

U.S. SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

[mark one]

QUARTERLY REPORT UNDER SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended: September 30, 2008

TRANSITION REPORT UNDER SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission File Number 333-119366

NOVELOS THERAPEUTICS, INC.

(Exact name of small business issuer as specified in its charter)

DELAWARE

*(State or other jurisdiction of
incorporation or organization)*

04-3321804

*(IRS Employer
Identification No.)*

One Gateway Center, Suite 504, Newton, Massachusetts 02458

(Address of principal executive offices)

(617) 244-1616

(Issuer's telephone number, including area code)

(Former name, former address, if changed since last report)

Check whether the issuer (1) filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the past 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 No

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

Number of shares outstanding of the issuer's common stock as of the latest practicable date: 43,975,656 shares of common stock, \$.00001 par value per share, as of November 1, 2008.

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

Smaller reporting company

(Do not check if a smaller reporting company)

NOVELOS THERAPEUTICS, INC.

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

NOVELOS THERAPEUTICS, INC.

BALANCE SHEETS

	September 30, 2008 (unaudited)	December 31, 2007 (audited)
ASSETS		
CURRENT ASSETS:		
Cash and equivalents	\$ 4,206,474	\$ 9,741,518
Restricted cash	—	1,184,702
Prepaid expenses and other current assets	196,215	133,281
Total current assets	4,402,689	11,059,501
FIXED ASSETS, NET	45,385	32,809
DEPOSITS	15,350	15,350
TOTAL ASSETS	\$ 4,463,424	\$ 11,107,660
LIABILITIES AND STOCKHOLDERS' DEFICIENCY		
CURRENT LIABILITIES:		
Accounts payable and accrued liabilities	\$ 5,620,499	\$ 6,372,478
Accrued compensation	247,204	349,412
Accrued dividends	1,060,935	337,500
Deferred revenue – current	33,333	—
Total current liabilities	6,961,971	7,059,390
DEFERRED REVENUE – NONCURRENT	441,667	—
COMMITMENTS AND CONTINGENCIES		
REDEEMABLE PREFERRED STOCK:		
Series D convertible preferred stock, \$0.00001 par value; 420 shares designated; 413.5 shares issued and outstanding at September 30, 2008 (liquidation preference \$21,605,375 at September 30, 2008) (Note 2)	13,904,100	—
Series B convertible preferred stock, \$0.00001 par value; 400 shares designated; 300 shares issued and outstanding at December 31, 2007 (Note 2)	—	9,918,666
	13,904,100	9,918,666
STOCKHOLDERS' DEFICIENCY:		
Preferred stock, \$0.00001 par value; 7,000 shares authorized: Series C 8% cumulative convertible preferred stock; 272 shares issued and outstanding at September 30, 2008 and December 31, 2007 (liquidation preference \$3,394,560 at September 30, 2008) (Note 2)	—	—
Common stock, \$0.00001 par value; 150,000,000 shares authorized; 43,975,656 shares issued and outstanding at September 30, 2008; 39,260,272 shares issued and outstanding at December 31, 2007	440	392
Additional paid-in capital	40,709,468	37,370,959
Accumulated deficit	(57,554,222)	(43,241,747)
Total stockholders' deficiency	(16,844,314)	(5,870,396)
TOTAL LIABILITIES, REDEEMABLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIENCY	\$ 4,463,424	\$ 11,107,660

See notes to financial statements.

NOVELOS THERAPEUTICS, INC.
STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	<u>2008</u>	<u>2007</u>	<u>2008</u>	<u>2007</u>
REVENUE	\$ 35,513	\$ —	\$ 89,523	\$ —
COSTS AND EXPENSES:				
Research and development	1,971,501	5,910,849	12,929,184	11,620,579
General and administrative	622,347	734,212	1,602,120	1,978,184
Total costs and expenses	<u>2,593,848</u>	<u>6,645,061</u>	<u>14,531,304</u>	<u>13,598,763</u>
LOSS FROM OPERATIONS	<u>(2,558,335)</u>	<u>(6,645,061)</u>	<u>(14,441,781)</u>	<u>(13,598,763)</u>
OTHER INCOME:				
Interest income	21,344	228,368	122,556	575,753
Miscellaneous	2,250	1,880	6,750	4,880
Total other income	<u>23,594</u>	<u>230,248</u>	<u>129,306</u>	<u>580,633</u>
NET LOSS	(2,534,741)	(6,414,813)	(14,312,475)	(13,018,130)
PREFERRED STOCK DIVIDENDS	(530,467)	(402,780)	(1,463,715)	(758,340)
PREFERRED STOCK DEEMED DIVIDENDS	—	—	(4,417,315)	(9,003,083)
NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS	<u>\$ (3,065,208)</u>	<u>\$ (6,817,593)</u>	<u>\$ (20,193,505)</u>	<u>\$ (22,779,553)</u>
BASIC AND DILUTED NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS PER COMMON SHARE	<u>\$ (0.07)</u>	<u>\$ (0.17)</u>	<u>\$ (0.50)</u>	<u>\$ (0.58)</u>
WEIGHTED AVERAGE SHARES USED IN COMPUTING BASIC AND DILUTED NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS PER COMMON SHARE	<u>41,667,964</u>	<u>39,258,913</u>	<u>40,132,085</u>	<u>39,243,239</u>

See notes to financial statements.

NOVELOS THERAPEUTICS, INC.
STATEMENTS OF CASH FLOWS
(Unaudited)

	Nine Months Ended September 30,	
	2008	2007
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (14,312,475)	\$ (13,018,130)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	11,955	10,015
Loss on disposal of fixed assets	6,472	—
Stock-based compensation	330,296	436,975
Changes in:		
Prepaid expenses and other current assets	(62,934)	89,484
Accounts payable and accrued liabilities	(751,979)	3,458,046
Accrued compensation	(102,208)	(18,730)
Deferred revenue	475,000	—
Cash used in operating activities	<u>(14,405,873)</u>	<u>(9,042,340)</u>
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of property and equipment	(31,003)	(22,674)
Change in restricted cash	1,184,702	1,507,251
Deposits	—	(4,475)
Cash provided by investing activities	<u>1,153,699</u>	<u>1,480,102</u>
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock, net	2,986,738	—
Proceeds from issuance of Series B convertible preferred stock and warrants, net	—	13,693,051
Proceeds from issuance of Series D convertible preferred stock and warrants, net	5,469,672	—
Dividends paid to preferred stockholders	(740,280)	(758,340)
Payment to preferred stockholders in connection with exchange of shares (1)	—	(40,000)
Proceeds from exercise of stock option	1,000	250
Cash provided by financing activities	<u>7,717,130</u>	<u>12,894,961</u>
INCREASE (DECREASE) IN CASH AND EQUIVALENTS	(5,535,044)	5,332,723
CASH AND EQUIVALENTS AT BEGINNING OF YEAR	<u>9,741,518</u>	<u>9,938,428</u>
CASH AND EQUIVALENTS AT END OF PERIOD	<u>\$ 4,206,474</u>	<u>\$ 15,271,151</u>
SUPPLEMENTAL DISCLOSURE OF NON-CASH INVESTING AND FINANCING ACTIVITIES		
Deemed dividends on preferred stock	<u>\$ 4,417,315</u>	<u>\$ 8,963,083</u>
Dividends accrued but not paid to preferred stockholders	<u>\$ 1,060,935</u>	<u>\$ —</u>
Issuance of warrants to preferred stockholders	<u>\$ 1,302,592</u>	<u>\$ 3,774,385</u>
Exchange of Series B for Series D preferred stock	<u>\$ 9,918,666</u>	<u>\$ —</u>
Issuance of warrants to placement agents	<u>\$ —</u>	<u>\$ 768,621</u>

(1) Included as a deemed dividend in the Statement of Operations.

See notes to financial statements.

Novelos Therapeutics, Inc.
Notes to Financial Statements

1. NATURE OF BUSINESS, BASIS OF PRESENTATION

Novelos Therapeutics, Inc. (“Novelos” or the “Company”) is a drug development company focused on the development of therapeutics for the treatment of cancer and hepatitis. Novelos owns exclusive worldwide intellectual property rights (excluding Russia and other states of the former Soviet Union) related to certain clinical compounds and other pre-clinical compounds based on oxidized glutathione.

The Company is subject to a number of risks similar to those of other companies in an early stage of development. Principal among these risks are dependence on key individuals, competition from substitute products and larger companies, the successful development and marketing of its products in a highly regulated environment and the need to obtain additional financing necessary to fund future operations.

The Company is devoting substantially all of its efforts toward the research and development of its products and has incurred operating losses since inception. The process of developing products will continue to require significant research and development, non-clinical testing, clinical trials and regulatory approval. The Company expects that these activities, together with general and administrative costs, will result in continuing operating losses for the foreseeable future. The Company believes that it has adequate funds at September 30, 2008 to continue operations at budgeted levels of expenditures through the end of 2008. The Company’s ability to execute its operating plan in 2009 and beyond is dependent on its ability to obtain additional capital (including through the sale of equity and debt securities and by entering into collaborative arrangements with partners) to fund our development activities. The Company is actively pursuing these alternatives, but there can be no assurance that we will obtain the additional capital necessary to fund our business beyond the end of the current fiscal year. Difficult conditions in the capital markets globally are adversely affecting the ability of the Company to obtain funding in a timely manner. The Company is evaluating measures to aggressively reduce costs to continue operations beyond year-end. If the Company is unable to obtain sufficient additional funding, it will be required in early 2009 to scale back its administrative activities and clinical development programs including the Phase 3 clinical development of our lead drug candidate, NOV-002.

The accompanying unaudited financial statements of the Company have been prepared in accordance with accounting principles generally accepted in the United States (“GAAP”) for interim financial information and with the instructions to Form 10-Q. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring accruals) considered necessary for the fair presentation of these financial statements have been included. 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 accompanying notes. Interim results are not necessarily indicative of results to be expected for other quarterly periods or for the entire year ending December 31, 2008. These unaudited financial statements should be read in conjunction with the audited financial statements and related notes thereto included in the Company’s latest annual report for the year ended December 31, 2007 on Form 10-KSB, which was filed with the Securities and Exchange Commission (“SEC”) on March 24, 2008.

2. STOCKHOLDERS’ EQUITY (DEFICIENCY)

2005 Common Stock Private Placement - From May 27, 2005 through August 9, 2005, the Company completed a private offering of securities, exempt from registration under the Securities Act of 1933, in which it sold to accredited investors 4,000,000 shares of common stock and issued 2,000,000 common stock warrants (initially exercisable at \$2.25 per share) for net cash proceeds of approximately \$3,715,000 (net of cash issuance costs of approximately \$735,000) and conversion of debt and accrued interest of \$550,000. In connection with the private placement, the Company also issued 125,000 shares of common stock to placement agents with a value of approximately \$156,000 and issued 340,000 common stock warrants to placement agents and finders at an initial exercise price of \$2.00 per share. Pursuant to anti-dilution provisions, the number of warrants issued to investors, placement agents and finders as well as the exercise price of the warrants have changed. On August 11, 2008, warrants to purchase 6,923,028 shares of preferred stock at an exercise price of \$.65 per share expired unexercised. These warrants were issued in 2004 to the purchasers of shares of common stock. At September 30, 2008, warrants to purchase 1,046,143 shares of common stock at an exercise price of \$0.65 per share held by placement agents remain outstanding.

