

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

FORM 10-Q

[mark one]

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

For the quarterly period ended: September 30, 2010

☐ TRANSITION REPORT PURSUANT TO 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 registrant 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
(Registrant's telephone number, including area code)

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

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

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

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

(Check one):

Large accelerated filer ☐

Accelerated filer ☐

Non-accelerated filer ☐

(Do not check if a smaller reporting company) Smaller reporting company ☒

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: 111,931,182 shares of common stock, \$0.00001 par value per share, as of November 17, 2010.

NOVELOS THERAPEUTICS, INC.

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

NOVELOS THERAPEUTICS, INC. BALANCE SHEETS

	September 30, 2010 (unaudited)	December 31, 2009
ASSETS		
CURRENT ASSETS:		
Cash and equivalents	\$ 3,365,741	\$ 8,769,529
Prepaid expenses and other current assets	99,771	102,923
Total current assets	3,465,512	8,872,452
FIXED ASSETS, NET	11,222	44,097
DEPOSITS	15,350	15,350
TOTAL ASSETS	\$ 3,492,084	\$ 8,931,899
LIABILITIES, REDEEMABLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIENCY		
CURRENT LIABILITIES:		
Accounts payable and accrued liabilities	\$ 770,748	\$ 3,299,217
Accrued compensation	146,790	245,711
Accrued liquidated damages (see Note 4)	819,000	—
Accrued dividends	4,088,067	2,902,963
Derivative liability (see Note 2)	507,126	10,486,594
Deferred revenue – current	33,333	33,333
Total current liabilities	6,365,064	16,967,818
DEFERRED REVENUE – NONCURRENT	375,000	400,000
COMMITMENTS AND CONTINGENCIES		
REDEEMABLE PREFERRED STOCK:		
Series E convertible preferred stock, \$0.00001 par value; 735 shares designated; 408.264045 and 548.26078125 shares issued and outstanding at September 30, 2010 and December 31, 2009, respectively (liquidation preference \$23,424,150 at September 30, 2010)	13,770,026	18,459,619
STOCKHOLDERS' DEFICIENCY:		
Preferred Stock, \$0.00001 par value; 7,000 shares authorized: Series C cumulative convertible preferred stock; 272 shares designated; 204 shares issued and outstanding at September 30, 2010 and December 31, 2009 (liquidation preference \$3,525,120 at September 30, 2010)	—	—
Common stock, \$0.00001 par value; 225,000,000 shares authorized; 111,931,182 and 69,658,002 shares issued and outstanding at September 30, 2010 and December 31, 2009, respectively	1,119	697
Additional paid-in capital	56,359,557	49,175,853
Accumulated deficit	(73,378,682)	(76,072,088)
Total stockholders' deficiency	(17,018,006)	(26,895,538)
TOTAL LIABILITIES, REDEEMABLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIENCY	\$ 3,492,084	\$ 8,931,899

See notes to financial statements.

NOVELOS THERAPEUTICS, INC.
STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
REVENUE	\$ 8,333	\$ 13,702	\$ 25,000	\$ 76,983
COSTS AND EXPENSES:				
Research and development	374,822	1,765,664	2,482,728	5,137,955
General and administrative	542,544	545,883	1,930,464	1,528,826
Total costs and expenses	917,366	2,311,547	4,413,192	6,666,781
LOSS FROM OPERATIONS	(909,033)	(2,297,845)	(4,388,192)	(6,589,798)
OTHER INCOME (EXPENSE):				
Interest income	1,300	—	1,300	1,012
Gain (loss) on derivatives	(2,860)	(446,685)	7,899,298	(2,830,274)
Liquidated damages (see Note 4)	(315,000)	—	(819,000)	—
Miscellaneous	—	1,500	—	6,233
Total other income (expense)	(316,560)	(445,185)	7,081,598	(2,823,029)
NET INCOME (LOSS)	(1,225,593)	(2,743,030)	2,693,406	(9,412,827)
PREFERRED STOCK DIVIDENDS	(581,697)	(842,996)	(1,820,029)	(2,495,902)
PREFERRED STOCK DEEMED DIVIDENDS	(586,050)	—	(586,050)	(714,031)
NET INCOME (LOSS) ATTRIBUTABLE TO COMMON STOCKHOLDERS	\$ (2,393,340)	\$ (3,586,026)	\$ 287,327	\$ (12,622,760)
BASIC NET INCOME (LOSS) ATTRIBUTABLE TO COMMON STOCKHOLDERS PER COMMON SHARE	\$ (0.02)	\$ (0.07)	\$ 0.00	\$ (0.27)
SHARES USED IN COMPUTING BASIC NET INCOME (LOSS) ATTRIBUTABLE TO COMMON STOCKHOLDERS PER COMMON SHARE	105,642,361	49,653,675	92,109,358	45,944,799
DILUTED NET INCOME (LOSS) ATTRIBUTABLE TO COMMON STOCKHOLDERS PER COMMON SHARE	\$ (0.02)	\$ (0.07)	\$ 0.00	\$ (0.27)
SHARES USED IN COMPUTING DILUTED NET INCOME (LOSS) ATTRIBUTABLE TO COMMON STOCKHOLDERS PER COMMON SHARE	105,642,361	49,653,675	95,193,685	45,944,799

See notes to financial statements.

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

	Nine months ended September 30,	
	2010	2009
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net income (loss)	\$ 2,693,406	\$ (9,412,827)
Adjustments to reconcile net income (loss) to cash used in operating activities:		
Depreciation and amortization	32,875	22,423
Stock-based compensation	191,762	503,161
(Gain) loss on derivative warrants	(7,899,298)	2,830,274
Changes in:		
Prepaid expenses and other current assets	3,152	(230,184)
Accounts payable and accrued liabilities	(2,528,469)	(1,965,443)
Accrued compensation	(98,921)	(53,375)
Accrued liquidated damages	819,000	—
Deferred revenue	(25,000)	(24,999)
Cash used in operating activities	(6,811,493)	(8,330,970)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of fixed assets	—	(18,000)
Cash used in investing activities	—	(18,000)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock, net	1,249,138	3,449,101
Proceeds from issuance of Series E convertible preferred stock and warrants, net	—	9,204,531
Proceeds from exercise of stock options	158,567	—
Cash provided by financing activities	1,407,705	12,653,632
INCREASE (DECREASE) IN CASH AND EQUIVALENTS	(5,403,788)	4,304,662
CASH AND EQUIVALENTS AT BEGINNING OF PERIOD	8,769,529	1,262,452
CASH AND EQUIVALENTS AT END OF PERIOD	\$ 3,365,741	\$ 5,567,114
SUPPLEMENTAL DISCLOSURES OF NON-CASH FINANCING ACTIVITIES		
Dividends accumulated on shares of Series E preferred stock exchanged or converted into shares of common stock	\$ 634,925	\$ 1,773,666
Fair value of derivative warrants upon adoption of new accounting principle	\$ —	\$ 998,945
Fair value of derivative warrants reclassified to additional paid-in capital upon cashless exercise or exchange	\$ 2,584,397	\$ 1,741,043
Carrying value of redeemable preferred stock converted into common stock	\$ 4,689,593	\$ 1,290,865
Exchange of Series D for Series E preferred stock	\$ —	\$ 13,904,100
Relative fair value of warrants issued to stockholders in financing transactions	\$ 504,227	\$ 3,659,692
Fair value of warrants issued to preferred stockholders in exchange for their consent	\$ 586,050	\$ —

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 biopharmaceutical company developing oxidized glutathione-based compounds for the treatment of cancer. Novelos is also seeking to expand its product pipeline by licensing or acquiring clinical stage compounds or technologies for oncology indications. Novelos owns exclusive worldwide intellectual property rights (excluding Russia and other states of the former Soviet Union (the “Russian Territory”), but including Estonia, Latvia and Lithuania) 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 small biopharmaceutical companies. 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.

