NOVADEL PHARMA INC
Form S-1/A
February 04, 2011

As filed with the Securities and Exchange Commission on February 4, 2011

Registration Statement No. 333-170066

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

Amendment No. 3
to
Form S-1

REGISTRATION STATEMENT
UNDER THE SECURITIES ACT OF 1933

NOVADEL PHARMA INC.
(Exact name of Registrant as Specified in Its Charter)

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

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

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

Copies to:

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502 Carnegie Center	**65 Livingston Avenue**
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(609) 919-6600	**(973) 597-2383**

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

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

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

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

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

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

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

(cover continued on next page)

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

(cover continued from previous page)

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to Be Registered	Proposed Maximum Aggregate Offering Price[2]	Amount of Registration Fee
Convertible Preferred Stock, $0.001 par value	$ 4,000,000	$ 464.40
Common Stock underlying Convertible Preferred Stock[1]		(3)
Warrants	$ 4,000,000	$ 464.40
Placement Agent Warrants	$ 80,000	$ 9.30
Total	$ 8,080,000	$ 938.10 (4)

(1) Pursuant to Rule 416, the securities being registered hereunder include such indeterminate number of additional shares of common stock as may be issuable upon conversion of the convertible preferred stock registered hereunder as a result of stock splits, stock

dividends, or similar transactions.

(2) Estimated solely for the purpose of computing the registration fee pursuant to Rule 457(o).

(3) No additional consideration is payable upon conversion of the Convertible Preferred Stock or upon issuance of the Warrants.

(4) Of this fee, (i) $713.00 was previously paid in connection with the initial filing of this Registration Statement on Form S-1 (File No. 333-170066), which was filed by the registrant on October 21, 2010, (ii) $285.20 was previously paid in connection with Amendment No. 1 to the

Registration Statement on Form S-1 (File No. 333-170066), which was filed by the registrant on November 5, 2010, and (iii) $23.22 was previously paid in connection with Amendment No. 2 to the Registration Statement on Form S-1 (File No. 333-170066), which was filed by the registrant on January 14, 2011.

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

Subject to Completion, dated February 4, 2011

PROSPECTUS

UP TO 4,000 SHARES OF SERIES A CONVERTIBLE PREFERRED STOCK AND UP TO 40,000,000 SHARES OF COMMON STOCK UNDERLYING THE CONVERTIBLE PREFERRED STOCK, TOGETHER WITH WARRANTS TO PURCHASE UP TO 40,000,000 SHARES OF COMMON STOCK

We are offering up to 4,000 shares of our Series A Convertible Preferred Stock, referred to herein as the convertible preferred stock, convertible into up to 40,000,000 shares of our common stock, par value $0.001 per share, together with Warrants to purchase up to 40,000,000 shares of our common stock, to purchasers in this offering. The maximum number of shares of common stock underlying the convertible preferred stock and the warrants issued in this offering is 80,000,000; provided, however, we are not registering the 40,000,000 shares issuable upon exercise of the warrants. Each share of convertible preferred stock we sell will be accompanied by a warrant to purchase one (1) share of common stock for each share of common stock issuable upon conversion of the preferred stock. The convertible preferred stock is convertible at any time at the option of the holder into shares of our common stock at a conversion ratio determined by dividing the stated value of the convertible preferred stock by a conversion price of $[*] per share. The warrants will be exercisable on the first anniversary following the issuance date so long as we obtain stockholder approval to increase the number of authorized shares of our common stock to effect such exercise and will be exercisable on or before the fifth year anniversary of their initial exercise date at an exercise price of $[*] per share of common stock. Each share of convertible preferred stock and the accompanying warrant will be sold at a assumed price of $1,000. The convertible preferred stock and warrants are immediately separable and will be issued separately.

Our common stock is presently quoted on the Over-the-Counter Bulletin Board under the symbol NVDL.OB We do not intend to apply for listing of the convertible preferred stock and warrants on any securities exchange or market. On February 3, 2011, the last reported sale price of our common stock as reported by the Over-the-Counter Bulletin Board was $0.17 per share.

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

	Per Share	Total
Offering Price per Share	$ [ ]	$ [ ]
Placement Agent s Fees	$ [ ]	$ [ ]
Offering Proceeds before expenses	$ [ ]	$ [ ]

Roth Capital Partners has agreed to act as our exclusive placement agent in connection with this offering. Roth may engage one or more sub placement agents or selected dealers. The placement agent is not purchasing the securities offered by us, and is not required to sell any specific number or dollar amount of securities, but will assist us in this offering on a best efforts basis. We have agreed to pay the placement agent a cash fee equal to 6% of the gross proceeds of the offering of securities by us, as well as Placement Agent Warrants to purchase shares of Common Stock of the Company equal to 2% of the aggregate number of shares of Common Stock issuable in the offering. The Placement Agent Warrants will be substantially on the same terms as the warrants offered hereby. We estimate the

total expenses of this offering, excluding the placement agent fees, will be approximately $[ ]. Because there is no minimum offering amount required as a condition to closing in this offering, the actual public offering amount, placement agent fees, and proceeds to us, if any, are not presently determinable and may be substantially less than the total maximum offering amounts set forth above. See Plan of Distribution beginning on page 84 of this prospectus for more information on this offering and the placement agent arrangements. All costs associated with the registration will be borne by us.

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

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

Roth Capital Partners

The date of this prospectus is _____, 2011.

