

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: March 31, 2009

☐ 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 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

(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 ☒

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☐ 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 May 8, 2009.

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.

FORM 10-Q INDEX

PART I. FINANCIAL INFORMATION

Item 1.	Financial Statements	3
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	14
Item 4.	Controls and Procedures	17

PART II. OTHER INFORMATION

Item 1.	Legal Proceedings	18
Item 1A.	Risk Factors	18
Item 2.	Unregistered Sales of Equity Securities and Use of Proceeds	19
Item 3.	Defaults Upon Senior Securities	19
Item 4.	Submission of Matters to a Vote of Security Holders	19
Item 5.	Other Information	19
Item 6.	Exhibits	20

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

NOVELOS THERAPEUTICS, INC. BALANCE SHEETS

	March 31, 2009 (unaudited)	December 31, 2008
ASSETS		
CURRENT ASSETS:		
Cash and equivalents	\$ 6,974,412	\$ 1,262,452
Prepaid expenses and other current assets	88,495	129,785
Total current assets	<u>7,062,907</u>	<u>1,392,237</u>
FIXED ASSETS, NET	52,220	58,451
DEPOSITS	15,350	15,350
TOTAL ASSETS	<u>\$ 7,130,477</u>	<u>\$ 1,466,038</u>
LIABILITIES AND STOCKHOLDERS' DEFICIENCY		
CURRENT LIABILITIES:		
Accounts payable and accrued liabilities	\$ 3,393,512	\$ 4,653,912
Accrued compensation	68,258	240,639
Accrued dividends	860,362	1,689,322
Derivative liability	586,824	—
Deferred revenue – current	<u>33,333</u>	<u>33,333</u>
Total current liabilities	<u>4,942,289</u>	<u>6,617,206</u>
DEFERRED REVENUE – NONCURRENT	<u>425,000</u>	<u>433,333</u>
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 December 31, 2008	—	13,904,100
Series E convertible preferred stock, \$0.00001 par value; 735 shares designated; 645.442875 shares issued and outstanding at March 31, 2009 (Note 5) (liquidation preference \$32,675,546 at March 31, 2009)	<u>21,672,675</u>	<u>—</u>
	<u>21,672,675</u>	<u>13,904,100</u>
STOCKHOLDERS' DEFICIENCY:		
Preferred stock, \$0.00001 par value; 7,000 shares authorized:		
Series C cumulative convertible preferred stock; 272 shares issued and outstanding at March 31, 2009 and December 31, 2008 (liquidation preference \$3,720,960 at March 31, 2009)	—	—
Common stock, \$0.00001 par value; 150,000,000 shares authorized; 43,975,656 shares issued and outstanding at March 31, 2009 and December 31, 2008	440	440
Additional paid-in capital	35,702,300	40,204,112
Accumulated deficit	<u>(55,612,227)</u>	<u>(59,693,153)</u>
Total stockholders' deficiency	<u>(19,909,487)</u>	<u>(19,488,601)</u>
TOTAL LIABILITIES, REDEEMABLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIENCY	<u>\$ 7,130,477</u>	<u>\$ 1,466,038</u>

See notes to financial statements.

NOVELOS THERAPEUTICS, INC.
STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended March 31, 2009	2008
REVENUE	\$ 30,968	\$ 8,333
COSTS AND EXPENSES:		
Research and development	1,783,832	6,911,925
General and administrative	476,197	263,075
Total costs and expenses	2,260,029	7,175,000
LOSS FROM OPERATIONS	(2,229,061)	(7,166,667)
OTHER INCOME:		
Interest income	1,013	63,321
Gain on derivatives	412,120	—
Miscellaneous	2,483	2,249
Total other income	415,616	65,570
NET LOSS	(1,813,445)	(7,101,097)
PREFERRED STOCK DIVIDENDS	(768,183)	(402,780)
PREFERRED STOCK DEEMED DIVIDENDS	(714,031)	—
NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS	<u>\$ (3,295,659)</u>	<u>\$ (7,503,877)</u>
BASIC AND DILUTED NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS PER COMMON SHARE	<u>\$ (0.07)</u>	<u>\$ (0.19)</u>
SHARES USED IN COMPUTING BASIC AND DILUTED NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS PER COMMON SHARE	<u>43,975,656</u>	<u>39,342,494</u>

See notes to financial statements.