Series A Preferred Stock Private Placement— On September 30, 2005 and October 3, 2005, the Company sold, in a private placement, a total of 3,200 shares of its Series A 8% Cumulative Convertible Preferred Stock (“Series A Preferred Stock”) with a stated value of \$1,000 and 969,696 common stock warrants for net proceeds of \$2,864,000, net of issuance costs of \$336,000. See “Series C Preferred” below for a description of the exchange of Series A Preferred Stock that occurred in May 2007. The warrants issued in connection with the sale of Series A Preferred Stock had anti-dilution provisions that provided for adjustments to the exercise price upon the occurrence of certain events. Pursuant to these anti-dilution provisions the exercise price of the warrants was subsequently adjusted and as of September 30, 2008, the warrants are exercisable at \$0.65 per share.

2006 Common Stock Private Placement - On March 7, 2006, the Company completed a private offering of securities, exempt from registration under the Securities Act of 1933, in which it sold to accredited investors 11,154,073 shares of common stock at \$1.35 per share and warrants to purchase 8,365,542 shares of its common stock exercisable at \$2.50 per share for net cash proceeds of approximately \$13,847,000 (net of issuance costs of approximately \$1,211,000, including placement agent fees of approximately \$1,054,000). In connection with the private placement, the Company issued 669,244 common stock warrants (exercisable at \$2.50 per share) to the placement agents. Pursuant to anti-dilution provisions, as a result of subsequent financings, as of September 30, 2008, the number of shares of common stock issuable upon exercise of the warrants issued to investors and placement agents was 11,267,480 and the exercise price was \$2.00 per share.

Series B Preferred Stock Private Placement - On May 2, 2007, pursuant to a securities purchase agreement with accredited investors dated April 12, 2007 (the “Purchase Agreement”), as amended May 2, 2007, the Company sold 300 shares of a newly created series of preferred stock, designated “Series B Convertible Preferred Stock”, with a stated value of \$50,000 per share (the “Series B Preferred Stock”), and issued warrants to purchase 7,500,000 shares of common stock for an aggregate purchase price of \$15,000,000. The Series B Preferred Stock was initially convertible into 15,000,000 shares of common stock at \$1.00 per share. See “Series D Preferred” below for a description of the exchange of Series B Preferred Stock that occurred in April 2008.

The common stock purchase warrants issued to investors were exercisable for an aggregate of 7,500,000 shares of the Company’s common stock at an initial exercise price of \$1.25 per share and had an initial expiration date of May 2012. The warrant exercise price and/or number of warrants is subject to adjustment only for stock dividends, stock splits or similar capital reorganizations so that the rights of the warrant holders after such event will be equivalent to the rights of warrant holders prior to such event. If there is an effective registration statement covering the shares underlying the warrants and the volume weighted average price (“VWAP”), as defined in the warrant, of the Company’s common stock exceeds \$2.50 for 20 consecutive trading days, then on the 31st day following the end of such period any remaining warrants for which a notice of exercise was not delivered shall no longer be exercisable and shall be converted into a right to receive \$.01 per share. See “Series D Preferred” below for a description of an amendment to these warrants that was executed in April 2008.

Upon the closing of the Series B Preferred Stock financing the Company issued to placement agents warrants to purchase a total of 900,000 shares of common stock with the same terms as the warrants issued to the investors.

The Company and the investors entered into a registration rights agreement in connection with the closing of the sale of the Series B Preferred Stock. The registration rights agreement was subsequently amended on April 11, 2008. The agreement, as amended, requires the Company to use its best efforts to keep a registration statement covering 12,000,000 shares of common stock continuously effective under the Securities Act until the earlier of the date when all securities covered by the registration statement have been sold or the second anniversary of the closing. In the event the Company does not fulfill the requirements of the registration rights agreement, the Company is required to pay to the investors liquidated damages equal to 1.5% per month of the aggregate purchase price of the preferred stock and warrants until the requirements have been met. The 12,000,000 shares of common stock are included on a registration statement that became effective on April 28, 2008.

Series C Preferred Stock - As a condition to closing of the sale of Series B Preferred Stock described above, the Company entered into an agreement to exchange and consent with the holders of the Series A Preferred Stock. Pursuant to that agreement, the holders of the Series A Preferred Stock exchanged their 3,264 shares of Series A Preferred Stock for 272 shares of a new Series C convertible preferred stock ("Series C Preferred Stock"), which were subordinated to the Series B Preferred Stock as set forth in the Series C Certificate of Designations. The Series C Preferred Stock is initially convertible at \$1.00 per share into 3,264,000 shares of common stock. As part of the exchange, the Company issued to the holders of the Series A Preferred Stock warrants to purchase 1,333,333 shares of common stock expiring on May 2, 2012 at a price of \$1.25 per share; paid them a cash allowance to defray expenses totaling \$40,000; and paid them an amount of cash equal to unpaid dividends accumulated through the date of the exchange.

The Series C Preferred Stock has an annual dividend rate of 8% until October 1, 2008 and thereafter has an annual dividend rate of 20%. The dividend rate also increases to 20% upon certain events of default as defined in the Series C Certificate of Designations. The dividends are payable quarterly. Such dividends shall be paid only after all outstanding dividends on the Series B Preferred Stock (with respect to the current fiscal year and all prior fiscal years) shall have been paid to the holders of the Series B Preferred Stock. The conversion price is subject to adjustment for stock dividends, stock splits or similar capital reorganizations.

In connection with the sale of Series D Preferred Stock described below, the conversion price of the Series C Preferred Stock was reduced to \$0.65.

Series D Preferred Stock Private Placement - On April 11, 2008, pursuant to a securities purchase agreement with accredited investors dated March 26, 2008, as amended on April 9, 2008 (the "Purchase Agreement"), the Company sold 113.5 shares of a newly created series of its preferred stock, designated "Series D Convertible Preferred Stock", par value \$0.00001 per share (the "Series D Preferred Stock") and issued warrants to purchase 4,365,381 shares of its common stock for an aggregate purchase price of \$5,675,000 (the "Series D Financing").

The shares of Series D Preferred Stock are convertible into shares of common stock any time after issuance at the option of the holder at \$0.65 per share of common stock. If there is an effective registration statement covering the shares of common stock underlying the Series D Preferred Stock and the VWAP, as defined in the Series D Certificate of Designations, of the Company's common stock exceeds \$2.00 for 20 consecutive trading days, then the outstanding Series D Preferred Stock will automatically convert into common stock at the conversion price then in effect. The conversion price will be subject to adjustment for stock dividends, stock splits or similar capital reorganizations.

The holders of Series D Preferred Stock are entitled to vote on all matters on which the holders of common stock are entitled to vote. The number of votes to which each holder of Series D Preferred Stock is entitled is equal to the number of shares of common stock that would be issued to such holder if the Series D Preferred Stock had been converted at the record date for the meeting of stockholders.

The Series D Preferred Stock has an annual dividend rate of 9%, payable semi-annually on June 30 and December 31. Such dividends may be paid in cash or in registered shares of the Company's common stock at the Company's option, subject to certain conditions.

The Series D Preferred Stock ranks senior to all other outstanding series of preferred stock and common stock as to the payment of dividends and the distribution of assets upon voluntary or involuntary liquidation, dissolution or winding up of the Company's affairs. The Series D preferred stockholders will be entitled to receive first, \$50,000 per share and all accrued and unpaid dividends. Subject to any distributions that are required for any other series of preferred stock, the Series D preferred stockholders are then entitled to participate with the holders of the common stock in the distribution of remaining assets on a pro rata basis. If, upon any winding up of the Company's affairs, assets available to pay the holders of Series D Preferred Stock are not sufficient to permit the payment in full, then all assets will be distributed to the holders of Series D Preferred Stock on a pro rata basis. If the Company sells, leases or otherwise transfers substantially all of its assets, consummates a business combination in which it is not the surviving corporation or, if it is the surviving corporation, if the holders of a majority of the common stock immediately before the transaction do not hold a majority of common stock immediately after the transaction, in one or a series of events, change the majority of the members of the board of directors, or if any person or entity (other than the holders of Series D Preferred Stock) acquires more than 50% of the Company's outstanding stock, then the holders of Series D Preferred Stock are entitled to receive the same liquidation preference as described above, except that after receiving \$50,000 per preferred share and any accrued but unpaid dividends, they are not entitled to participate with the holders of any other series of preferred or common stock in a distribution of the remaining assets.

For as long as any shares of Series D Preferred Stock remain outstanding, the Company is prohibited from (i) paying dividends to its common stockholders, (ii) amending its certificate of incorporation, (iii) issuing any equity security or any security convertible into or exercisable for any equity security at a price of \$0.65 or less or with rights senior to the Series D Preferred Stock (except for certain exempted issuances), (iv) increasing the number of shares of Series D Preferred Stock or issuing any additional shares of Series D Preferred Stock, (v) selling or otherwise disposing of all or substantially all of its assets or intellectual property or entering into a merger or consolidation with another company unless the Company is the surviving corporation, the Series D Preferred Stock remains outstanding and there are no changes to the rights and preferences of the Series D Preferred Stock, (vi) redeeming or repurchasing any capital stock other than Series D Preferred Stock, (vii) incurring any new debt for borrowed money in excess of \$500,000 and (viii) changing the number of directors. The Company is required to reserve, out of authorized shares of common stock, 100% of the number of shares of common stock into which Series D Preferred Stock is convertible.

Exchange of Series B Preferred Stock for Series D Preferred Stock

In connection with the closing of the Series D Financing, the holders of the Company's Series B Preferred Stock, exchanged all 300 of their shares of Series B Preferred Stock for 300 shares of Series D Preferred Stock. Following the exchange, no shares of Series B Preferred Stock are outstanding. The rights and preferences of the Series D Preferred Stock are substantially the same as the Series B Preferred Stock. However, the conversion price of the Series D Preferred Stock is \$0.65. In addition, the holders of Series B Preferred Stock waived liquidated damages that had accrued from September 7, 2007 through the closing date as a result of the Company's failure to register for resale 100% of the shares of common stock underlying the Series B Preferred Stock and warrants. As a result, in the nine months ended September 30, 2008, the Company recorded a reduction of general and administrative expenses of \$395,000 relating to the reversal of estimated liquidated damages that had been accrued through the date of the closing. The Purchase Agreement provided that the dividends that accrued on the shares of Series B Preferred Stock from April 1, 2008 through the date of exchange be paid, out of legally available funds, on June 30, 2008. As of June 30 and September 30, the Company did not have legally available funds for the payment of dividends under Delaware corporate law and therefore has not been able to pay any dividends accrued in respect of the preferred stock.

Board and Observer Rights

Pursuant to the Purchase Agreement, from and after the closing, Xmark Opportunity Fund, L.P., Xmark Opportunity Fund, Ltd. and Xmark JV Investment Partners, LLC (collectively, the "Xmark Entities"), have the right to designate one member to the Company's Board of Directors. This right shall last until such time as the Xmark Entities no longer hold at least one-third of the Series D Preferred Stock issued to them at closing. In addition, the Xmark Entities, Caduceus Master Fund Limited, Caduceus Capital II, L.P., Summer Street Life Sciences Hedge Fund Investors, LLC, UBS Eucalyptus Fund, LLC and PW Eucalyptus Fund, Ltd. (collectively, the "Lead Investors") have the right to designate one observer to attend all meetings of the Company's Board of Directors, committees thereof and access to all information made available to members of the Board. This right shall last until such time as the Lead Investors no longer hold at least one-third of the Series D Preferred Stock issued to them at closing. The rights to designate a board member and board observer have not yet been exercised.