On February 24, 2010, the Company announced that its Phase 3 clinical trial for NOV-002 in non-small cell lung cancer (“NSCLC”) (the “Phase 3 Trial”) did not meet its primary endpoint of a statistically significant increase in median overall survival. Following evaluation of the detailed trial data, on March 18, 2010, the Company announced that the secondary endpoints had also not been met in the Phase 3 Trial and that it had discontinued development of NOV-002 for NSCLC in combination with first-line paclitaxel and carboplatin chemotherapy, although development for other indications is continuing.

The Company has generated insignificant revenues and has incurred operating losses since inception in devoting substantially all of its efforts toward research and development. The Company expects that it will continue to generate operating losses for the foreseeable future. On October 29, 2010, the Company received notification from the Internal Revenue Service that it had been awarded a cash grant of approximately \$245,000 as a Qualifying Therapeutic Discovery Project Credit under the Patient Protection and Affordable Care Act, H.R. 3590. The Company believes that it has adequate cash, after including the proceeds of this grant, to fund its operations through the first quarter of 2011. The Company’s ability to operate beyond the first quarter of 2011 is dependent on its ability to obtain additional funding via the sale of equity and/or debt securities, a strategic transaction or otherwise. The negative outcome of the Phase 3 Trial, as well as continuing difficult conditions in the capital markets globally, may adversely affect the ability of the Company to obtain funding in a timely manner. If the Company is unable to obtain new funding, it would begin to wind down operations in March 2011. The Company plans to continue to actively pursue financing alternatives, but there can be no assurance that it will obtain the funding necessary to continue its operations. In the interim, the Company is continuously evaluating measures to reduce costs to conserve its limited cash resources.

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, 2010. 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, 2009 on Form 10-K, which was filed with the Securities and Exchange Commission (“SEC”) on March 30, 2010. The report from the Company’s independent registered public accounting firm dated March 23, 2010 and included with its annual report on Form 10-K indicated that factors exist that raised substantial doubt about the Company’s ability to continue as a going concern.

Comprehensive Income (Loss) – The Company had no components of comprehensive income (loss) other than the net income (loss) in all periods presented.

Derivative Instruments – The Company generally does not use derivative instruments to hedge exposures to cash flow or market risks. However, certain warrants to purchase common stock that do not meet the requirements for classification as equity, in accordance with the Derivatives and Hedging Topic of the Financial Accounting Standards Board Accounting Standards Codification (“FASB ASC”), are classified as liabilities. In such instances, net-cash settlement is assumed for financial reporting purposes, even when the terms of the underlying contracts do not provide for a net-cash settlement. These warrants are considered derivative instruments because the agreements contain “down-round” provisions whereby the number of shares for which the warrants are exercisable and/or the exercise price of the warrants are subject to change in the event of certain issuances of stock at prices below the then-effective exercise price of the warrants. The number of such warrants was 21,207,625 at September 30, 2010. The primary underlying risk exposure pertaining to the warrants is the change in fair value of the underlying common stock. Such financial instruments are initially recorded at fair value, or relative fair value, when issued with other instruments, with subsequent changes in fair value recorded as a component of gain or loss on derivatives in each reporting period. If these instruments subsequently meet the requirements for equity classification, the Company reclassifies the fair value to equity. At September 30, 2010, these warrants represented the only outstanding derivative instruments issued or held by the Company. As a result of the significant decline in the Company’s stock price following the announcement of the results of the Phase 3 Trial, the Company recorded a gain of approximately \$7,899,000 during the nine months ended September 30, 2010 in connection with the revaluation of the derivative liability balance at September 30, 2010.

2. FAIR VALUES OF ASSETS AND LIABILITIES

In accordance with Fair Value Measurements and Disclosures Topic of the FASB ASC, the Company groups its financial assets and financial liabilities generally measured at fair value in three levels, based on the markets in which the assets and liabilities are traded and the reliability of the assumptions used to determine fair value.

- Level 1: Input prices quoted in an active market for identical financial assets or liabilities.
- Level 2: Inputs other than prices quoted in Level 1, such as prices quoted for similar financial assets and liabilities in active markets, prices for identical assets and liabilities in markets that are not active or other inputs that are observable or can be corroborated by observable market data.
- Level 3: Input prices quoted that are significant to the fair value of the financial assets or liabilities which are not observable or supported by an active market.

Assets and liabilities measured at fair value on a recurring basis are summarized below:

		September 30, 2010			
		Level 1	Level 2	Level 3	Fair Value
Liabilities:					
Warrants		\$ -	\$ 507,126	\$ -	\$ 507,126
		December 31, 2009			
		Level 1	Level 2	Level 3	Fair Value
Liabilities:					
Warrants		\$ -	\$ 10,486,594	\$ -	\$ 10,486,594

The fair value of warrants has been estimated using the Black-Scholes option pricing model based on the closing price of the common stock at the valuation date, estimated volatility of 90%, terms ranging from five months to 4.8 years at September 30, 2010 and three to fourteen months at December 31, 2009 and risk-free interest rates ranging from 0.19% to 1.27% at September 30, 2010 and 0.04% to 0.47% at December 31, 2009.

3. COLLABORATION AGREEMENTS

2007 Collaboration Agreement with Lee's Pharmaceutical (HK) Ltd.

In December 2007 the Company entered into a Collaboration Agreement with Lee's Pharmaceutical (HK) Ltd. ("Lee's Pharm"). Pursuant to this agreement, Lee's Pharm obtained an exclusive license to develop, manufacture and commercialize NOV-002 and NOV-205 in China, Hong Kong, Taiwan and Macau (the "Chinese Territory"). The Company has suspended further development of NOV-205; however, this suspension will not impact the development strategy of Lee's Pharm. Under the terms of the agreement the Company received a 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 Pharm. This initial \$500,000 payment received is being amortized over the estimated term of this agreement, 15 years. Accordingly, \$8,000 and \$25,000 of license revenue was recognized in each of the three- and nine-month periods, respectively, ended September 30, 2010 and 2009.