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

	Three Months Ended March 31, 2009	2008
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (1,813,445)	\$ (7,101,097)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	6,231	3,491
Stock-based compensation	126,587	87,689
Gain on derivatives	(412,120)	—
Change in:		
Prepaid expenses and other current assets	41,290	33,533
Accounts payable and accrued liabilities	(1,260,400)	2,173,202
Accrued compensation	(172,381)	(45,172)
Deferred revenue	(8,333)	491,667
Cash used in operating activities	<u>(3,492,571)</u>	<u>(4,356,687)</u>
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of fixed assets	—	(12,271)
Change in restricted cash	—	1,184,702
Deferred financing costs	—	(57,213)
Cash provided by investing activities	<u>—</u>	<u>1,115,218</u>
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from the sale of preferred stock and warrants, net	9,204,531	—
Proceeds from exercise of stock option	—	1,000
Cash provided by financing activities	<u>9,204,531</u>	<u>1,000</u>
INCREASE (DECREASE) IN CASH AND EQUIVALENTS	5,711,960	(3,240,469)
CASH AND EQUIVALENTS AT BEGINNING OF YEAR	1,262,452	9,741,518
CASH AND EQUIVALENTS AT END OF PERIOD	<u>\$ 6,974,412</u>	<u>\$ 6,501,049</u>
SUPPLEMENTAL DISCLOSURES OF NON-CASH FINANCING ACTIVITIES		
Deemed dividends to preferred stockholders	\$ 714,031	\$ —
Dividends paid to preferred stockholders in shares of Series E preferred stock	\$ 1,597,144	\$ —
Dividends accrued but not paid to preferred stockholders	\$ 566,602	\$ 402,780
Relative fair value of warrants to preferred stockholders	\$ 2,907,208	\$ —
Exchange of Series D preferred stock for Series E preferred stock	\$ 13,904,100	\$ —

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 funds at March 31, 2009 will allow it to continue operations into late 2009, which is when it was previously anticipated that the results of its Phase 3 clinical trial in non-small cell lung cancer would be available. The primary endpoint of the Phase 3 trial is increased median overall survival, to be measured following the occurrence of 725 events (deaths), and based on evaluation of activity through April 2009, the Company now anticipates that the results from its Phase 3 trial will be available in early 2010. The Company’s ability to execute its operating plan beyond late 2009 is dependent on its ability to obtain additional capital (including through the sale of equity and debt securities at any time and by entering into collaborative arrangements for licensing rights in North America, which is not likely to occur before 2010) to fund its development activities. The Company plans to actively pursue these alternatives during 2009 and 2010, but there can be no assurance that it will obtain the additional capital necessary to fund its business beyond the end of 2009. The timing and content of the Phase 3 clinical trial results may impact the Company’s projected cash requirements and its ability to obtain capital. Furthermore, continuing difficult conditions in the capital markets globally may adversely affect the ability of the Company to obtain funding in a timely manner. The Company is continually evaluating measures to further reduce costs to preserve existing capital. If the Company is unable to obtain sufficient additional funding, it will be required, beginning in late 2009, to scale back its administrative activities and clinical development programs, including the Phase 3 clinical development of its lead drug candidate, NOV-002, or it may be required to cease operations entirely.

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, 2009. 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, 2008 on Form 10-K, which was filed with the Securities and Exchange Commission (“SEC”) on March 30, 2009.