Common Stock Purchase Warrants

The common stock purchase warrants issued to the investors are exercisable for an aggregate of 4,365,381 shares of the Company's common stock at an exercise price of \$0.65 and expire in April 2013. If after the six-month anniversary of the date of issuance of the warrants there is no effective registration statement registering, or no current prospectus available for, the resale of the shares issuable upon the exercise of the warrants, the holder may conduct a cashless exercise whereby the holder may elect to pay the exercise price by having the Company withhold, upon exercise, shares having a fair market value equal to the applicable aggregate exercise price. In the event of a cashless exercise, the Company would receive no proceeds from the sale of common stock in connection with such exercise.

The warrant exercise price and/or number of warrants is subject to adjustment only for stock dividends, stock splits or similar capital reorganizations so that the rights of the warrant holders after such event will be equivalent to the rights of warrant holders prior to such event.

If there is an effective registration statement covering the shares underlying the warrants and the VWAP, as defined in the warrant, of the Company's common stock exceeds \$2.50 for 20 consecutive trading days, then on the 31st day following the end of such period any remaining warrants for which a notice of exercise was not delivered shall no longer be exercisable and shall be converted into a right to receive \$.01 per share.

Registration Rights Agreement

The Company entered into a registration rights agreement with the investors that requires the Company to file with the Securities and Exchange Commission no later than 5 business days following the six-month anniversary of the closing of the Series D Financing, a registration statement covering the resale of (i) a number of shares of common stock equal to 100% of the shares issuable upon conversion of the Series D Preferred Stock (excluding 12,000,000 shares of common stock issuable upon conversion of the Series D Preferred Stock that were included on a prior registration statement), (ii) a number of shares of common stock equal to 100% of the shares issuable upon exercise of the warrants issued in the Series D Financing and (iii) 7,500,000 shares of common stock issuable upon exercise of warrants dated May 2, 2007 held by the investors. The Company is required to use its best efforts to have the registration statement declared effective and keep the registration statement continuously effective under the Securities Act until the earlier of the date when all the registrable securities covered by the registration statement have been sold or the second anniversary of the closing. In the event the Company fails to file the registration statement within the timeframe specified by the Registration Rights Agreement, the investors are entitled to receive liquidated damages equal to 1.5% per month (pro-rated on a daily basis for any period of less than a full month) of the aggregate purchase price of the Series D Preferred Stock and warrants until the Company files the delinquent registration statement. The Company is allowed to suspend the use of the registration statement for not more than 15 consecutive days or for a total of not more than 30 days in any 12-month period. The registration statement was required to be filed by October 18, 2008. As of the date of filing of this report, the Company has not yet filed the registration statement. As of September 30, 2008, and through the date of this filing, the Company has not concluded that it is probable that damages will become due, therefore no accrual for damages has been recorded. The Company plans to file the registration statement during the fourth quarter of 2008.

Placement Agent Fee and Other Costs

Following the closing of the Series D Financing, the Company paid Rodman & Renshaw LLC a cash fee of \$100,000 and paid other closing costs of approximately \$105,000.

Amendments to Prior Warrants and Registration Rights Agreement

At the closing, the Company entered into an amendment to the registration rights agreement dated May 2, 2007 with the holders of its Series B Preferred Stock to revise the definition of registrable securities under the agreement to include only the 12,000,000 shares of common stock that were included on a prior registration statement and to extend the registration obligations under the agreement by one year. On April 28, 2008, the amended registration statement covering the 12,000,000 shares of common stock required to be registered was declared effective. Accordingly, the Company has not accrued any liquidated damages at September 30, 2008 in connection with its registration obligation under the agreement. If the Company is unable to maintain the effectiveness of that registration statement through April 11, 2010, the Company may become liable for liquidated damages in future periods.

In addition, in connection with the closing, the warrants to purchase common stock issued in connection with the sale of Series B Preferred Stock were amended to conform the terms of those warrants to the terms of the warrants issued in the Series D Financing.

Accounting Treatment of Series B and Series D Preferred Stock

The terms of the Series B Preferred Stock contained provisions that allow the holders to elect to receive a liquidation payment in circumstances that are beyond the Company's control. Therefore the shares have been recorded as redeemable preferred stock outside of permanent equity in the balance sheet. The shares were initially recorded at their estimated as-converted fair value of \$19,050,000, net of cash issuance costs of \$1,306,949. That value was further reduced by the intrinsic value of the beneficial conversion feature of \$7,824,385. As a result of the effective adjustment to the conversion price of preferred stock and the adjustment to the exercise price of warrants that occurred in connection with the exchange of all outstanding shares of Series B Preferred Stock for shares of Series D Preferred Stock, in the quarter ended June 30, 2008, a deemed dividend of \$4,598,961 was recorded. This amount represents the incremental fair value on the date of the exchange resulting from the adjustment to the conversion price of the Series B Preferred Stock from \$1.00 to \$0.65 (\$3,876,912) and the exercise price of the warrants from \$1.25 to \$0.65 (\$722,049). These amounts were recorded as both debits and credits to temporary and permanent equity, respectively, in the quarter ended June 30, 2008. The incremental fair value of the adjustment to the conversion price of the Series B Preferred Stock was determined based on the market value of the additional 8,076,900 shares of common stock that became issuable following the exchange. The incremental fair value of the modification to the warrants was the difference between the fair value of the warrants immediately before and after modification using the Black-Scholes option pricing model.

Since the terms of the Series D Preferred Stock also contain provisions that may require redemption in circumstances that are beyond the Company's control, the shares have been recorded as redeemable preferred stock outside of permanent equity in the balance sheet as of September 30, 2008. The gross proceeds of \$5,675,000 received in conjunction with the Series D Financing were allocated on a relative fair value basis between the Series D Preferred Stock and the warrants. The relative fair value of the warrants issued to investors of \$1,302,592 was recorded as additional paid-in capital while the relative fair value of the Series D Preferred Stock of \$4,372,408 was recorded as temporary equity. The carrying value of the Series D Preferred Stock was immediately adjusted to its fair value of \$4,190,762 based on the fair value of the as-converted common stock. The difference of \$181,646 was recorded as a reduction to the deemed dividend described above. Issuance costs related to the Series D Financing of \$205,328 were netted against temporary equity. The total carrying value of temporary equity at September 30, 2008 of \$13,904,100 consists of the \$9,918,666 carrying value of the Series B Preferred Stock on the date of exchange plus the \$3,985,434 carrying value of the Series D Preferred Stock issued in the Series D Financing.

Since the Company has concluded it is not probable that an event will occur which would allow the holders of Series D Preferred Stock to elect to receive a liquidation payment, the carrying value will not be adjusted until the time that such event becomes probable. The liquidation preference (redemption value) is \$21,605,375 at September 30, 2008.

2008 Common Stock Private Placement - On August 15, 2008, the Company sold 4,615,384 shares of its common stock to two related accredited investors for gross proceeds of approximately \$3 million, pursuant to a securities purchase agreement (the "Common Stock Purchase Agreement") dated August 14, 2008.

The Common Stock Purchase Agreement provides that on and after six months following the closing, if there is not an available exemption from Rule 144 under the Securities Act to permit the sale of the common stock by the purchasers, then the Company will use its best efforts to file a registration statement (the "Registration Statement") under the Securities Act with the SEC covering the resale of the common stock. It further provides that the Company will use its best efforts to maintain the effectiveness of the Registration Statement until one year from closing or until all the common stock has been sold or transferred, whichever occurs first.

The Common Stock Purchase Agreement also provides that if, prior to the public announcement of the conclusion of the Company's NOV-002 Phase 3 clinical trial in non-small cell lung cancer (the "Announcement Date"), the Company completes a Subsequent Equity Financing (as defined therein) and the holders of shares of our Series D Preferred Stock (the "Series D Shares") receive a reduction in the effective conversion price or exercise price, as applicable, of the Series D Shares or common stock purchase warrants issued in connection with the issuance of the Series D Shares or receive additional shares of common stock, as consideration in connection with any consent given by the holders of the Series D Shares, then the purchasers shall be entitled to receive substantially equivalent consideration, on a proportional basis, in the form of additional shares of common stock based on the formula detailed in the Common Stock Purchase Agreement.

Common Stock Warrants — The following table summarizes information with regard to outstanding warrants issued in connection with equity and debt financings as of September 30, 2008.

Offering	Outstanding (as adjusted)	Exercise Price (as adjusted)	Expiration Date
2005 Bridge Loans	720,000	\$ 0.625	April 1, 2010
2005 PIPE - Placement agents and finders	1,046,143	\$ 0.65	August 9, 2010
Series A Preferred (1):			
Investors – September 30, 2005 closing	909,090	\$ 0.65	September 30, 2010
Investors – October 3, 2005 closing	60,606	\$ 0.65	October 3, 2010
2006 PIPE – Investors and placement agents	11,267,480	\$ 2.00	March 7, 2011
Series B Preferred:			
Investors	7,500,000	\$ 0.65	April 11, 2013
Placement agents	900,000	\$ 1.25	May 2, 2012
Series C Exchange	1,333,333	\$ 1.25	May 2, 2012
Series D Preferred	4,365,381	\$ 0.65	April 11, 2013
Total	28,102,033		

(1) Concurrently with the closing of the Series B Financing, all shares of Series A Preferred Stock were exchanged for shares of Series C Preferred Stock.

No warrants have been exercised as of September 30, 2008. On August 11, 2008, warrants to purchase 6,923,028 shares of common stock expired unexercised.

3. COLLABORATION AGREEMENT

In December 2007 the Company entered into a Collaboration Agreement with Lee's Pharmaceutical (HK) Ltd ("Lee's Pharma"). Pursuant to the agreement, Lee's Pharma obtained an exclusive license to develop, manufacture and commercialize NOV-002 and NOV-205 in Hong Kong, Macau, China and Taiwan (the "territory"). Under the terms of the agreement the Company received an upfront license fee of \$500,000 in March 2008 and is entitled to receive up to \$1,700,000 in future milestone payments upon the completion of development and marketing milestones by Lee's Pharma. The \$500,000 milestone payment received is being amortized over the estimated term of the agreement, 15 years. Accordingly, \$25,000 of license revenue was recognized in the nine months ended September 30, 2008.

The Company will receive royalty payments of 20-25% of net sales of NOV-002 in the territory and will receive royalty payments of 12-15% of net sales of NOV-205 in the territory. Lee's Pharma will also reimburse the Company for the manufacturing cost of pharmaceutical products provided to Lee's Pharma in connection with the agreement. Lee's Pharma has committed to spend certain minimum amounts on development in the first four years of the agreement. The agreement expires upon the expiration of the last patent covering any of the licensed products, or twelve years from the date of the first commercial sale in China, whichever occurs later.