The Lee's Pharm agreement provides that the Company receive royalty payments of 20-25% of net sales of NOV-002 in the Chinese Territory and receive royalty payments of 12-15% of net sales of NOV-205 in the Chinese Territory. Lee's Pharm is obligated to reimburse the Company for the manufacturing cost of pharmaceutical products provided to Lee's Pharm in connection with the agreement. Lee's Pharm has committed to spend a minimum amount 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.

2009 Collaboration Agreement with Mundipharma

On February 11, 2009, Novelos entered into a collaboration agreement (the "Collaboration Agreement") with Mundipharma International Corporation Limited ("Mundipharma") to develop, manufacture and commercialize, on an exclusive basis, Licensed Products (as defined in the Collaboration Agreement), which includes the Company's lead compound, NOV-002, in Europe (other than the Russian Territory), Asia (other than the Chinese Territory) and Australia (collectively referred to as the "Mundipharma Territory"). Mundipharma is an independent associated company of Purdue Pharma, L.P. ("Purdue"). The Collaboration Agreement provides for Mundipharma to pay the Company royalties and fixed milestone payments based on sales and commercial launches in the licensed territories.

For countries in which patents are held, the Collaboration Agreement expires on a country-by-country basis within the Mundipharma Territory on the earlier of (1) expiration of the last applicable Novelos patent within the country or (2) the determination that any patents within the country are invalid, obvious or otherwise unenforceable. For countries in which no patents are held, the Collaboration Agreement expires the earlier of 15 years from its effective date or upon generic product competition in the country resulting in a 20% drop in Mundipharma's market share. Novelos may terminate the Collaboration Agreement upon breach or default by Mundipharma. Mundipharma may terminate the Collaboration Agreement upon breach or default, filing of voluntary or involuntary bankruptcy by Novelos, the termination of certain agreements with companies associated with the originators of the licensed technology, or 30-day notice for no reason. If any regulatory approval within the Mundipharma Territory is suspended as a result of issues related to the safety of the Licensed Products, then Mundipharma's obligations under the Collaboration Agreement will be suspended until the regulatory approval is reinstated. If that reinstatement does not occur within 12 months of the suspension, then Mundipharma may terminate the Collaboration Agreement.

Concurrently with the execution of the Collaboration Agreement, Novelos completed a private placement of Series E preferred stock and common stock purchase warrants to Purdue.

The Company expects that the negative results of its Phase 3 Trial will adversely affect development and commercialization of NOV-002 under the collaboration agreements with Lee's Pharm and Mundipharma.

4. STOCKHOLDERS' DEFICIENCY

July 2010 Direct Offering

On July 27, 2010, pursuant to securities purchase agreements entered into with institutional investors on July 21, 2010, the Company completed the sale, in an offering registered under the Securities Act of 1933, as amended, of an aggregate of 21,428,576 shares of its common stock and five-year warrants to purchase up to an aggregate of 16,071,434 shares of its common stock at an exercise price of \$0.07 per share, for gross proceeds of \$1,500,000 and net proceeds of \$1,249,000 after deducting transaction costs. The warrant exercise price is subject to adjustment in certain circumstances and therefore, the relative fair value of the warrants at the date of issuance, \$504,000, has been bifurcated from the proceeds and recorded as a derivative liability (see Note 1). The fair value has been estimated using the Black-Scholes option pricing model based on the closing price of the common stock at the valuation date, a volatility of 90%, risk-free interest rate of 1.76% and a term of five years.

Since the securities in this financing were issued at a price less than \$0.66 per share, the Company obtained the consent of its preferred stockholders pursuant to a consent and waiver dated July 6, 2010, as amended on July 21, 2010. In connection with obtaining this consent, the Company issued five-year warrants (the "Incentive Warrants") to its preferred stockholders for the purchase of up to an aggregate of 16,071,434 shares of common stock at an exercise price of \$0.105 per share. No adjustments to the conversion price of the preferred stock or warrants held by preferred stockholders were made in connection with the financing. The fair value of the Incentive Warrants at date of issuance, \$586,000, is shown as a deemed dividend to the preferred stockholders on the statement of operations for the three and nine months ended September 30, 2010. The fair value of the warrants has been estimated using the Black-Scholes option pricing model based on the closing price of the common stock at the valuation date, a volatility of 90%, risk-free interest rate of 1.76% and a term of five years.

The financing resulted in adjustments to certain warrants pursuant to their terms. Warrants issued in 2005 that were exercisable for 243,476 shares at an exercise price of \$0.65 per share as of immediately prior to the transaction became exercisable for 2,260,845 shares at an exercise price of \$0.07 per share, and warrants issued in 2006 that were exercisable for 4,557,461 shares at an exercise price of \$1.72 per share as of immediately prior to the transaction became exercisable for 5,136,191 shares at an exercise price of \$1.53 per share. The 2005 warrants expired unexercised on August 9, 2010, and the 2006 warrants will expire in March 2011.

Registration Rights Agreements

Simultaneous with the execution of the Series E preferred stock purchase agreement in 2009, the Company entered into a registration rights agreement (the "Series E Registration Agreement") with Purdue and the investors in the Company's Series D preferred stock (the "Series D Investors"). The Series E Registration Agreement replaced a prior agreement dated April 11, 2008 between Novelos and the Series D Investors. The Series E Registration Agreement required Novelos to file with the SEC no later than 5 business days following the six-month anniversary of the execution of the Series E purchase agreement (the "Filing Deadline"), 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 E preferred stock (excluding 12,000,000 shares of common stock issuable upon conversion of the Series E preferred stock issued in exchange for shares of outstanding Series D preferred stock during 2008 that are included on a prior registration statement) and (ii) an aggregate of 21,096,150 shares of common stock issuable upon exercise of warrants issued in connection with Series B, Series D and Series E preferred stock. Novelos was required to use its best efforts to have the registration statement declared effective and to 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 of the Series E purchase agreement. Purdue and the Series D Investors consented to extend the Filing Deadline to September 15, 2009. The registration statement was filed on that date. The Series E Registration Agreement was amended on January 21, 2010 principally to consent to a reduction in the number of shares offered. The registration statement covering the resale of a total of 19,000,000 shares of the Company's common stock was declared effective on February 12, 2010 and a post-effective amendment was declared effective on May 3, 2010. The use of the registration statement may be suspended for not more than 15 consecutive days or for a total of not more than 30 days in any 12-month period. The Company will use its reasonable best efforts to register the shares excluded from the registration statement as may be permitted by the SEC until such time as all of these shares either have been registered or may be sold without restriction in reliance on Rule 144 under the Securities Act.