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

FOR INVESTORS OUTSIDE THE UNITED STATES: We have not done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required,

other than in the United States. You are required to inform yourselves about, and to observe any restrictions relating to, this offering and the distribution of this prospectus.

PROSPECTUS SUMMARY

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

Overview

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

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

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

NitroMist®

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

Zolpimist™

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

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

Duromist™

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

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

Zensana™

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

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

NVD-201

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

NVD-301

NVD-301 is our oral spray formulation of midazolam. Midazolam is a leading benzodiazepine used for sedation during diagnostic, therapeutic and endoscopic procedures. We believe that NVD-301 has the potential to be an

easy-to-use, rapid onset product useful to relieve the

pre-procedure anxiety suffered by many patients prior to undergoing a wide variety of procedures performed in hospitals, imaging centers, ambulatory surgery centers and dental offices. In order to pursue further clinical development, we will need to secure project financing, equity financing or a development partner.

Going Concern and Management s Plan

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

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

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

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

Corporate Information

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

SUMMARY OF THE OFFERING

Securities offered:	Up to 4,000 shares of our convertible preferred stock (convertible into up to 40,000,000 shares of our common stock) together with warrants to purchase up to 40,000,000 shares of our common stock. The maximum number of shares of common stock underlying the convertible preferred stock and the warrants issued in this offering is 80,000,000; provided, however, we are not registering the 40,000,000 shares issuable upon exercise of the warrants as described further under Description of the Securities Description of Warrants. Each share of convertible preferred stock we sell will be accompanied by a warrant to purchase one (1) share of common stock for each share of common stock issuable upon conversion of the preferred stock.
Convertible Preferred Stock:	The convertible preferred stock is convertible at any time at the option of the holder into shares of our common stock at a conversion ratio determined by dividing the stated value of the convertible preferred stock by a conversion price of $[*] per share.
Description of Warrants:	The warrants will be exercisable on the first anniversary following the issuance date so long as we obtain stockholder approval to increase the number of authorized shares of our common stock to effect such exercise and will be exercisable on or before the fifth year anniversary of their initial exercise date at an exercise price of $[*] per share of common stock. We do not have a sufficient number of authorized shares to permit full exercise of the warrants. The exercisability of the warrants will be subject to receipt by us of stockholder approval to effect an amendment to our certificate of incorporation to increase our authorized shares to an amount sufficient to permit full exercise of the warrants. See Description of the Securities Description of Warrants.
Common stock outstanding prior to the offering:	98,383,458 shares.
Common stock outstanding after the offering:	178,383,458 shares, assuming all of the convertible preferred stock and the warrants are sold and are fully converted into shares of common stock.
Use of proceeds:	We expect to use the proceeds received from the offering to further clinical development of Duromist and our other product candidates, and for working capital and other general corporate purposes.
OTCBB Symbol:	NVDL.OB
Risk Factors:	See Risk Factors beginning on page 7 and the other information in this prospectus for a discussion of the factors you should consider before you decide to invest in the securities.

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

- 40,000,000 shares of common stock issuable upon exercise of the warrants offered hereby;
- 800,000 shares of common stock issuable upon exercise of warrants issued to the placement agent in connection with this offering;
- 8,659,243 shares of common stock issuable upon exercise of stock options outstanding as of September 30, 2010 under our stock option plans at a weighted average exercise price of $0.73 per

share;

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

10,651,257 additional shares of common stock reserved for future issuance under our 1998 Stock Option Plan and 2006 Equity Incentive Plan, as amended.

SUMMARY OF SELECTED FINANCIAL INFORMATION

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

	Nine months ended September 30,		Year ended December 31,		
	2010	2009	2009	2008	2007
	(unaudited)				
Consolidated Statements of Operations Data					
Total Revenues	$ 261,000	$ 356,000	$ 422,000	$ 361,000	$ 469
Total Expenses	4,382,000	5,147,000	6,517,000	8,951,000	18,656
Loss from Operations	(4,121,000)	(4,791,000)	(6,095,000)	(8,590,000)	(18,187
Other Income (Expense), net	391,000	301,000	(385,000)		(66
Interest Expense	1,000	717,000	2,160,000	1,868,000	
Interest Income	1,000	6,000	6,000	137,000	632
Income Tax Benefit			(1,057,000)	(735,000)	(658
Net Loss	$ (3,730,000)	$ (5,201,000)	$ (7,577,000)	$ (9,586,000)	$ (16,963
Basic and Diluted Loss Per Common Share	$ (0.04)	$ (0.09)	$ (0.12)	$ (0.16)	$
Weighted Average Number of Shares of Common Stock Used in Computation of Basic and Diluted Loss	94,786,590	60,458,548	61,346,000	59,592,000	59,497

Per Share

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

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RISK FACTORS

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

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

Risks Related to Our Business

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

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

We will require significant additional capital to fund our operations.

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

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

On October 27, 2009, we entered into a license and distribution agreement with privately-held Mist Acquisition, LLC to manufacture and commercialize NitroMist, our lingual spray version of nitroglycerine, a widely-prescribed and leading short-acting nitrate for the treatment of angina pectoris. Under the terms of the agreement, we received an upfront payment of $1,000,000, a milestone payment of $500,000 in October 2010 and a milestone payment of $500,000 in January
2011. We are also eligible to receive royalty payments of up to seventeen percent (17%) of net sales.

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

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

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

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

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

On March 31, 2010, we received approximately $1.5 million in gross proceeds from our registered dir