Comprehensive Income (Loss) – The Company had no components of comprehensive income (loss) other than the net 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 Emerging Issues Task Force Issue No. 00-19 (“EITF 00-19”), *Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company’s Own Stock* and EITF No. 07-5, *Determining Whether an Instrument (or Embedded Feature) is Indexed to an Entity’s Own Stock* (“EITF 07-5”), 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 since the agreements contain “down-round” 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 dilutive stock issuances. The number of such warrants was 14,003,319 at January 1, 2009 and 15,115,687 at March 31, 2009. 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 charged (credited) to operations as a gain or loss on derivatives in each reporting period. If these instruments subsequently meet the requirements for equity classification under EITF 00-19 and EITF 07-5, the Company reclassifies the fair value to equity. At March 31, 2009, these warrants represent the only derivative instruments held by the Company.

2. CHANGE IN ACCOUNTING PRINCIPLE

Effective January 1, 2009, the Company adopted EITF 07-5, which establishes a framework for determining whether certain freestanding and embedded instruments are indexed to a company's own stock for purposes of evaluation of the accounting for such instruments under existing accounting literature. As a result of the adoption of EITF 07-5, certain warrants that were previously determined to be indexed to the Company's common stock upon issuance were determined not to be indexed to the Company's common stock because they include 'down-round' anti-dilution provisions. The fair value of the warrants at the dates of issuance totaling \$6,893,000 was initially recorded as a component of additional paid-in capital. Upon adoption of EITF 07-5, the Company recorded a decrease to the opening balance of additional-paid-in capital of \$6,893,000 and recorded a decrease to accumulated deficit totaling \$5,894,000, representing the decrease in the fair value of the warrants from the date of issuance to December 31, 2008. The decrease in fair value of the warrants of \$412,000 during the three months ended March 31, 2009 has been included as a component of other income in the accompanying statement of operations for such period. The fair value of the warrants at March 31, 2009 of \$587,000 is included as a current liability in the accompanying balance sheet as of such date.

3. FAIR VALUES OF ASSETS AND LIABILITIES

In accordance with SFAS No. 157, 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 nor supported by an active market.

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

	March 31, 2009			
	Level 1	Level 2	Level 3	Fair Value
Liabilities:				
Warrants	\$ -	\$ 587,000	\$ -	\$ 587,000

The fair value of warrants have been estimated based on the closing price of the common stock at the valuation date using the Black-Scholes option pricing model with assumed volatility of 80%, terms ranging from 1-2 years and discount rates ranging from 0.57% to 0.81%.

4. COLLABORATION AGREEMENTS

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 Licensed Products (as defined in the Collaboration Agreement), which includes the Company's lead compound, NOV-002, in Europe and Asia/Pacific (excluding China) (the "Territory"). Mundipharma is an independent associated company of Purdue Pharma, L.P. ("Purdue").

Under the Collaboration Agreement, Mundipharma received an exclusive license to develop, manufacture, market, sell or otherwise distribute the Licensed Products and improvements thereon in the Territory. Novelos is responsible for the cost and execution of development, regulatory submissions and commercialization of NOV-002 outside the Territory, and Mundipharma is responsible for the cost and execution of certain development activities, all regulatory submissions and all commercialization within the Territory. In the unlikely event that Mundipharma is required to conduct an additional Phase 3 clinical trial in first-line advanced-stage non-small cell lung cancer in order to gain regulatory approval in Europe, Mundipharma will be entitled to recover the full cost of such trial by reducing milestone, fixed sales-based payments and royalty payments to Novelos by up to 50% of the payments owed until Mundipharma recovers the full costs of such trial. In order for Mundipharma or Novelos to access the other party's data or intellectual property related to Independent Trials (as defined in the Collaboration Agreement), the accessing party must pay the sponsoring party 50% of the cost of such trial.

The launch of Licensed Products, including initiation of regulatory and pricing approvals, and subsequent commercial efforts to market and sell Licensed Products in each country in the Territory, will be determined by Mundipharma based on its assessment of the commercial viability of the Licensed Products, the regulatory environment and other factors. Novelos has no assurance that it will receive any amount of the launch payments, fixed sales-based payments or royalties described below.