As part of a common stock private placement in August 2009, the Company entered into a registration rights agreement with Purdue (the "Purdue Registration Agreement"). The Purdue Registration Agreement requires the Company to have filed with the SEC no later than May 17, 2010, a registration statement covering the resale of all the shares of common stock issued pursuant to the August 2009 purchase agreement and all shares of common stock issuable upon exercise of the warrants issued pursuant to the August 2009 purchase agreement. The Company is required to use its best efforts to have the registration statement declared effective and to 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 final closing. The Company will be allowed to suspend the use of the registration for not more than 15 consecutive days or for a total of not more than 30 days in any 12-month period. The Company failed to timely file the registration statement and as of September 30, 2010, and through the date of this filing, the registration statement has not been filed. The registration rights agreement provides for 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 common stock until the delinquent registration statement is filed. The Company has undertaken to renegotiate the terms of the Purdue Registration Agreement and reach an alternative settlement for the accumulated damages. The Company has accrued \$819,000 in the nine months ended September 30, 2010 which represents management's best estimate of the probable total liquidated damages that may be settled. This amount has been included as a component of other income (expense).

Conversions of Preferred Stock – During the nine months ended September 30, 2010, 140 shares of the Company’s Series E preferred stock, having an aggregate stated value of \$7,000,000, and accumulated dividends thereon, were converted at a conversion price of \$0.65 per share of common stock into 11,745,779 shares of common stock. The associated carrying value of the converted shares totaling approximately \$4,690,000 was reclassified to permanent equity from temporary equity.

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, 2010:

Offering	Outstanding (as adjusted)	Exercise Price (as adjusted)	Expiration Date
2006 Issuance of Common Stock	5,136,191	\$ 1.53	March 7, 2011
Series B Preferred Stock – placement agents	825,000	\$ 1.25	May 2, 2012
Series C Exchange	1,250,000	\$ 1.25	May 2, 2012
Series E Preferred Stock	9,230,769	\$ 0.65	December 31, 2015
August 2009 Private Placement	4,772,730	\$ 0.66	December 31, 2015
July 2010 Direct Offering	16,071,434	\$ 0.07	July 27, 2015
Preferred Incentive Warrants	16,071,434	\$ 0.105	July 27, 2015
Total	53,357,558		

During the three months ended September 30, 2010, warrants to purchase 2,260,845 shares of common stock at \$0.07 and 909,090 shares of common stock at \$0.65 expired unexercised.

During the nine months ended September 30, 2010, 8,182,158 shares of the Company’s common stock were issued upon the cashless exercise of warrants to purchase 13,732,580 shares of the Company’s common stock. The Company reclassified \$2,584,000 from derivative liability to additional paid-in capital upon the exercise of warrants. The following is a summary of the exercises:

Original private placement	Shares of Common Stock Issued	Warrants Exercised	Exercise Price
2005 Bridge Financing	314,982	400,000	\$ 0.625
2005 Issuance of Common Stock – placement agents	226,544	317,350	\$ 0.65
2006 Issuance of Common Stock	366,492	991,516	\$ 1.72
Series B Preferred Stock – purchasers	4,545,447	7,500,000	\$ 0.65
Series B Preferred Stock – placement agents	35,106	75,000	\$ 1.25
Series D Preferred Stock	2,645,685	4,365,381	\$ 0.65
Series C Exchange	47,902	83,333	\$ 1.25
Total	8,182,158	13,732,580	

5. STOCK-BASED COMPENSATION

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Employee and director stock option grants:				
Research and development	\$ 58,198	\$ 34,953	\$ 172,789	\$ 106,500
General and administrative	92,448	62,130	267,290	219,449
	<u>150,646</u>	<u>97,083</u>	<u>440,079</u>	<u>325,949</u>
Non-employee consultant stock option grants:				
Research and development	(4,729)	32,825	(220,370)	111,658
General and administrative	(645)	13,163	(27,947)	65,554
	<u>(5,374)</u>	<u>45,988</u>	<u>(248,317)</u>	<u>177,212</u>
Total stock-based compensation	<u>\$ 145,272</u>	<u>\$ 143,071</u>	<u>\$ 191,762</u>	<u>\$ 503,161</u>

There were no stock option grants during the three or nine months ended September 30, 2010 or 2009.

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, 2010	9,219,825	\$ 0.63	7.5	\$ 17,650,255
Options exercised	(916,667)	\$ 0.17		
Options cancelled	(171,426)	\$ 1.99		
Outstanding at September 30, 2010	<u>8,131,732</u>	<u>\$ 0.65</u>	<u>7.2</u>	<u>\$ 49,684</u>
Exercisable at September 30, 2010	<u>5,390,039</u>	<u>\$ 0.68</u>	<u>6.5</u>	<u>\$ 49,684</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. During the nine months ended September 30, 2010, the total intrinsic value of options exercised was \$663,000 and the total amount of cash received from exercise of these options was \$158,600.

As of September 30, 2010, there was approximately \$794,000 of total unrecognized compensation cost related to unvested stock-based compensation arrangements. Of this total amount, 18%, 57% and 25% is expected to be recognized during 2010, 2011 and 2012, respectively. The Company expects 2,741,693 in unvested options to vest in the future. The weighted-average grant-date fair value of both vested and unvested options outstanding at September 30, 2010 was \$0.42 and \$0.41, respectively.

6. NET INCOME (LOSS) PER SHARE

Basic net income (loss) per share is computed by dividing net income (loss) attributable to common stockholders by the weighted average number of shares of common stock outstanding during the period. Diluted net income per share is computed by dividing net income attributable to common stockholders by the sum of 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 and accumulated dividends. Since the Company has a net loss for the three and nine months ended September 30, 2009 and the three months ended September 30, 2010, the inclusion of common stock equivalents in the computation for those periods would be antidilutive. Accordingly, basic and diluted net loss per share were the same for those periods.

The following table sets forth the shares and net income used in the diluted earnings per share computation for the nine months ended September 30, 2010:

Numerator:

Net income available to common stockholders used in basic earnings per share calculation	\$ 287,327
Derivative gain recorded on dilutive warrants	(24,040)

Net income available to common stockholders used in diluted earnings per share calculation	<u>\$ 263,287</u>
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Denominator:

Weighted average shares of common stock used in the computation of basic earnings per share	92,109,358
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Dilutive effect of stock options	1,391,653
Dilutive effect of warrants to purchase common stock	<u>1,692,674</u>

Shares used in computation of diluted earnings per share	<u>95,193,685</u>
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The following potentially dilutive securities have been excluded from the computation of diluted net income (loss) per share since their inclusion would be antidilutive:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Stock options	<u>8,131,732</u>	<u>7,279,825</u>	<u>3,984,721</u>	<u>7,279,825</u>
Warrants	<u>53,357,558</u>	<u>33,197,725</u>	<u>53,357,558</u>	<u>33,197,725</u>
Conversion of preferred stock	<u>41,460,413</u>	<u>53,589,726</u>	<u>41,460,413</u>	<u>53,589,726</u>

7. INCOME TAXES

The Company accounts for income taxes in accordance with the Income Taxes Topic of the FASB ASC. Under this guidance, 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 three and nine months ended September 30, 2010 because the Company has experienced losses on a tax basis since inception. The net income reported for the nine months ended September 30, 2010 is a result of the gain recorded on the revaluation of derivative warrant liability during that period, which is a nontaxable item. The Company has not recorded deferred tax assets as their realization is uncertain.

