance, Par, Velcera and Talon, 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 products and 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.

With the exception of DPT Laboratories, we operate primarily on a purchase order basis with suppliers where 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 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.

We face intense competition.

There is intense competition in our market. 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. In addition, these companies and others are developing or may, in the future, engage in the development of products competitive with our products. Many of these companies possess greater marketing capabilities than we do, including the resources necessary to enable them to implement extensive advertising campaigns. Additionally, prices of drug products are significantly affected by competitive factors and tend to decline as competition increases. We expect that technological developments will occur at a rapid rate and that competition is likely to intensify as enhanced dosage form technologies gain greater acceptance. 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 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. The mere existence of a product liability claim could affect the market price of our common stock. In addition, certain food and drug retailers require minimum product liability insurance coverage as a condition precedent to purchasing or accepting products for retail distribution. Product liability insurance coverage includes various deductibles, limitations and exclusions from coverage, and in any event might not fully cover any potential claims. Failure to satisfy such insurance requirements could impede the ability of us or our distributors to achieve broad retail distribution of our product candidates, which could have a material adverse effect on us.

Extensive government regulation may affect our business.

The development, manufacture and commercialization of pharmaceutical products is generally subject to extensive regulation by various federal and state governmental entities. The FDA, which is the principal U.S. regulatory authority over pharmaceutical products, has the power to seize adulterated or misbranded products and unapproved new drugs, to request their recall from the market, to enjoin further manufacture or sale, to publicize certain facts concerning a product and to initiate criminal proceedings. As a result of federal statutes and FDA regulations pursuant to which new pharmaceuticals are required to undergo extensive and rigorous testing, obtaining pre-market regulatory approval requires extensive time and expenditures. Under the Federal Food, Drug, and Cosmetic Act, or FFDCA, as amended (21 U.S.C. 301 et. seq.), a new drug may not be commercialized or otherwise distributed in the U.S. without the prior approval of the FDA or pursuant to an applicable exemption from the FFDCA. The FDA approval processes relating to new drugs differ, depending on the nature of the particular drug for which approval is sought. Given that our current product candidates are based on a new technology for formulation and delivery of active pharmaceutical ingredients that have been previously approved and that have been shown to be safe and effective in previous clinical trials, we believe that we will be eligible to submit what is known as a 505(b)(2) NDA. We estimate that the development of new formulations of 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 agreements, 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.

We have entered into strategic license agreements with: (i) Talon, for the development and marketing rights in the U.S. and Canada which were subsequently sublicensed to Par for our ondansetron oral spray Zensana, (ii) Velcera, in connection with veterinary applications for currently marketed veterinary drugs, (iii) BioAlliance Pharma SA, for the European rights for ondansetron oral spray Zensana, (iv) Mist Acquisition, LLC, for the manufacturing and commercialization rights in the United States, Canada and Mexico for our lingual spray version of nitroglycerine, NitroMist, (v) ECR Pharmaceuticals Company, for the manufacturing and commercialization rights in the United States and Canada for our oral spray formulation of zolpidem tartrate, Zolpimist, and (vi) Kwang Dong Pharmaceuticals, for the South Korean rights for ondansetron oral spray Zensana.

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 Talon regarding the development of Zensana. We cannot assure you that Par or Talon 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:

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

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

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

Section 505(b)(2) of the FFDCA was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, otherwise known as the Hatch-Waxman Act. Section 505(b)(2) permits the submission of a 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 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.

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.

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 and new regulations promulgated by the Securities and Exchange Commission, or SEC, 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.

There are certain interlocking relationships and potential conflicts of interest.

Mr. Steven B. Ratoff, our Chairman, President, Chief Executive Officer and Interim Chief Financial Officer, has a relationship both with us as well as with certain of our affiliates, which creates the potential for a perceived conflict of interest. As of June 30, 2011, ProQuest Investments II, L.P., ProQuest Investments II Advisors Fund, L.P., and ProQuest Investments III, L.P., collectively referred to herein as ProQuest, directly and indirectly, beneficially owns approximately 38% of our outstanding common stock (assuming full exercise of the warrants held by ProQuest). As such, ProQuest may be deemed to be our affiliate. This determination of affiliate status is not necessarily a conclusive determination for other purposes. Mr. Ratoff has served as a venture partner with ProQuest since December 2004. However, he has no authority for investment decisions by ProQuest.