4. STOCK-BASED COMPENSATION

The following table summarizes amounts charged to expense for stock-based compensation related to employee and director stock option grants and stock-based compensation recorded in connection with stock options and restricted stock awards granted to non-employee consultants:

	Three months ended September 30,		Nine months ended September 30,	
	2008	2007	2008	2007
Employee and director stock option grants:				
Research and development	\$ 21,049	\$ 17,928	\$ 135,333	\$ 144,307
General and administrative	57,476	53,054	174,028	136,515
	<u>78,525</u>	<u>70,982</u>	<u>309,361</u>	<u>280,822</u>
Non-employee consultants stock option grants and restricted stock awards:				
Research and development	(4,976)	(3,134)	4,339	18,787
General and administrative	(288)	45,743	16,596	137,366
	<u>(5,264)</u>	<u>42,609</u>	<u>20,935</u>	<u>156,153</u>
Total stock-based compensation	<u>\$ 73,261</u>	<u>\$ 113,591</u>	<u>\$ 330,296</u>	<u>\$ 436,975</u>

Determining Fair Value

The following table summarizes weighted-average values and assumptions used for options granted to employees, directors and consultants in the periods indicated:

	Three months ended September 30,		Nine months ended September 30,	
	2008	2007	2008	2007
Volatility	—	80%	80%	80%
Weighted-average volatility	—	80%	80%	80%
Risk-free interest rate	—	4.18%-4.51%	3.14%	4.18%-4.66%
Expected life (years)	—	5	5	5
Dividend	—	0	0	0
Weighted-average exercise price	— \$	0.64 \$	0.60 \$	0.82 \$
Weighted-average grant-date fair value	— \$	0.43 \$	0.39 \$	0.55 \$

There were no stock option grants during the three months ended September 30, 2008.

A summary of stock option activity is as follows:

	Options Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Contracted Term in Years	Aggregate Intrinsic Value
Outstanding at January 1, 2008	4,847,651	\$ 0.67		
Options granted	435,000	\$ 0.60		
Options cancelled	(27,826)	\$ 2.23		
Options exercised	(100,000)	\$ 0.01		
Outstanding at September 30, 2008	<u>5,154,825</u>	<u>\$ 0.67</u>	<u>7.2</u>	<u>\$ 752,223</u>
Exercisable at September 30, 2008	<u>3,647,320</u>	<u>\$ 0.69</u>	<u>6.5</u>	<u>\$ 752,223</u>

The aggregate intrinsic value of options outstanding is calculated based on the positive difference between the closing market price of the Company's common stock at the end of the respective period and the exercise price of the underlying options.

As of September 30, 2008, there was approximately \$394,000 of total unrecognized compensation cost related to unvested stock-based compensation arrangements. Of this total amount, 23%, 59% and 18% are expected to be recognized during 2008, 2009 and 2010, respectively. The Company expects 1,507,505 in unvested options to vest in the future. The weighted-average grant-date fair value of vested and unvested options outstanding at September 30, 2008 was \$0.41 and \$0.40, respectively.

On May 13, 2008, the Company entered into a separation agreement with M. Taylor Burtis, a former officer of the Company, that provided, among other things that all 166,667 unvested options held by Ms. Burtis as of May 13, 2008 were immediately vested and that she will have until December 31, 2009 to exercise the total 350,000 options held by her, at which time any unexercised options will expire. During the three months ended June 30, 2008, incremental stock-based compensation expense of \$23,700 was recorded in connection with the modification of the option terms.

5. NET LOSS PER SHARE

Basic net loss per share is computed by dividing net loss attributable to common stockholders by the weighted average number of shares of common stock outstanding during the period. Diluted net loss per share is computed by dividing net loss attributable to common stockholders by the weighted average number of shares of common stock and the dilutive potential common stock equivalents then outstanding. Potential common stock equivalents consist of stock options, warrants and convertible preferred stock. Since the Company has a net loss for all periods presented, the inclusion of common stock equivalents in the computation would be antidilutive. Accordingly, basic and diluted net loss per share are the same.

The following potentially dilutive securities have been excluded from the computation of diluted net loss per share since their inclusion would be antidilutive:

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2008</u>	<u>2007</u>	<u>2008</u>	<u>2007</u>
Stock options	5,154,825	3,917,651	5,154,825	3,917,651
Warrants	28,102,033	26,873,047	28,102,033	26,873,047
Conversion of preferred stock	36,829,192	18,264,000	36,829,192	18,264,000

6. INCOME TAXES

The Company accounts for income taxes in accordance with Statement of Financial Accounting Standards (“SFAS”) No. 109, *Accounting for Income Taxes* (SFAS 109). Under SFAS 109, deferred tax assets or liabilities are computed based on the difference between the financial-statement and income-tax basis of assets and liabilities, and net operating loss carryforwards, using the enacted tax rates. Deferred income tax expense or benefit is based on changes in the asset or liability from period to period. The Company did not record a provision or benefit for federal, state or foreign income taxes for the nine months ended September 30, 2008 and 2007 because the Company has experienced losses since inception. The Company has not recorded a benefit for deferred tax assets as their realization is uncertain.

7. COMMITMENTS AND RELATED PARTY TRANSACTIONS

The Company is obligated to ZAO BAM under a royalty and technology transfer agreement. Mark Balazovsky, a director of the Company until November 2006, is the majority shareholder of ZAO BAM. Pursuant to the royalty and technology transfer agreement between the Company and ZAO BAM, the Company is required to make royalty payments of 1.2% of net sales of oxidized glutathione-based products. The Company is also required to pay ZAO BAM \$2 million for each new oxidized glutathione-based drug within eighteen months following FDA approval of such drug.

If a royalty is not being paid to ZAO BAM on net sales of oxidized glutathione products, then the Company is required to pay ZAO BAM 3% of all license revenues. If license revenues exceed the Company’s cumulative expenditures including, but not limited to, preclinical and clinical studies, testing, FDA and other regulatory agency submission and approval costs, general and administrative costs, and patent expenses, then the Company would be required to pay ZAO BAM an additional 9% of the amount by which license revenues exceed the Company’s cumulative expenditures. During the nine months ended September 30, 2008, the Company paid ZAO BAM \$15,000, which was 3% of license payments received under the collaboration agreement described in Note 3.

As a result of the assignment to Novelos of the exclusive worldwide intellectual property and marketing rights of oxidized glutathione (excluding Russia and the other states of the former Soviet Union), Novelos is obligated to the Oxford Group, Ltd. for future royalties. Simyon Palmin, a founder of Novelos, a director until August 15, 2008 and the father of the Company’s president and chief executive officer, is president of Oxford Group, Ltd. Mr. Palmin was also an employee of the Company and is now a consultant to the Company. Pursuant to the agreement, as revised May 26, 2005, Novelos is required to pay Oxford Group, Ltd. a royalty in the amount of 0.8% of the Company’s net sales of oxidized glutathione-based products.

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

Forward-Looking Statements

This quarterly report on Form 10-Q includes forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, which we refer to as the Exchange Act. For this purpose, any statements contained herein regarding our strategy, future operations, financial position, future revenues, projected costs, prospects, plans and objectives of management, other than statements of historical facts, are forward-looking statements. The words "anticipates," "believes," "estimates," "expects," "intends," "may," "plans," "projects," "will," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We cannot guarantee that we actually will achieve the plans, intentions or expectations disclosed in our forward-looking statements. There are a number of important factors that could cause actual results or events to differ materially from those disclosed in the forward-looking statements we make. These important factors include our "critical accounting estimates" and the risk factors set forth below under the caption "Factors That May Affect Future Results." Although we may elect to update forward-looking statements in the future, we specifically disclaim any obligation to do so, even if our estimates change, and readers should not rely on those forward-looking statements as representing our views as of any date subsequent to the date of this quarterly report.

Overview

We are a biopharmaceutical company, established in 1996, commercializing oxidized glutathione-based compounds for the treatment of cancer and hepatitis.

NOV-002, our lead compound currently in Phase 3 development for non-small cell lung cancer (NSCLC), acts as a chemoprotectant and a chemopotentiator. In May 2006, we finalized a Special Protocol Assessment (SPA) with the FDA for a single pivotal Phase 3 trial in advanced NSCLC in combination with first-line chemotherapy, and received Fast Track designation in August 2006. The primary endpoint of this trial is improvement in median overall survival. Patient enrollment commenced in November 2006 and targeted enrollment of 840 patients was reached in March 2008. We anticipate that results from this trial will be available in the second half of 2009.

NOV-002 is also being developed to treat chemotherapy-resistant ovarian cancer. In a U.S. Phase 2 chemotherapy-resistant ovarian cancer trial at Massachusetts General Hospital and Dana-Farber Cancer Institute from July 2006 through March 2008, NOV-002 (plus carboplatin) slowed progression of the disease in 60% of evaluable patients (9 out of 15 women). The median progression-free survival was 15.4 weeks, almost double the historical control of 8 weeks.

NOV-002 is also being developed to treat early-stage breast cancer. These patients are often treated with chemotherapy to minimize surgical intervention. In June 2007 we commenced enrollment in a U.S. Phase 2 trial in order to evaluate the ability of NOV-002 to enhance the effectiveness of such chemotherapy. The interim efficacy target was achieved in May 2008, earlier than expected, and the trial is moving into its second stage, continuing enrollment to 46 patients.

Based on results to-date, in 2009 we intend to initiate several Phase 2 trials with NOV-002 in cancers as well as chemotherapy-induced anemia. Our ability to initiate these trials will depend on available funding, principally from partnering arrangements or the issuance of debt or equity securities.

NOV-205, our second compound, acts as a hepatoprotective agent with immunomodulating and anti-inflammatory properties. Our Investigational New Drug Application for NOV-205 as monotherapy for chronic hepatitis C has been accepted by the FDA. A U.S. Phase 1b clinical trial in patients who previously failed treatment with pegylated interferon plus ribavirin was completed in December 2007. Based on favorable safety results of that trial, we plan to initiate a longer duration, proof-of-concept trial in early 2009, subject to availability of funds.

Both compounds have completed clinical trials in humans and have been approved for use in Russia, where they were originally developed. We own all intellectual property rights worldwide (excluding Russia and other states of the former Soviet Union) related to compounds based on oxidized glutathione, including NOV-002 and NOV-205. Our patent portfolio includes six U.S. issued patents, two European issued patents and one Japanese issued patent.

Plan of Operation

Our plan of operation for the next 12 months is to continue the clinical development of our two product candidates. We expect our principal expenditures during these 12 months to largely consist of the costs associated with clinical trials. Subject to available funding, we will continue to maintain a low number of permanent employees and utilize senior advisors, consultants, contract research and manufacturing organizations and third parties to perform certain aspects of product development, including clinical and non-clinical development, manufacturing and, in some cases, regulatory and quality assurance functions. See further discussion below under "Liquidity and Capital Resources".

Capital Structure and Financings

In 2005 following the settlement of certain of our indebtedness, we completed a two-step reverse merger with Common Horizons, Inc. ("Common Horizons"), a Nevada-based developer of web portals, and its wholly-owned subsidiary Nove Acquisition, Inc. After the completion of the reverse merger, Novelos became the surviving corporation, the business of Common Horizons, which was insignificant, was abandoned and the business of Novelos was adopted. The transaction was therefore treated as a reverse-acquisition recapitalization, with Novelos as the acquiring party and Common Horizons as the acquired party for accounting purposes.