8. LITIGATION

A purported class action complaint was filed on March 5, 2010 in the United States District Court for the District of Massachusetts by an alleged shareholder of the Company, on behalf of himself and all others who purchased or otherwise acquired the Company's common stock in the period between December 14, 2009 and February 24, 2010, against the Company and its President and Chief Executive Officer, Harry S. Palmin. On October 1, 2010, the court appointed lead plaintiffs (Boris Urman and Ramona Mc Donald) and appointed lead plaintiffs' counsel. On October 22, an amended complaint was filed. The amended complaint claims that the Company violated Section 10(b) of the Securities Exchange Act of 1934, as amended, and Rule 10b-5 promulgated thereunder in connection with alleged disclosures related to the Phase 3 clinical trial of NOV-002 for non-small cell lung cancer. The Company expects to file its initial responsive pleading by December 6, 2010. The Company believes the allegations are without merit and intends to defend vigorously against the allegations.

On June 28, 2010, the Company received a letter from counsel to ZAO BAM and ZAO BAM Research Laboratories (collectively, “BAM”) alleging that the Company modified the chemical composition of NOV-002 without prior notice to or approval from BAM, constituting a material breach of a technology and assignment agreement the Company had entered into with BAM on June 20, 2000 (the “June 2000 Agreement”). The letter references the Company’s amendment, submitted to the FDA on August 30, 2005, to its investigational new drug application dated August 1999 as the basis for BAM’s claims and demands the transfer of all intellectual property rights concerning NOV-002 to BAM. Mark Balazovsky, a director of Novelos from June 1996 until November 2006 and a shareholder of Novelos through at least June 25, 2010, is, to the Company’s knowledge, still the general director and principal shareholder of ZAO BAM. The Company believes the allegations are without merit and intends to defend vigorously against any proceedings that BAM may initiate as to these allegations. On September 24, 2010, the Company filed a request for declaratory judgment in Suffolk Superior Court. The action seeks to obtain a judgment by the court that the June 2000 Agreement has been replaced by a subsequent agreement between the parties dated April 1, 2005 (the “April 2005 Agreement”), that the Company’s obligations to BAM are governed solely by the April 2005 Agreement and that the obligations of the June 2000 agreement have been performed and fully satisfied.

9. COMMITMENTS

Retention Agreements

On May 14, 2010, the Company entered into retention agreements with each of its four vice-president executive officers other than its Chief Executive Officer, Harry S. Palmin. The agreements provide for the lump-sum payment of six months’ base salary and benefits to each such officer following a termination without cause or a resignation with good reason occurring on or before November 14, 2011. The agreements further provide that if the executives remain employed with the Company as of October 1, 2010, they will receive a payment of two months’ base salary as a retention bonus on that date. The retention bonus, an aggregate of \$140,000, was paid in October 2010 and will be deducted from the severance amounts that may become payable upon a subsequent involuntary termination. The agreements expire November 14, 2011. The total remaining amounts that may become payable to the Company’s Named Executive Officers pursuant to the retention agreements are approximately \$78,000 to Christopher Pazoles and \$75,000 to Elias Nyberg. Concurrently with the execution of the retention agreements, the employment agreement between the Company and Christopher Pazoles dated July 15, 2005 was terminated. Following the voluntary resignation of the Company’s Vice President of Clinical Development and Operations in November 2010, her retention agreement is no longer in effect.

On May 14, 2010, the Company also entered into retention agreements with each of its three non-executive employees. The agreements provide for the lump-sum payment of six months’ base salary and benefits to each employee following a termination without cause or a resignation with good reason occurring on or before November 14, 2011. The agreements expire November 14, 2011.

10. SUBSEQUENT EVENTS

Increase in Authorized Shares of Common Stock

On October 18, 2010 the Company held a special meeting in lieu of annual meeting of stockholders. At the meeting, the Company’s stockholders approved an amendment to the certificate of incorporation to increase the total number of authorized shares of the Company’s common stock by 525 million shares, from 225 million to 750 million. Following the adjournment of the meeting, the amendment was filed with the Secretary of State of Delaware, and it went into effect on October 18, 2010.

Class Action Litigation

As more fully described in Note 8, on October 22, 2010, an amended complaint was filed amending the purported class action complaint initially filed on March 5, 2010 in the United States District Court for the District of Massachusetts.

Government Grant

On October 29, 2010, the Company received notification from the Internal Revenue Service that it had been awarded a cash grant of approximately \$245,000 as a Qualifying Therapeutic Discovery Project Credit.

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 significant accounting estimates, such as those for unbilled contract service fees and amounts due to clinical research organizations, clinical investigators and contract manufacturers, the risk factors set forth below under the caption “Risk Factors” and the risk factors set forth in Item 1A of our annual report for the year ended December 31, 2009 on Form 10-K, which was filed with the SEC on March 30, 2010. 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 developing oxidized glutathione-based compounds for the treatment of cancer. We are also seeking to expand our product pipeline by licensing or acquiring clinical stage compounds or technologies for oncology indications.

NOV-002, our lead compound, is a small-molecule compound based on a proprietary formulation of oxidized glutathione that has been administered to approximately 1,000 cancer patients in clinical trials and is in Phase 2 development for solid tumors in combination with chemotherapy. According to Cancer Market Trends (2008-2012, URCH Publishing), Datamonitor (July 3, 2006) and PharmaLive (October 9, 2009), the global market for cancer pharmaceuticals reached an estimated \$66 billion in 2007, nearly doubling from \$35 billion in 2005, and is expected to grow to \$80 billion by 2012.

From November 2006 through January 2010, we conducted a pivotal Phase 3 trial of NOV-002 plus first-line chemotherapy in advanced non-small cell lung cancer (“NSCLC”). The Phase 3 trial enrolled 903 patients, 452 of whom received NOV-002. On February 24, 2010, we announced that the primary endpoint of improvement in overall survival compared to first-line chemotherapy alone was not met in this trial. Following evaluation of the detailed trial data, we announced on March 18, 2010 that the secondary endpoints also were not met in the trial and that adding NOV-002 to paclitaxel and carboplatin chemotherapy was not statistically or meaningfully different in terms of efficacy-related endpoints or recovery from chemotherapy toxicity versus chemotherapy alone. However, NOV-002 was safe and did not add to the overall toxicity of chemotherapy. Based on the results from the Phase 3 trial, we have determined to discontinue development of NOV-002 for advanced NSCLC in combination with first-line paclitaxel and carboplatin chemotherapy.