As a result of this and other relationships, the potential for perceived conflicts of interest exists. In addition, in the event that we become involved in stockholder litigation regarding these potential conflicts, we might be required to devote significant resources and management time defending the company from these claims, which could adversely affect our results of operations.

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.

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. Our certificate of incorporation allows us to issue shares of preferred stock without any vote or further action by our common stockholders. Our Board has the authority to fix and determine the relative rights and preferences of such 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.

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.

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.

Because our common stock is quoted on the Over-the-Counter Bulletin Board, or 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 Equities or another national securities exchange.

We are influenced by current stockholders, officers and directors.

Our directors, executive officers and principal stockholders have the ability to influence corporation actions, including the election of our directors and most other stockholder actions and significant corporate events. As of June 30, 2011, our directors, executive officers and principal stockholders own approximately 27% of our common stock. Specifically, ProQuest has the ability to exert significant influence over matters submitted to our stockholders for approval. Such position 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.

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 specialty 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 SEC from time to time.

During the six months ended June 30, 2011, the closing price of our common stock has ranged from $0.04 to $0.22. 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.

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 result in dilution or adversely affect the market.

We are authorized to issue a total of 750,000,000 shares of common stock and 1,000,000 shares of preferred stock. Such securities may be issued without the approval or other consent of our stockholders. As of June 30, 2011, there were 133,590,615 shares of common stock issued and outstanding. However, the total number of shares of our common stock issued and outstanding does not include shares reserved in anticipation of the exercise of options or warrants.

As of June 30, 2011, we had outstanding stock options and warrants to purchase approximately 103.5 million shares of common stock, the exercise prices of which range between $0.035 per share and $3.18 per share. We have reserved shares of our common stock for issuance in connection with the potential exercises thereof. In addition, as of June 30, 2011, 720,000 and 10,281,000 shares remain available for issuance under the 1998 Stock Option Plan and the 2006 Equity Incentive Plan, respectively.

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

While we have no present plans to issue any additional 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 sell their securities provided that (i) such person is not deemed to have been one of our affiliates at the time of, or at any time during the three months preceding, a sale and (ii) we are subject to the Exchange Act periodic reporting requirements for at least three months before the sale. A person who has beneficially owned restricted shares of our common stock for at least six months but who is also our affiliate at the time of, or at any time during the three months preceding, a sale would be subject to additional restrictions, by which such person would be entitled to 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. Sales both by affiliates and by non-affiliates may also need to comply with the manner of sale, current public information and notice provisions of Rule 144.

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.

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.

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 or securities convertible into our common stock to investors.

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

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

- The depth and liquidity of the markets for our common stock;
- Investor perception of us and the industry in which we participate; and
- General economic and market conditions.

As of June 30, 2011, we have 133,590,615 shares of common stock issued and outstanding and approximately 103.5 million shares of common stock issuable upon the exercise of outstanding stock options and warrants.

In the event we wish to offer and sell shares of our common stock in excess of the 750,000,000 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.

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.

Item 6. Exhibits

INDEX TO EXHIBITS

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

Exhibit No.	Description	Method of Filing
3.1	Certificate of Amendment to the Certificate of Incorporation of the Company	Filed herewith.
10.1	Form of Consent Agreement by and among the Company and certain investors	Incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed on May 31, 2011.
31.1	Certification of Principal Executive, Financial and Accounting Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	Filed herewith.
32.1	Certification of the Principal Executive, Financial and Accounting Officer under 18 USC 1350, Section 1330 as adopted, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	Furnished.
101.INS	XBRL Instance Document	
101.SCH	XBRL Taxonomy Extension Schema Document	
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document	
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document	
101.LAB	XBRL Taxonomy Extension Label Linkbase Document	
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document	

SIGNATURES

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

NovaDel Pharma Inc.

Date: August 12, 2011 By: /s/ Steven B. Ratoff
Steven B. Ratoff
President, Chief Executive Officer
and Interim Chief Financial Officer
(principal executive, financial and
accounting officer)