Since 2005 we have completed various private placements of securities. In May through August of 2005 we sold an aggregate of 4,000,000 shares of common stock and warrants to purchase 2,000,000 shares of common stock for net cash proceeds of \$3,715,000 and the conversion of \$550,000 of convertible debt and accrued interest. In September and October 2005, we sold in a private placement 3,200 shares of Series A preferred stock and warrants to purchase 969,696 shares of common stock for aggregate net proceeds of \$2,864,000. On March 7, 2006, we sold 11,154,073 shares of our common stock and warrants to purchase 8,365,542 shares of our common stock for net proceeds of \$13,847,000. On May 2, 2007, we sold 300 shares of our Series B preferred stock and warrants to purchase 7,500,000 shares of our common stock for net proceeds of \$13,693,000. In connection with that financing, the holders of the existing Series A preferred stock exchanged their 3,264 shares of Series A preferred stock for 272 shares of a new Series C convertible preferred stock, which are convertible into 3,264,000 shares of common stock. On April 11, 2008, we sold 113.5 shares of our Series D preferred stock and warrants to purchase 4,365,381 shares of common stock for net proceeds of \$5,470,000 (net of issuance costs). The shares of Series D preferred stock sold in the financing are convertible into 8,730,755 shares of common stock. In connection with that financing, the holders of the existing Series B preferred stock exchanged their 300 shares of Series B preferred stock for 300 shares of Series D preferred stock, which are convertible into 23,076,900 shares of common stock. In August 2008, we sold 4,615,384 shares of our common stock, receiving gross proceeds of approximately \$3 million.

Results of Operations

Revenue. Revenue consists of amortization of upfront license fees received in connection with partner agreements and income received from a grant from the U.S. Department of Health and Human Services.

Research and development expense. Research and development expense consists of costs incurred in identifying, developing and testing product candidates, which primarily consist of salaries and related expenses for personnel, fees paid to professional service providers for independent monitoring and analysis of our clinical trials, costs of contract research and manufacturing and costs to secure intellectual property. We are currently developing two proprietary compounds, NOV-002 and NOV-205. To date, most of our research and development costs have been associated with our NOV-002 compound.

General and administrative expense. General and administrative expense consists primarily of salaries and other related costs for personnel in executive, finance and administrative functions. Other costs include facility costs, insurance, costs for public and investor relations, directors' fees and professional fees for legal and accounting services.

Three Months Ended September 30, 2008 and 2007

Revenue. During the three months ended September 30, 2008 we recognized \$8,000 in license fees in connection with our collaboration with Lee's Pharmaceutical (HK) Ltd ("Lee's Pharma"). Under the terms of the agreement the Company received an upfront license fee of \$500,000 in March 2008 and is entitled to receive up to \$1,700,000 in future milestone payments upon the completion of development and marketing milestones by Lee's Pharma. The \$500,000 milestone payment received is being amortized over the estimated term of the agreement, 15 years. No such agreement existed during 2007. During the three months ended September 30, 2008, we also recognized \$27,000 in grant revenue related to a grant received from the U.S. Department of Health and Human Services.

Research and Development. Research and development expense for the three months ended September 30, 2008 was \$1,972,000 compared to \$5,911,000 for the three months ended September 30, 2007. The \$3,939,000, or 67%, decrease in research and development expense was due to a combination of factors. In March 2008, we reached the enrollment target for our Phase 3 clinical trial of NOV-002. As a result, certain clinical costs have leveled out or declined. The cost of chemotherapy drug to be provided to patients in Europe decreased by \$1,814,000. Clinical investigator expenses, which are affected by the number of patients that remain on treatment, decreased by \$1,366,000. Contract research and consulting services decreased by \$485,000, and drug manufacturing and distribution costs (including storing and shipping chemotherapy drug) decreased by \$397,000. Salaries and overhead costs such as travel and related expenses increased \$123,000, principally from the addition of employees in the first half of 2008.

General and Administrative. General and administrative expense for the three months ended September 30, 2008 was \$622,000 compared to \$734,000 for the three months ended September 30, 2007. The \$112,000, or 15%, decrease in general and administrative expense was due to two factors. First, the three months ended September 30, 2007 included \$81,000 in accrued expense for potential liquidated damages associated with registration rights agreements. Those damages were waived in connection with the sale of Series D Preferred Stock described in Note 2. Second, stock-based compensation decreased by \$42,000 as a result of the completion of vesting for certain stock option grants. These decreases were slightly offset by increases in professional and consulting costs and overhead.

Interest Income. Interest income for the three months ended September 30, 2008 was \$21,000 compared to \$228,000 for the same period in 2007. This decrease is a result of lower cash balances as well as a decline in prevailing interest rates.

Preferred Stock Dividends and Deemed Dividends. During the three months ended September 30, 2008 we accrued \$465,000 of dividends due to our Series D preferred stockholders and accrued \$65,000 in dividends due to our Series C preferred stockholders. These dividends have not been paid because we do not have legally available funds for the payment of dividends under Delaware corporate law.

During the three months ended September 30, 2007 we paid cash dividends to Series A and C preferred stockholders of \$65,000 and declared and paid \$338,000 of dividends to our Series D preferred stockholders.

The dividends have been included in the calculation of net loss attributable to common stockholders of \$3,065,000, or \$0.07 per share, for the three months ended September 30, 2008 and \$6,818,000, or \$0.17 per share, for the three months ended September 30, 2007. The dividends are excluded from net loss (from operating activities) of \$2,535,000, or \$0.06 per share, for the three months ended September 30, 2008 and \$6,415,000, or \$0.16 per share, for the three months ended September 30, 2007.

Nine Months Ended September 30, 2008 and 2007

Revenue. During the nine months ended September 30, 2008 we recognized \$25,000 in license fees in connection with our collaboration with Lee's Pharmaceutical (HK) Ltd ("Lee's Pharma"). Under the terms of the agreement the Company received an upfront license fee of \$500,000 in March 2008 and is entitled to receive up to \$1,700,000 in future milestone payments upon the completion of development and marketing milestones by Lee's Pharma. The \$500,000 milestone payment received is being amortized over the estimated term of the agreement, 15 years. No such agreement existed during 2007. During the nine months ended September 30, 2008, we also recognized \$65,000 in grant revenue related to a grant received from the U.S. Department of Health and Human Services.

Research and Development. Research and development expense for the nine months ended September 30, 2008 was \$12,929,000 compared to \$11,621,000 for the nine months ended September 30, 2007. The \$1,308,000, or 11%, increase in research and development expense was due to increased funding of our clinical, contract manufacturing and non-clinical activities. The overall increase resulted principally from expanded activities relating to our pivotal Phase 3 clinical trial of NOV-002 for non-small cell lung cancer in the first half of 2008 leading up to and following full enrollment in March 2008. The increase includes \$1,298,000 in additional contract research and consulting services and an increase of \$485,000 in clinical investigator expenses. Salaries and overhead costs increased by \$448,000 principally as a result of the hiring of additional personnel in late 2007 and early 2008. These increases were offset by a \$303,000 decrease in drug manufacturing and distribution costs (including storing and shipping chemotherapy drugs) and a decrease of \$597,000 in the purchase of chemotherapy drugs during the first nine months of 2008 to be used in the Phase 3 clinical trial, specifically for clinical sites in Eastern and Western Europe. Since we did not recover any of the costs of the chemotherapy and we do not have a reliable method for tracking the drugs that have been administered to patients or evaluating any losses associated with spoilage, we recorded the entire amount as an expense in the periods purchased. Stock-based compensation expense also decreased \$23,000 during the first nine months of 2008 as compared to the same period in 2007.

General and Administrative. General and administrative expense for the nine months ended September 30, 2008 was \$1,602,000 compared to \$1,978,000 for the nine months ended September 30, 2007. The \$376,000, or 19%, decrease in general and administrative expense was due principally to the \$484,000 decrease in accrued expense for potential liquidated damages associated with registration rights agreements. Those damages were waived in connection with the sale of Series D Preferred Stock described in Note 2. Stock-based compensation also decreased by \$83,000 in the nine months ended September 30, 2008 compared to the same period of the prior year. These decreases were partially offset by a \$121,000 increase in salary, directors fees and overhead costs and a \$70,000 increase in professional and consulting fees.

Interest Income. Interest income for the nine months ended September 30, 2008 was \$123,000 compared to \$576,000 for the same period in 2007. This decrease is a result of lower cash balances as well as a decline in prevailing interest rates.

Preferred Stock Dividends. During the nine months ended September 30, 2008 we paid cash dividends to Series B and C preferred stockholders of \$740,000 and accrued \$1,060,000 of dividends due to our Series B, C and D preferred stockholders. These dividends have not been paid because we do not have legally available funds for the payment of dividends under Delaware corporate law. During the nine months ended September 30, 2008 we also recorded deemed dividends to preferred stockholders totaling \$4,417,000. This amount represents the value attributed to the reduction in exercise and conversion prices of the warrants and preferred stock issued in May 2007 in connection with the financing that occurred in April 2008, as described in Note 2.

During the nine months ended September 30, 2007 we paid cash dividends to Series A and C preferred stockholders of \$195,000 and declared \$563,000 of dividends to our Series B and D preferred stockholders. During the nine months ended September 30, 2007 we also recorded deemed dividends to preferred stockholders totaling \$9,003,000. This amount represents the value attributed to the beneficial conversion feature of the Series B convertible preferred stock of \$7,824,000 and the fair value of warrants and cash totaling \$1,179,000 transferred to the former Series A preferred stockholders in connection with the exchange of their shares for shares of Series C preferred stock that were subordinated to the Series B shares.

The deemed dividends and cash dividends have been included in the calculation of net loss attributable to common stockholders of \$20,194,000, or \$0.50 per share, for the nine months ended September 30, 2008 and \$22,780,000, or \$0.58 per share, for the nine months ended September 30, 2007. The deemed dividends and cash dividends are excluded from net loss (from operating activities) of \$14,312,000, or \$0.36 per share, for the nine months ended September 30, 2008 and \$13,018,000, or \$0.33 per share, for the nine months ended September 30, 2007.

Liquidity and Capital Resources

We have financed our operations since inception through the sale of securities and the issuance of debt (which was subsequently paid off or converted into equity). As of September 30, 2008, we had \$4,206,000 in cash and equivalents.

During the nine months ended September 30, 2008, approximately \$14,406,000 in cash was used in operations, primarily due to a net loss of \$14,312,000, a net decrease of \$854,000 in accounts payable and accrued liabilities, an increase in deferred revenue of \$475,000 and an increase in prepaid expenses of \$63,000. The cash impact of the loss was offset by non-cash stock-based compensation expense of \$330,000 and depreciation, amortization and loss on disposal of fixed assets totaling \$18,000. During the nine months ended September 30, 2008, cash of approximately \$1,154,000 was provided by investing activities resulting from the release of restrictions on \$1,185,000 of cash that had been previously restricted in connection with a standby letter of credit, offset by payments of \$31,000 to purchase fixed assets.

During the nine months ended September 30, 2008, we received net proceeds of \$5,470,000 from the sale of our Series D Preferred stock (see Note 2), proceeds of \$2,987,000 from the sale of common stock and proceeds of \$1,000 from the exercise of stock options. We paid dividends totaling \$740,000 to our Series B and Series C preferred stockholders.