NOV-002 is being developed to treat breast cancer in combination with chemotherapy. In June 2007 we commenced enrollment in a U.S. Phase 2 neoadjuvant breast cancer trial, which is ongoing at The University of Miami to evaluate the ability of NOV-002 to enhance the effectiveness of chemotherapy in HER-2 negative patients. On July 12, 2010, we announced the 12th pathologic complete response (pCR), which is the minimum number of pCRs required in order for NOV-002 to be declared active, in the first 31 patients (39%) who completed chemotherapy and underwent surgery. The historical control pCR rate is in the range of 10-20%. We submitted the trial results for presentation to the AACR Breast Cancer Symposium taking place in San Antonio, TX, in December 2010.

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 May 2008, NOV-002, in combination with carboplatin, slowed progression of the disease in 60% of evaluable patients (nine out of 15 women). The median progression-free survival was 15.4 weeks, almost double the historical control of eight weeks. Furthermore, patients experienced decreased hematologic toxicities. These results were presented at the American Society of Clinical Oncology in May 2008.

NOV-205, our second glutathione-based compound, acts as a hepatoprotective agent with immunomodulating and anti-inflammatory properties. NOV-205 has been administered to approximately 200 hepatitis patients in clinical trials and is in Phase 2 development for chronic hepatitis C non-responders. An Investigational New Drug Application (“IND”) for NOV-205 as a monotherapy for chronic hepatitis C was accepted by the FDA in 2006. A U.S. Phase 1b clinical trial with NOV-205 in patients who previously failed treatment with pegylated interferon plus ribavirin was completed in December 2007. Based on favorable safety results of that trial, in March 2010 we initiated a multi-center U.S. Phase 2 trial evaluating NOV-205 as monotherapy in up to 40 chronic hepatitis C genotype 1 patients who previously failed treatment with pegylated interferon plus ribavirin. Safety was established in twenty patients receiving either 30mg or 60mg of NOV-205 daily for 49 days; however, no viral load reduction was observed. Due to NOV-205’s lack of clinical activity as a monotherapy and our limited financial resources, we intend to put NOV-205 development on hold and focus efforts on expanding our oncology product pipeline and further developing NOV-002 in combination with immunogenic chemotherapy.

As evidenced by our Phase 3 trial in NSCLC, although promising Phase 2 results may advance the clinical development of compounds, such results are not necessarily determinative that the efficacy and safety of the compounds will be successfully demonstrated in a Phase 3 clinical trial.

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 (the “Russian Territory”), but including Estonia, Latvia and Lithuania) 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.

We entered into a collaboration agreement with Mundipharma International Corporation Limited (“Mundipharma”) to develop, manufacture and commercialize NOV-002 in Europe, excluding the Russian Territory, most of Asia (other than China, Hong Kong, Taiwan and Macau, the “Chinese Territory”) and Australia. We have a collaboration agreement with Lee’s Pharmaceutical (HK) Ltd. (“Lee’s Pharm”) to develop, manufacture and commercialize NOV-002 and NOV-205 in the Chinese Territory. We expect that the negative results of our Phase 3 trial in advanced NSCLC will adversely affect development and commercialization of NOV-002 under these collaboration agreements.

Results of Operations

Revenue. Revenue consists of amortization of 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 have been 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.

Quarters Ended September 30, 2010 and 2009

Revenue. During each of the three months ended September 30, 2010 and 2009, we recognized \$8,000 in license fees in connection with our collaboration agreement with Lee’s Pharm. During the three months ended September 30, 2009, we also recognized \$5,000 in grant revenue related to a grant received from the U.S. Department of Health and Human Services. The related costs are included as a component of research and development expense in that period.

Research and Development. Research and development expense for the three months ended September 30, 2010 was \$375,000, compared to \$1,766,000 for the same period in 2009. The \$1,391,000, or 79%, decrease in research and development expense was due to a combination of factors. In February 2010, we completed our Phase 3 trial in NSCLC. Following the completion of that trial, contract research costs related to the trial decreased \$1,204,000 in the three months ended September 30, 2010 as compared to the three months ended September 30, 2009. This reduction in Phase 3 clinical research costs includes the effect of a \$254,000 reduction in the accrual of estimated amounts due to a large vendor, following a negotiated payment settlement during the three months ended September 30, 2010. Preclinical research and drug manufacturing costs decreased by \$292,000. Stock-based compensation decreased \$14,000 as a result of the decline in our stock price following the Phase 3 trial results. These decreases were partially offset by a \$119,000 increase in clinical development costs for NOV-205 as a result of the commencement, in March 2010, of a Phase 2 trial evaluating NOV-205 in chronic hepatitis patients.

General and Administrative. General and administrative expense for the three months ended September 30, 2010 was \$543,000 compared to \$546,000 in the same period in 2009. Although costs were basically flat, there were some notable changes in expenses. First, professional fees decreased by \$28,000 principally due to a decrease in professional fees associated with partnering activities. Stock-based compensation costs increased by \$17,000. Overhead costs increased by \$8,000 principally resulting from an increase in liability insurance premium costs.

Gain (Loss) on Derivative Warrants. We recorded a loss on derivative warrants of \$3,000 during the three months ended September 30, 2010 compared to a loss of \$447,000 in the same period of the previous year. This amount represents the change in fair value, during the respective periods, of outstanding warrants which contain “down-round” anti-dilution provisions whereby the number of shares for which the options are exercisable and/or the exercise price of the warrants is subject to change in the event of certain issuances of stock at prices below the then-effective exercise prices of the warrants.

Liquidated Damages. During the three months ended September 30, 2010, we accrued \$315,000 in estimated liquidated damages as a result of our failure to file, on a timely basis, a registration statement covering the resale of shares of common stock sold pursuant to the August 2009 purchase agreement with Purdue Pharma, L.P. (the “August 2009 Purchase Agreement”) and all shares of common stock issuable upon exercise of the warrants issued pursuant to the August 2009 Purchase Agreement. The accrual of \$315,000 was required to adjust the recorded liability to our best estimate of liquidated damages that may be settled under the applicable registration rights agreement.

Preferred Stock Dividends. During the three months ended September 30, 2010 and 2009, we accrued \$582,000 and \$843,000, respectively, in dividends accumulating on our Series C and E preferred stock. No dividends were paid during those periods.

Nine Months Ended September 30, 2010 and 2009

Revenue. During each of the nine months ended September 30, 2010 and 2009, we recognized \$25,000 in license fees in connection with our collaboration agreement with Lee’s Pharm. During the nine months ended September 30, 2009, we also recognized \$52,000 in grant revenue related to a grant received from the U.S. Department of Health and Human Services. The related costs are included as a component of research and development expense in that period.

Research and Development. Research and development expense for the nine months ended September 30, 2010 was \$2,483,000, compared to \$5,138,000 for the same period in 2009. The \$2,655,000, or 52%, decrease in research and development expense was due to a combination of factors. In February 2010, we completed our Phase 3 trial in NSCLC. Following the completion of that trial, contract research costs related to the trial decreased \$3,272,000 in the nine months ended September 30, 2010 as compared to the nine months ended September 30, 2009. This reduction in Phase 3 clinical research costs includes the effect of a \$772,000 reduction in the accrual of estimated amounts owed to two large vendors, following negotiated payment settlements during the nine months ended September 30, 2010. Stock-based compensation also decreased \$266,000 as a result of the decline in our stock price following the Phase 3 trial results. Salaries and overhead costs decreased by \$52,000 as a result of efforts to contain costs. These decreases were partially offset by a \$531,000 increase in consulting costs related to preclinical and manufacturing work. In anticipation of the results of our Phase 3 clinical trial of NOV-002 in advanced NSCLC, announced in February 2010, we increased certain preclinical research and manufacturing activities in preparation of a possible filing of a new drug application later in 2010. There was also a \$404,000 increase in clinical development costs for NOV-205 as a result of the commencement, in March 2010, of a Phase 2 trial evaluating NOV-205 in chronic hepatitis patients.

General and Administrative. General and administrative expense for the nine months ended September 30, 2010 was \$1,930,000 compared to \$1,529,000 in the same period in 2009. The \$401,000, or 26%, increase is due to a number of factors. First, professional fees increased by \$302,000 principally due to increased corporate legal costs relating to the resale and registration of our securities and legal defense costs. Overhead costs increased by \$145,000 principally resulting from an increase in liability insurance premium costs. These increases were offset in part by a \$46,000 decrease in stock-based compensation as a result of the decline in our stock price following the Phase 3 trial results.

Gain (Loss) on Derivative Warrants. We recorded a gain on derivative warrants of \$7,899,000 during the nine months ended September 30, 2010 and recorded a loss on derivative warrants of \$2,830,000 in the same period of the previous year. This amount represents the change in fair value, during the respective periods, of outstanding warrants which contain “down-round” anti-dilution provisions whereby the number of shares for which the options are exercisable and/or the exercise price of the warrants is subject to change in the event of certain issuances of stock at prices below the then-effective exercise prices of the warrants. The large decrease in value of the liability during the nine months ended September 30, 2010 is a result of the significant drop in our stock price following the announcement of negative Phase 3 Trial results on February 24, 2010. This gain is not taxable; accordingly, no tax provision has been recorded.

Liquidated Damages. During the nine months ended September 30, 2010, we accrued \$819,000 in estimated liquidated damages as a result of our failure to file, on a timely basis, a registration statement covering the resale of shares of common stock, and the shares of common stock underlying warrants, sold pursuant to the August 2009 purchase agreement with Purdue Pharma, L.P. The accrual of \$819,000 represents our best estimate of liquidated damages that may be settled under the applicable registration rights agreement.

Preferred Stock Dividends. During the nine months ended September 30, 2010 and 2009, we accrued \$1,820,000 and \$2,496,000, respectively, in dividends accumulating on our Series C, D and E preferred stock. No dividends were paid during those periods. On February 11, 2009, all shares of Series D preferred stock and accrued dividends thereon totaling \$1,597,000 (including \$202,000 that accrued during 2009 prior to the exchange) were exchanged for approximately 445.5 shares of Series E preferred stock. During the nine months ended September 30, 2010, we recorded deemed dividends on preferred stock totaling \$586,000. This amount was recorded in connection with the financing that occurred in July 2010 and represents the fair value attributed to warrants that were issued to preferred stockholders in exchange for their consent for the financing transaction. During the nine months ended September 30, 2009, we also recorded deemed dividends on preferred stock totaling \$714,000. This amount was recorded in connection with the financing that occurred in February 2009 and represents the value attributed to the modification of certain warrants less the net adjustment required to record the newly issued shares of Series E preferred stock at fair value.

Liquidity and Capital Resources

We have financed our operations since inception via the sale of securities and the issuance of debt (which was subsequently paid off or converted into equity). As of September 30, 2010, we had approximately \$3,366,000 in cash and equivalents.

During the nine months ended September 30, 2010, approximately \$6,811,000 in cash was used in operations. During this period we reported \$2,693,000 in net income. However, this included the following non-cash items: a \$7,899,000 gain on derivative warrants, \$192,000 in stock-based compensation and \$33,000 in depreciation and amortization expense. After adjustment for these non-cash items, we used \$2,627,000 in cash for the payment of accounts payable and accrued liabilities and accrued \$819,000 in estimated liquidated damages for registration rights penalties. Other changes in working capital used cash of \$22,000.

During the nine months ended September 30, 2010, we received net proceeds of \$1,249,000 from the sale of our common stock and warrants and received \$159,000 upon the exercise of stock options.

On February 24, 2010, we announced that our Phase 3 clinical trial for NOV-002 in NSCLC (the “Phase 3 Trial”) did not meet its primary endpoint of a statistically significant increase in median overall survival. On March 18, 2010, we announced that the secondary endpoints had also not been met in the Phase 3 Trial and that we had discontinued development of NOV-002 for NSCLC in combination with first-line paclitaxel and carboplatin chemotherapy.

We are continuing development of NOV-002 in cancer indications other than NSCLC and are seeking to expand our product pipeline by acquiring or licensing clinical stage compounds or technologies for oncology indications. We expect that we will generate operating losses for the foreseeable future.

In the recently passed Patient Protection and Affordable Care Act, H.R. 3590, a new incentive for biotechnology companies like ours was provided: the Qualifying Therapeutic Discovery Project Credit, or Therapeutic Credit. The Therapeutic Credit allows small businesses to apply for a grant in an amount equal to 50% of their investment in qualifying therapeutic discovery projects for 2009 and 2010. Qualifying therapeutic discovery projects, among others include those designed to treat or prevent diseases or conditions by conducting pre-clinical or clinical activities for the purpose of securing FDA approval of a product. We applied for certification of approximately \$8.0 million of expenditures during 2009 and 2010 under this program. On October 29, 2010, the Company received notification from the Internal Revenue Service that it had been awarded a cash grant of approximately \$245,000 as a Therapeutic Credit.

We believe that we have adequate cash, after including the proceeds of this grant, to fund our operations through the first quarter of 2011. Our ability to operate beyond the first quarter of 2011 is dependent on our ability to obtain additional funding via the sale of equity and/or debt securities, a strategic transaction, or otherwise. The negative outcome of the Phase 3 Trial, as well as continuing difficult conditions in the capital markets globally, may adversely affect our ability to obtain funding in a timely manner. If we are unable to obtain new funding, we would begin to wind down operations in March 2011. We plan to continue to actively pursue financing alternatives, but there can be no assurance that we will obtain the necessary capital. In the interim, we are continuously evaluating measures to reduce our costs to conserve our limited cash resources.