We believe that we have adequate funds at September 30, 2008 to continue operations at budgeted levels through the end of 2008. Our ability to execute our operating plan in 2009 and beyond is dependent on our ability to obtain additional capital (including through the sale of equity and debt securities and by entering into collaborative arrangements with partners) to fund our development activities. We are actively pursuing these alternatives, but there can be no assurance that we will obtain the additional capital necessary to fund our business beyond the end of the current fiscal year. Difficult conditions in the capital markets globally are adversely affecting our ability to obtain funding in a timely manner. We are evaluating measures to aggressively reduce costs to continue operations beyond year-end. If we are unable to obtain sufficient additional funding, we will be required in early 2009 to scale back our administrative activities and clinical development programs, including the Phase 3 clinical development of our lead drug candidate, NOV-002.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2008. Disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, are controls and procedures that are designed to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms and that such information is accumulated and communicated to our management, including our principal executive and financial officers, to allow timely decisions regarding required disclosures.

Based on the evaluation of our disclosure controls and procedures as of September 30, 2008, our Chief Executive Officer and our Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were operating effectively.

Change in Internal Control over Financial Reporting

The Company's management, in connection with its evaluation of internal controls (with the participation of the Company's principal executive officer and principal financial officer), did not identify any change in internal control over the financial reporting process that occurred during the Company's third quarter of 2008 that would have materially affected, or would have been reasonably likely to materially affect, the Company's internal control over financial reporting.

Limitations on Effectiveness of Controls

In designing and evaluating our disclosure controls and procedures, our management recognizes that any system of controls, however well designed and operated, can provide only reasonable, and not absolute, assurance that the objectives of the system are met. In addition, the design of any control system is based in part on certain assumptions about the likelihood of future events. Because of these and other inherent limitations of control systems, there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions, regardless of how remote.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

None.

Item 1A. Risk Factors

The report from our independent registered public accounting firm included in our annual report on Form 10-KSB indicates that there is substantial doubt about whether we will be able to continue as a going concern.

The report from our independent registered public accounting firm included with our annual report on Form 10-KSB indicates that factors exist that raise substantial doubt about our ability to continue as a going concern. We believe that we have adequate funds at September 30, 2008 to continue operations at budgeted levels through the end of 2008. Our ability to continue as a going concern is dependent on our ability to obtain capital (through the sale of equity and debt securities and through collaborative arrangements with partners) to fund our development activities. We are actively pursuing these alternatives, but there can be no assurance that we will obtain the additional capital necessary to fund our business beyond the end of the current fiscal year. Difficult conditions in the capital markets globally are adversely affecting our ability to raise capital in a timely manner. We are evaluating measures to aggressively reduce costs to continue operations beyond year-end. If we are unable to obtain additional capital, we will be required in early 2009 to scale back our administrative activities and clinical development programs, including the Phase 3 clinical development of our lead drug candidate, NOV-002.

We may have difficulty raising needed capital because of our limited operating history and our business risks.

We currently generate insignificant revenue from our proposed products or otherwise. We do not know when this will change. We have expended and will continue to expend substantial funds in the research, development and clinical and pre-clinical testing of our drug compounds. We will require additional funds to conduct research and development, establish and conduct clinical and pre-clinical trials, establish commercial-scale manufacturing arrangements and provide for the marketing and distribution of our products. Additional funds may not be available on acceptable terms, if at all. If adequate funding is not available to us, we may have to delay, reduce the scope of or eliminate one or more of our research or development programs or product launches or marketing efforts, which may materially harm our business, financial condition and results of operations.

Our long-term capital requirements are expected to depend on many factors, including:

- the number of potential products and technologies in development;
- continued progress and cost of our research and development programs;
- progress with pre-clinical studies and clinical trials;
- the time and costs involved in obtaining regulatory clearance;
- costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims;
- costs of developing sales, marketing and distribution channels and our ability to sell our drugs;
- costs involved in establishing manufacturing capabilities for clinical trial and commercial quantities of our drugs;
- competing technological and market developments;
- market acceptance of our products;
- costs for recruiting and retaining management, employees and consultants;
- costs for training physicians;
- our status as a Bulletin-Board listed company and the prospects for our stock to be listed on a national exchange;
- uncertainty and economic instability resulting from terrorist acts and other acts of violence or war; and
- the condition of capital markets and general economic conditions.

We may consume available resources more rapidly than currently anticipated, resulting in the need for additional funding. We may seek to raise any necessary additional funds through the issuance of warrants, equity or debt financings or executing collaborative arrangements with corporate partners or other sources, which may be dilutive to existing stockholders or otherwise have a material effect on our current or future business prospects. In addition, in the event that additional funds are obtained through arrangements with collaborative partners or other sources, we may have to relinquish economic and/or proprietary rights to some of our technologies or products under development that we would otherwise seek to develop or commercialize by ourselves. If adequate funds are not available, we may be required to significantly reduce or refocus our development efforts with regard to our drug compounds. Currently, we believe that we have available cash sufficient to meet our working capital requirements through the end of 2008, assuming our expense levels do not exceed our current plan and that we maintain a vendor payment cycle that is consistent with our past practice. If we do not generate revenues or raise additional capital, we will not be able to sustain our operations at existing levels much beyond the remainder of 2008.

The failure to complete development of our therapeutic technology, obtain government approvals, including required U.S. Food and Drug Administration (FDA) approvals, or to comply with ongoing governmental regulations could prevent, delay or limit introduction or sale of proposed products and result in failure to achieve revenues or maintain our ongoing business.

Our research and development activities and the manufacture and marketing of our intended products are subject to extensive regulation for safety, efficacy and quality by numerous government authorities in the United States and abroad. Before receiving FDA clearance to market our proposed products, we will have to demonstrate that our products are safe and effective for the patient population for the diseases that are to be treated. Clinical trials, manufacturing and marketing of drugs are subject to the rigorous testing and approval process of the FDA and equivalent foreign regulatory authorities. The Federal Food, Drug and Cosmetic Act and other federal, state and foreign statutes and regulations govern and influence the testing, manufacturing, labeling, advertising, distribution and promotion of drugs and medical devices. As a result, clinical trials and regulatory approval can take many years to accomplish and require the expenditure of substantial financial, managerial and other resources.

In order to be commercially viable, we must successfully research, develop, obtain regulatory approval for, manufacture, introduce, market and distribute our technologies. For each drug using oxidized glutathione-based compounds, including NOV-002 and NOV-205, we must successfully meet a number of critical developmental milestones including:

- demonstrating benefit from delivery of each specific drug for specific medical indications;
- demonstrating through pre-clinical and clinical trials that each drug is safe and effective; and
- demonstrating that we have established a viable Good Manufacturing Practices capable of potential scale-up.

The timeframe necessary to achieve these developmental milestones may be long and uncertain, and we may not successfully complete these milestones for any of our intended products in development.

In addition to the risks previously discussed, our technology is subject to additional developmental risks that include the following:

- uncertainties arising from the rapidly growing scientific aspects of drug therapies and potential treatments;
- uncertainties arising as a result of the broad array of alternative potential treatments related to cancer, hepatitis and other diseases; and
- anticipated expense and time believed to be associated with the development and regulatory approval of treatments for cancer, hepatitis and other diseases.

In order to conduct the clinical trials that are necessary to obtain approval by the FDA to market a product, it is necessary to receive clearance from the FDA to conduct such clinical trials. The FDA can halt clinical trials at any time for safety reasons or because we or our clinical investigators do not follow the FDA's requirements for conducting clinical trials. If we are unable to receive clearance to conduct clinical trials or the trials are halted by the FDA, we would not be able to achieve any revenue from such product, as it is illegal to sell any drug for human consumption in the U.S. without FDA approval.

Data obtained from clinical trials is susceptible to varying interpretations, which could delay, limit or prevent regulatory clearances.

Data already obtained, or in the future obtained, from pre-clinical studies and clinical trials does not necessarily predict the results that will be obtained from later pre-clinical studies and clinical trials. Moreover, pre-clinical and clinical data are susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials, even after promising results in earlier trials. The failure to adequately demonstrate the safety and effectiveness of an intended product under development could delay or prevent regulatory clearance of the potential drug, resulting in delays to commercialization, and could materially harm our business. Our clinical trials may not demonstrate sufficient levels of safety and efficacy necessary to obtain the requisite regulatory approvals for our drugs, and our proposed drugs may not be approved for marketing.

We may encounter delays or rejections based on additional government regulation from future legislation or administrative action or changes in FDA policy during the period of development, clinical trials and FDA regulatory review. We may encounter similar delays in foreign countries. Sales of our products outside the U.S. would be subject to foreign regulatory approvals that vary from country to country. The time required to obtain approvals from foreign countries may be shorter or longer than that required for FDA approval, and requirements for foreign licensing may differ from FDA requirements. We may be unable to obtain requisite approvals from the FDA and foreign regulatory authorities, and even if obtained, such approvals may not be on a timely basis, or they may not cover the uses that we request.

Even if we do ultimately receive FDA approval for any of our products, it will be subject to extensive ongoing regulation. This includes regulations governing manufacturing, labeling, packaging, testing, dispensing, prescription and procurement quotas, record keeping, reporting, handling, shipment and disposal of any such drug. Failure to obtain and maintain required registrations or comply with any applicable regulations could further delay or preclude us from developing and commercializing our drugs and subject us to enforcement action.

Our drugs or technology may not gain FDA approval in clinical trials or be effective as a therapeutic agent, which could affect our future profitability and prospects.

In order to obtain regulatory approvals, we must demonstrate that each drug is safe and effective for use in humans and functions as a therapeutic against the effects of a disease or other physiological response. To date, studies conducted in Russia involving our NOV-002 and NOV-205 products have shown what we believe to be promising results. In fact, NOV-002 has been approved for use in Russia for general medicinal use as an immunostimulant in combination with chemotherapy and antimicrobial therapy, and specifically for indications such as tuberculosis and psoriasis. NOV-205 has been approved in Russia as a monotherapy agent for the treatment of hepatitis B and C. Russian regulatory approval is not equivalent to FDA approval. Pivotal Phase 3 studies with a large number of patients, typically required for FDA approval, were not conducted for NOV-002 and NOV-205 in Russia. Further, all of our Russian clinical studies were completed prior to 2000 and may not have been conducted in accordance with current guidelines either in Russia or the United States.

A U.S.-based Phase 1/2 clinical trial of NOV-002 involving 44 non-small cell lung cancer patients provided what we believe to be a favorable outcome. As a result, we enrolled the first patient in the pivotal Phase 3 trial of NOV-002 for non-small cell lung cancer in November 2006. We reached our enrollment target in March 2008 and we expect trial conclusion in the second half of 2009. We enrolled the first patient in the Phase 2 clinical study for NOV-002 for chemotherapy-resistant ovarian cancer in July 2006 and presented what we believe to be encouraging results in May 2008. We also commenced a Phase 2 clinical study for NOV-002 for early-stage breast cancer, and achieved an interim efficacy target in May 2008, earlier than expected. In December 2007, we concluded a U.S. Phase 1b clinical trial of NOV-205 for chronic hepatitis C non-responders based on favorable safety profile. There can be no assurance that we can demonstrate that these products are safe or effective in advanced clinical trials. We are also not able to give assurances that the results of the tests already conducted can be repeated or that further testing will support our applications for regulatory approval. As a result, our drug and technology research program may be curtailed, redirected or eliminated at any time.

There is no guarantee that we will ever generate substantial revenue or become profitable even if one or more of our drugs are approved for commercialization.