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, 2010. 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, 2010, 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 2010 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

A purported class action complaint was filed on March 5, 2010 in the United States District Court for the District of Massachusetts by an alleged shareholder on behalf of himself and all others who purchased or otherwise acquired our common stock in the period between December 14, 2009 and February 24, 2010, against Novelos and our President and Chief Executive Officer, Harry S. Palmin. On October 1, 2010, the court appointed lead plaintiffs (Boris Urman and Ramona Mc Donald) and appointed lead plaintiffs' counsel. On October 22, 2010, an amended complaint was filed. The amended complaint claims that we violated Section 10(b) of the Securities Exchange Act of 1934, as amended, and Rule 10b-5 promulgated thereunder in connection with alleged disclosures related to the Phase 3 clinical trial for NOV-002 in non-small cell lung cancer ("NSCLC") (the "Phase 3 Trial"). We believe the allegations are without merit and intend to defend vigorously against the allegations. The Company expects to file its initial responsive pleading by December 6, 2010.

On June 28, 2010, we received a letter from counsel to ZAO BAM and ZAO BAM Research Laboratories (collectively, "BAM") alleging that we modified the chemical composition of NOV-002 without prior notice to or approval from BAM, constituting a material breach of a technology and assignment agreement we had entered into with BAM on June 20, 2000. The letter references our amendment, submitted to the FDA on August 30, 2005, to our investigational new drug application dated August 1999 as the basis for BAM's claims and demands the transfer of all intellectual property rights concerning NOV-002 to BAM. Mark Balazovsky, a director of Novelos from June 1996 until November 2006 and a shareholder of Novelos through at least June 25, 2010, is, to our knowledge, still the general director and principal shareholder of ZAO BAM. We believe the allegations are without merit and intend to defend vigorously against any proceedings that BAM may initiate as to these allegations. On September 24, 2010, the Company filed a request for declaratory judgment in Suffolk Superior Court. The action seeks to obtain a judgment by the court that the June 2000 Agreement has been replaced by a subsequent agreement between the parties dated April 1, 2005 (the "April 2005 Agreement"), that the Company's obligations to BAM are governed solely by the April 2005 Agreement and that the obligations of the June 2000 agreement have been performed and fully satisfied.

Item 1A. Risk Factors

We will require additional capital to continue operations beyond March 2011.

On February 24, 2010, we announced that our Phase 3 Trial did not meet its primary endpoint of a statistically significant increase in median overall survival. On March 18, 2010, we announced that the secondary endpoints had not been met in the Phase 3 Trial and that we had discontinued development of NOV-002 for NSCLC in combination with first-line paclitaxel and carboplatin chemotherapy. We are continuing development of NOV-002 in cancer indications other than NSCLC and are seeking to expand our product pipeline by acquiring or licensing clinical stage compounds or technologies for oncology indications. We expect that we will continue to generate operating losses for the foreseeable future. On October 29, 2010, we received notification from the Internal Revenue Service that we had been awarded a cash grant of approximately \$245,000 as a Qualifying Therapeutic Discovery Project Credit under the Patient Protection and Affordable Care Act, H.R. 3590. We believe that we have adequate cash, after including the proceeds of this grant, to fund operations through the first quarter of 2011. Our ability to operate beyond the first quarter of 2011 is dependent on our ability to obtain additional funding, via the sale of equity and/or debt securities, a strategic transaction or otherwise. The negative outcome of the Phase 3 Trial, as well as continuing difficult conditions in the capital markets globally, may adversely affect our ability to obtain funding in a timely manner. If we are unable to obtain new funding, we would begin to wind down operations in March 2011. We plan to actively pursue financing alternatives, but there can be no assurance that we will obtain the necessary capital. In the interim, we are continuously evaluating measures to reduce our costs to conserve our limited cash resources.

Our common stock could be diluted as the result of the issuance of the additional 525 million shares of common stock, or securities convertible into or exercisable or exchangeable for shares of common stock, that were authorized by amendment to our certificate of incorporation on October 18, 2010.

On October 18, 2010 the Company held a special meeting in lieu of annual meeting of stockholders. At the meeting, the Company's stockholders approved an amendment to the certificate of incorporation to increase the total number of authorized shares of the Company's common stock by 525 million shares, from 225 million to 750 million. Following the adjournment of the meeting, the amendment was filed with the Secretary of State of Delaware, and it went into effect on October 18, 2010. The issuance of the additional shares of common stock authorized under our certificate of incorporation could result in substantial dilution to our existing or future stockholders.

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

On July 27, 2010, we issued five-year warrants (the "Incentive Warrants") to our preferred stockholders for the purchase of up to an aggregate of 16,071,434 shares of common stock at an exercise price of \$0.105 per share pursuant to a consent and waiver dated July 6, 2010, as amended on July 21, 2010. The Incentive Warrants were issued in connection with an offering registered under the Securities Act of 1933, as amended, of an aggregate of 21,428,576 shares of its common stock and five-year warrants to purchase up to an aggregate of 16,071,434 shares of its common stock, for gross proceeds of \$1,500,000.

Item 3. Defaults Upon Senior Securities

During the three months ended September 30, 2010, no dividends were paid or converted into common stock, dividends of \$459,297 accrued with respect to our Series E Convertible Preferred Stock and dividends of \$122,400 accrued with respect to our Series C Convertible Preferred Stock. As of September 30, 2010, there is a total of \$3,010,947 in accumulated unpaid dividends with respect to our Series E Convertible Preferred Stock and a total of \$1,077,120 in accumulated unpaid dividends with respect to our Series C Convertible Preferred Stock.

Item 5. Other Information

Change in Executive Officers

On November 18, 2010, Kristin Schuhwerk, our Vice President of Clinical Development and Operations, resigned to pursue another opportunity. On that same date, Kimberly Hawkins was appointed to the position of Vice President of Clinical Development. Ms. Hawkins previously held the position of Senior Director of Clinical Development with Novelos.

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
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 C cumulative convertible preferred stock		10-QSB	August 10, 2007	3.6
3.6	Certificate of Designations of Series E convertible preferred stock		8-K	February 18, 2009	4.1
3.7	Certificate of Amendment to Amended and Restated Certificate of Incorporation dated November 3, 2009		10-Q	November 16, 2009	3.7
3.8	Certificate of Amendment to Amended and Restated Certificate of Incorporation dated October 18, 2010		8-K	October 19, 2010	3.1
3.9	Amended and Restated By-Laws		8-K	August 26, 2009	3.1
10.1	Written Consent and Waiver of Holders of Series C Convertible Preferred Stock and Series E Convertible Preferred Stock dated July 7, 2010		S-1	July 7, 2010	10.52
10.2	Form of Securities Purchase Agreement dated July 21, 2010		8-K	July 22, 2010	10.1
10.3	Amendment to Consent and Waiver of Holders of Series C Convertible Preferred Stock and Series E Convertible Preferred Stock dated July 21, 2010		8-K	July 22, 2010	10.2
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 19, 2010

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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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 registrant, 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 19, 2010

/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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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 registrant, 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 19, 2010

/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, 2010, 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 19, 2010

/s/ Joanne M. Protano

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

Date: November 19, 2010