We expect to incur increasing operating losses over the next several years as we incur increasing costs for research and development and clinical trials. Our ability to generate revenue and achieve profitability depends on our ability, alone or with others, to complete the development of, obtain required regulatory approvals for and manufacture, market and sell our proposed products. Development is costly and requires significant investment. In addition, if we choose to license or obtain the assignment of rights to additional drugs, the license fees for such drugs may increase our costs.

To date, we have not generated any revenue from the commercial sale of our proposed products or any drugs and do not expect to receive such revenue in the near future. Our primary activity to date has been research and development. A substantial portion of the research results and observations on which we rely were performed by third parties at those parties' sole or shared cost and expense. We cannot be certain as to when or whether to anticipate commercializing and marketing our proposed products in development, and do not expect to generate sufficient revenues from proposed product sales to cover our expenses or achieve profitability in the near future.

We rely solely on research and manufacturing facilities at various universities, hospitals, contract research organizations and contract manufacturers for all of our research, development, and manufacturing, which could be materially delayed should we lose access to those facilities.

At the present time, we have no research, development or manufacturing facilities of our own. We are entirely dependent on contracting with third parties to use their facilities to conduct research, development and manufacturing. Our inability to have the facilities to conduct research, development and manufacturing may delay or impair our ability to gain FDA approval and commercialization of our drug delivery technology and products.

We currently maintain a good working relationship with our contractors. Should the situation change and we are required to relocate these activities on short notice, we do not currently have an alternate facility where we could relocate our research, development and/or manufacturing activities. The cost and time to establish or locate an alternate research, development and/or manufacturing facility to develop our technology would be substantial and would delay gaining FDA approval and commercializing our products.

We are dependent on our collaborative agreements for the development of our technologies and business development, which expose us to the risk of reliance on the viability of third parties.

In conducting our research, development and manufacturing activities, we rely and expect to continue to rely on numerous collaborative agreements with universities, hospitals, governmental agencies, charitable foundations, manufacturers and others. The loss of or failure to perform under any of these arrangements, by any of these entities, may substantially disrupt or delay our research, development and manufacturing activities including our anticipated clinical trials.

We may rely on third-party contract research organizations, service providers and suppliers to support development and clinical testing of our products. Failure of any of these contractors to provide the required services in a timely manner or on reasonable commercial terms could materially delay the development and approval of our products, increase our expenses and materially harm our business, financial condition and results of operations.

We are exposed to product, clinical and preclinical liability risks that could create a substantial financial burden should we be sued.

Our business exposes us to potential product liability and other liability risks that are inherent in the testing, manufacturing and marketing of pharmaceutical products. We cannot assure that such potential claims will not be asserted against us. In addition, the use in our clinical trials of pharmaceutical products that we may develop and then subsequently sell or our potential collaborators may develop and then subsequently sell may cause us to bear a portion of or all product liability risks. A successful liability claim or series of claims brought against us could have a material adverse effect on our business, financial condition and results of operations.

Although we have not received any product liability claims to date, we have an insurance policy of \$5,000,000 per occurrence and \$5,000,000 in the aggregate to cover such claims should they arise. There can be no assurance that material claims will not arise in the future or that our insurance will be adequate to cover all situations. Moreover, there can be no assurance that such insurance, or additional insurance, if required, will be available in the future or, if available, will be available on commercially reasonable terms. Any product liability claim, if successful, could have a material adverse effect on our business, financial condition and results of operations. Furthermore, our current and potential partners with whom we have collaborative agreements or our future licensees may not be willing to indemnify us against these types of liabilities and may not themselves be sufficiently insured or have a net worth sufficient to satisfy any product liability claims. Claims or losses in excess of any product liability insurance coverage that may be obtained by us could have a material adverse effect on our business, financial condition and results of operations.

Acceptance of our products in the marketplace is uncertain and failure to achieve market acceptance will prevent or delay our ability to generate revenues.

Our future financial performance will depend, at least in part, on the introduction and customer acceptance of our proposed products. Even if approved for marketing by the necessary regulatory authorities, our products may not achieve market acceptance. The degree of market acceptance will depend on a number of factors including:

- the receipt of regulatory clearance of marketing claims for the uses that we are developing;
- the establishment and demonstration of the advantages, safety and efficacy of our technologies;
- pricing and reimbursement policies of government and third-party payers such as insurance companies, health maintenance organizations and other health plan administrators;
- our ability to attract corporate partners, including pharmaceutical companies, to assist in commercializing our intended products; and
- our ability to market our products.

Physicians, patients, payers or the medical community in general may be unwilling to accept, utilize or recommend any of our products. If we are unable to obtain regulatory approval or commercialize and market our proposed products when planned, we may not achieve any market acceptance or generate revenue.

We may face litigation from third parties who claim that our products infringe on their intellectual property rights, particularly because there is often substantial uncertainty about the validity and breadth of medical patents.

We may be exposed to future litigation by third parties based on claims that our technologies, products or activities infringe on the intellectual property rights of others or that we have misappropriated the trade secrets of others. This risk is exacerbated by the fact that the validity and breadth of claims covered in medical technology patents and the breadth and scope of trade-secret protection involve complex legal and factual questions for which important legal principles are unresolved. Any litigation or claims against us, whether or not valid, could result in substantial costs, could place a significant strain on our financial and managerial resources and could harm our reputation. Most of our license agreements would likely require that we pay the costs associated with defending this type of litigation. In addition, intellectual property litigation or claims could force us to do one or more of the following:

- cease selling, incorporating or using any of our technologies and/or products that incorporate the challenged intellectual property, which would adversely affect our future revenue;
- obtain a license from the holder of the infringed intellectual property right, which license may be costly or may not be available on reasonable terms, if at all; or
- redesign our products, which would be costly and time-consuming.

If we are unable to adequately protect or enforce our rights to intellectual property or secure rights to third-party patents, we may lose valuable rights, experience reduced market share, assuming any, or incur costly litigation to protect such rights.

Our ability to obtain licenses to patents, maintain trade secret protection and operate without infringing the proprietary rights of others will be important to our commercializing any products under development. Therefore, any disruption in access to the technology could substantially delay the development of our technology.

The patent positions of biotechnology and pharmaceutical companies, including us, that involve licensing agreements, are frequently uncertain and involve complex legal and factual questions. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued or in subsequent legal proceedings. Consequently, our patent applications and any issued and licensed patents may not provide protection against competitive technologies or may be held invalid if challenged or circumvented. Our competitors may also independently develop products similar to ours or design around or otherwise circumvent patents issued or licensed to us. In addition, the laws of some foreign countries may not protect our proprietary rights to the same extent as U.S. law.

We also rely on trade secrets, technical know-how and continuing technological innovation to develop and maintain our competitive position. We generally require our employees, consultants, advisors and collaborators to execute appropriate confidentiality and assignment-of-inventions agreements. Our competitors may independently develop substantially equivalent proprietary information and techniques, reverse engineer our information and techniques, or otherwise gain access to our proprietary technology. We may be unable to meaningfully protect our rights in trade secrets, technical know-how and other non-patented technology.

Although our trade secrets and technical know-how are important, our continued access to the patents is a significant factor in the development and commercialization of our products. Aside from the general body of scientific knowledge from other drug delivery processes and technology, these patents, to the best of our knowledge and based on our current scientific data, are the only intellectual property necessary to develop our products, including NOV-002 and NOV-205. We do not believe that we are or will be violating any patents in developing our technology.

We may have to resort to litigation to protect our rights for certain intellectual property, or to determine their scope, validity or enforceability. Enforcing or defending our rights is expensive, could cause diversion of our resources and may not prove successful. Any failure to enforce or protect our rights could cause us to lose the ability to exclude others from using our technology to develop or sell competing products.

We have limited manufacturing experience and, if our products are approved, we may not be able to manufacture sufficient quantities at an acceptable cost, or may be subject to risk that contract manufacturers could experience shut-downs or delays.

We remain in the research and development and clinical and pre-clinical trial phase of product commercialization. Accordingly, if our products are approved for commercial sale, we will need to establish the capability to commercially manufacture our products in accordance with FDA and other regulatory requirements. We have limited experience in establishing, supervising and conducting commercial manufacturing. If we fail to adequately establish, supervise and conduct all aspects of the manufacturing processes, we may not be able to commercialize our products.

We presently plan to rely on third-party contractors to manufacture our products. This may expose us to the risks of not being able to directly oversee the production and quality of the manufacturing process. Furthermore, these contractors, whether foreign or domestic, may experience regulatory compliance difficulties, mechanical shutdowns, employee strikes or other unforeseeable acts that may delay production.

Due to our limited marketing, sales and distribution experience, we may be unsuccessful in our efforts to sell our products, enter into relationships with third parties or develop a direct sales organization.

We have not yet had to establish marketing, sales or distribution capabilities for our proposed products. Until such time as our products are further along in the regulatory process, we will not devote any meaningful time and resources to this effort. At the appropriate time, we intend to enter into agreements with third parties to sell our products or we may develop our own sales and marketing force. We may be unable to establish or maintain third-party relationships on a commercially reasonable basis, if at all. In addition, these third parties may have similar or more established relationships with our competitors.

If we do not enter into relationships with third parties for the sale and marketing of our products, we will need to develop our own sales and marketing capabilities. We have limited experience in developing, training or managing a sales force. If we choose to establish a direct sales force, we may incur substantial additional expenses in developing, training and managing such an organization. We may be unable to build a sales force on a cost-effective basis or at all. Any such direct marketing and sales efforts may prove to be unsuccessful. In addition, we will compete with many other companies that currently have extensive marketing and sales operations. Our marketing and sales efforts may be unable to compete against these other companies. We may be unable to establish a sufficient sales and marketing organization on a timely basis, if at all.

We may be unable to engage qualified distributors. Even if engaged, these distributors may:

- fail to adequately market our products
- fail to satisfy financial or contractual obligations to us;
- offer, design, manufacture or promote competing products ; or
- cease operations with little or no notice.

If we fail to develop sales, marketing and distribution channels, we would experience delays in product sales and incur increased costs, which would harm our financial results.

If we are unable to convince physicians as to the benefits of our intended products, we may incur delays or additional expense in our attempt to establish market acceptance.

Achieving broad use of our products may require physicians to be informed regarding these products and their intended benefits. The time and cost of such an educational process may be substantial. Inability to successfully carry out this physician education process may adversely affect market acceptance of our products. We may be unable to timely educate physicians regarding our intended products in sufficient numbers to achieve our marketing plans or to achieve product acceptance. Any delay in physician education may materially delay or reduce demand for our products. In addition, we may expend significant funds towards physician education before any acceptance or demand for our products is created, if at all.

Fluctuations in foreign exchange rates could increase costs to complete international clinical trial activities.

We have initiated a portion of our clinical trial activities in both Western and Eastern Europe. We anticipate that approximately 40% of the remaining Phase 3 clinical trial budget of approximately \$6 million will be incurred in Euros. Significant depreciation in the value of the U.S. Dollar against principally the Euro could adversely affect our ability to complete the trials, particularly if we are unable to redirect funding or raise additional funds. Since the timing and amount of foreign-denominated payments are uncertain and dependent on a number of factors, it is difficult to cost-effectively hedge the potential exposure. Therefore, to date, we have not entered into any foreign currency hedges to mitigate the potential exposure.

The market for our products is rapidly changing and competitive, and new therapeutics, new drugs and new treatments that may be developed by others could impair our ability to maintain and grow our business and remain competitive.

The pharmaceutical and biotechnology industries are subject to rapid and substantial technological change. Developments by others may render our technologies and intended products noncompetitive or obsolete, or we may be unable to keep pace with technological developments or other market factors. Technological competition from pharmaceutical and biotechnology companies, universities, governmental entities and others diversifying into the field is intense and is expected to increase. Most of these entities have significantly greater research and development capabilities and budgets than we do, as well as substantially more marketing, manufacturing, financial and managerial resources. These entities represent significant competition for us. Acquisitions of, or investments in, competing pharmaceutical or biotechnology companies by large corporations could increase such competitors' financial, marketing, manufacturing and other resources.

We are an early-stage enterprise that operates with limited day-to-day business management, serves as a vehicle to hold certain technology for possible future exploration, and has been and will continue to be engaged in the development of new drugs and therapeutic technologies. As a result, our resources are limited and we may experience management, operational or technical challenges inherent in such activities and novel technologies. Competitors have developed or are in the process of developing technologies that are, or in the future may be, the basis for competition. Some of these technologies may have an entirely different approach or means of accomplishing similar therapeutic effects from our technology. Our competitors may develop drugs and drug delivery technologies that are more effective than our intended products and, therefore, present a serious competitive threat to us.

The potential widespread acceptance of therapies that are alternatives to ours may limit market acceptance of our products even if commercialized. Many of our targeted diseases and conditions can also be treated by other medication or drug delivery technologies. These treatments may be widely accepted in medical communities and have a longer history of use. The established use of these competitive drugs may limit the potential for our technologies and products to receive widespread acceptance if commercialized.

If users of our products are unable to obtain adequate reimbursement from third-party payers, or if new restrictive legislation is adopted, market acceptance of our products may be limited and we may not achieve anticipated revenues.

The continuing efforts of government and insurance companies, health maintenance organizations and other payers of healthcare costs to contain or reduce costs of health care may affect our future revenues and profitability, and the future revenues and profitability of our potential customers, suppliers and collaborative partners and the availability of capital. For example, in certain foreign markets, pricing or profitability of prescription pharmaceuticals is subject to government control. In the United States, given recent federal and state government initiatives directed at lowering the total cost of health care, the U.S. Congress and state legislatures will likely continue to focus on healthcare reform, the cost of prescription pharmaceuticals and the reform of the Medicare and Medicaid systems. While we cannot predict whether any such legislative or regulatory proposals will be adopted, the announcement or adoption of such proposals could materially harm our business, financial condition and results of operations.

Our ability to commercialize our products will depend in part on the extent to which appropriate reimbursement levels for the cost of our products and related treatment are obtained by governmental authorities, private health insurers and other organizations, such as health maintenance organizations (HMOs). Third-party payers are increasingly challenging the prices charged for medical drugs and services. Also, the trend toward managed health care in the United States and the concurrent growth of organizations such as HMOs that could control or significantly influence the purchase of healthcare services and drugs, as well as legislative proposals to reform health care or reduce government insurance programs, may all result in lower prices for or rejection of our drugs. The cost containment measures that healthcare payers and providers are instituting and the effect of any healthcare reform could materially harm our ability to operate profitably.

We depend on key personnel who may terminate their employment with us at any time, and we would need to hire additional qualified personnel.

Our success will depend to a significant degree on the continued services of key management and advisors to us. There can be no assurance that these individuals will continue to provide service to us. In addition, our success will depend on our ability to attract and retain other highly skilled personnel. We may be unable to recruit such personnel on a timely basis, if at all. Our management and other employees may voluntarily terminate their employment with us at any time. The loss of services of key personnel, or the inability to attract and retain additional qualified personnel, could result in delays in development or approval of our products, loss of sales and diversion of management resources.

Compliance with changing corporate governance and public disclosure regulations may result in additional expense.

Keeping abreast of, and in compliance with, changing laws, regulations and standards relating to corporate governance, public disclosure and internal controls, including the Sarbanes-Oxley Act of 2002, new SEC regulations and, in the event we seek and are approved for listing on a registered national securities exchange, the stock exchange rules, will require an increased amount of management attention and external resources. We intend to continue to invest all reasonably necessary resources to comply with evolving standards, which may result in increased general and administrative expense and a diversion of management time and attention from revenue-generating activities to compliance activities. Beginning with the annual report for the fiscal year ending December 31, 2007 we were required to include a report of our management on internal control over financial reporting. In our annual report for the fiscal year ending December 31, 2009 we will be required to include an attestation report of our independent registered public accounting firm on internal control over financial reporting.

Our executive officers, directors and principal stockholders have substantial holdings, which could delay or prevent a change in corporate control favored by our other stockholders.

Our directors, officers and holders of our Series D preferred stock beneficially own, in the aggregate, approximately 46% of our outstanding voting shares. The interests of our current officers, directors and Series D investors may differ from the interests of other stockholders. Further, our current officers, directors and Series D investors may have the ability to significantly affect the outcome of all corporate actions requiring stockholder approval, including the following actions:

- the election of directors;
- the amendment of charter documents;
- issuance of blank-check preferred or convertible stock, notes or instruments of indebtedness which may have conversion, liquidation and similar features, or completion of other financing arrangements; or
- the approval of certain mergers and other significant corporate transactions, including a sale of substantially all of our assets, or merger with a publicly-traded shell or other company.

Our common stock could be further diluted as the result of the issuance of additional shares of common stock, convertible securities, warrants or options.

In the past, we have issued common stock, convertible securities, such as convertible preferred stock, and warrants in order to raise money. We have also issued options and warrants as compensation for services and incentive compensation for our employees and directors. We have shares of common stock reserved for issuance upon the conversion and exercise of these securities and may increase the shares reserved for these purposes in the future. Our issuance of additional common stock, convertible securities, options and warrants could affect the rights of our stockholders, and could reduce the market price of our common stock.

We are prohibited from taking certain actions and entering into certain transactions as a result of the issuance of our Series D preferred stock.

For as long as any shares of Series D Preferred Stock remain outstanding we are prohibited from taking certain actions or entering into certain transactions without the prior consent of the holders of outstanding shares of Series D preferred stock. We are prohibited from paying dividends to common stockholders, amending our certificate of incorporation, issuing any equity security or any security convertible into or exercisable for any equity security at a price of \$0.65 or less or with rights senior to the Series D Preferred Stock (except for certain exempted issuances), increasing the number of shares of Series D Preferred Stock or issuing any additional shares of Series D Preferred Stock other than the 420 shares designated in the Series D Certificate of Designations, or changing the number of our directors. We are also prohibited from entering into certain transactions such as selling or otherwise disposing of all or substantially all of our assets or intellectual property or entering into a merger or consolidation with another company unless we are the surviving corporation, the Series D Preferred Stock remains outstanding and there are no changes to the rights and preferences of the Series D Preferred Stock, redeeming or repurchasing any capital stock other than Series D Preferred Stock, or incurring any new debt for borrowed money in excess of \$500,000.

If the board of directors determines that any of these actions are in the best interest of the Company or our shareholders, we may be unable to complete them if we do not get the approval of the holders of the outstanding shares of Series D preferred stock.

We were unable to pay dividends to our preferred stockholders on June 30, 2008 and September 30, 2008 and may be unable to pay dividends to preferred stockholders when due in future periods.

As a result of continuing losses during the nine months ended September 30, 2008, as of June 30, 2008 and September 30, 2008 we did not have legally available funds for the payment of dividends under Delaware corporate law. Accordingly, we were unable to pay dividends totaling \$1,060,935 that were accrued in respect of the Series D and Series C preferred stock as of September 30, 2008. Our ability to pay dividends on stated future dividend payment dates will be dependent on a number of factors including the timing of future financings and the amount of net losses in future periods.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

On August 15, 2008, we sold 4,615,384 shares of our common stock to two related accredited investors for gross proceeds of approximately \$3 million, pursuant to a securities purchase agreement dated August 14, 2008.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Submission of Matters to a Vote of Security Holders

None.

Item 5. Other Information

None.

Item 6. Exhibits

Exhibit No.	Description	Filed with this Form 10-Q	Incorporated by Reference		
			Form	Filing Date	Exhibit No.
2.1	Agreement and plan of merger among Common Horizons, Inc., Nove Acquisition, Inc. and Novelos Therapeutics, Inc. dated May 26, 2005		8-K	June 2, 2005	99.2
2.2	Agreement and plan of merger between Common Horizons and Novelos Therapeutics, Inc. dated June 7, 2005		10-QSB	August 15, 2005	2.2
3.1	Amended and Restated Certificate of Incorporation filed as Exhibit A to the Certificate of Merger merging Nove Acquisition, Inc. with and into Novelos Therapeutics, Inc. dated May 26, 2005		10-QSB	August 10, 2007	3.1

Exhibit No.	Description	Filed with this Form 10-Q	Incorporated by Reference		
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3.2	Certificate of Merger merging Common Horizons, Inc. with and into Novelos Therapeutics, Inc. dated June 13, 2005		10-QSB	August 10, 2007	3.2
3.3	Certificate of Correction dated March 3, 2006		10-QSB	August 10, 2007	3.3
3.4	Certificate of Amendment to Amended and Restated Certificate of Incorporation dated July 16, 2007		10-QSB	August 10, 2007	3.4
3.5	Certificate of Designations of Series B convertible preferred stock		10-QSB	August 10, 2007	3.5
3.6	Certificate of Designations of Series C cumulative convertible preferred stock		10-QSB	August 10, 2007	3.6
3.7	Certificate of Designations of Series D convertible preferred stock		8-K	April 14, 2008	4.1
3.8	Certificate of Elimination Series A 8% Cumulative Convertible Preferred Stock of Novelos Therapeutics, Inc.		8-K	April 14, 2008	4.2
3.9	By-Laws		8-K	June 17, 2005	2
10.1	Securities Purchase Agreement dated August 14, 2008		8-K	August 18, 2008	10.1
31.1	Certification of the chief executive officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	X			
31.2	Certification of the chief financial officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	X			
32.1	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	X			

SIGNATURES

In accordance with the requirements of the Exchange Act, the registrant caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

NOVELOS THERAPEUTICS, INC.

Date: November 12, 2008

By: /s/ Harry S. Palmin

Harry S. Palmin

President and Chief Executive Officer

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I, HARRY S. PALMIN, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Novelos Therapeutics, Inc., a Delaware Corporation;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the small business issuer, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 12, 2008

/s/ Harry S. Palmin

Harry S. Palmin

President and Chief Executive Officer (Principal Executive Officer)

I, JOANNE M. PROTANO, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Novelos Therapeutics, Inc., a Delaware Corporation;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the small business issuer, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 12, 2008

/s/ Joanne M. Protano

Joanne M. Protano

Chief Financial Officer (Principal Financial and Accounting Officer)

**CERTIFICATION PURSUANT TO
18 U.S.C. § 1350
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report on Form 10-Q of Novelos Therapeutics, Inc., (the "Company") for the quarter ended September 30, 2008, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), we, Harry S. Palmin, President and Chief Executive Officer of the Company, and Joanne M. Protano, Vice President, Chief Financial Officer and Treasurer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to our knowledge, that:

- 1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- 2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Harry S. Palmin

Harry S. Palmin
President, Chief Executive Officer (Principal Executive Officer)

Date: November 12, 2008

/s/ Joanne M. Protano

Joanne M. Protano
Chief Financial Officer (Principal Financial and Accounting Officer)

Date: November 12, 2008