Mundipharma will pay Novelos \$2.5 million upon the launch of NOV-002 in each country, up to a maximum of \$25 million. In addition, Mundipharma will make fixed sales-based payments up to an aggregate of \$60 million upon the achievement of certain annual sales levels payable once the annual net sales exceed the specified thresholds. Mundipharma will also pay as royalties to Novelos, during the term of the Collaboration Agreement, a double-digit percentage on net sales of Licensed Products, based upon a four-tier royalty schedule, in countries within the Territory where Novelos held patents on the licensed technology as of the effective date of the agreement. Royalties in countries in the Territory where Novelos does not hold patents as of the effective date will be paid at 50% of the royalty rates in countries where patents are held. The royalties will be calculated based on the incremental net sales in the respective royalty tiers and shall be due on net sales in each country in the Territory where patents are held until the last patent expires in the respective country. In countries in the Territory where Novelos does not hold patents as of the effective date of the Collaboration Agreement, royalties will be due until the earlier of 15 years from the date of Agreement or the introduction of a generic in the respective country resulting in a 20% drop in Mundipharma's market share in such country.

For countries in which patents are held, the Collaboration Agreement expires on a country-by-country basis within the 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 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.

Concurrent with the execution of the Collaboration Agreement, Novelos completed a private placement of preferred stock and warrants to Purdue Pharma L.P. ("Purdue"), an independent associated company of Mundipharma. See 'Series E Preferred Stock Private Placement' below.

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 Pharma"). Pursuant to this 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 "Lee's Pharma Territory"). 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 Pharma. This initial \$500,000 payment received is being amortized over the estimated term of this agreement, 15 years. Accordingly, \$8,333 of license revenue was recognized in each of the three month periods ended March 31, 2009 and 2008.

The Company will receive royalty payments of 20-25% of net sales of NOV-002 in the Lee's Pharma Territory and will receive royalty payments of 12-15% of net sales of NOV-205 in the Lee's Pharma 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 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.

5. STOCKHOLDERS' DEFICIENCY

Series E Preferred Stock Private Placement

Sale of Series E Preferred Stock to Purdue Pharma

Concurrently with the execution of the Collaboration Agreement, Novelos sold to Purdue, 200 shares of a newly created series of the Company's preferred stock, designated "Series E Convertible Preferred Stock", par value \$0.00001 per share (the "Series E Preferred Stock") and a warrant (the "Series E Warrant") to purchase 9,230,769 shares of Novelos common stock for an aggregate purchase price of \$10,000,000 (the "Series E Financing"). Pursuant to the related securities purchase agreement with Purdue (the "Purchase Agreement"), Purdue has 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 Purdue no longer holds at least one-half of the Series E Preferred Stock issued to them at closing. Purdue has the right to participate in future equity financings that result in proceeds to the Company of at least \$20 million.

The Series E Warrant is exercisable for an aggregate of 9,230,769 shares of Novelos common stock at an exercise price of \$0.65 per share. The warrant expires on December 31, 2015. The warrant exercise price and/or the common stock issuable pursuant to such warrant are subject to adjustment 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.

Exchange of Series D Preferred Stock for Series E Preferred Stock

The Company also entered into an exchange agreement with the holders (the "Series D Investors") of the Company's Series D Convertible Preferred Stock (the "Series D Preferred Stock") under which all 413.5 outstanding shares of Series D Preferred Stock and accumulated but unpaid dividends thereon were exchanged for 445.442875 shares of Series E Preferred Stock. The rights and preferences of the Series E Preferred Stock are substantially the same as the Series D Preferred Stock. In addition, the holders of Series D Preferred Stock waived liquidated damages through the date of the exchange as a result of the Company's failure to file a registration statement covering the shares of common stock underlying the Series D Preferred Stock and warrants not otherwise registered. In connection with the execution of this exchange agreement, warrants held by the Series D Investors to purchase a total of 11,865,381 shares of the Company's common stock were amended to extend the expiration of the warrants to December 31, 2015 (from April 11, 2013) and to remove the forced exercise provision. Also, the registration rights agreement dated May 2, 2007 with the Series D Investors was amended to revise the definition of registrable securities under the agreement to refer to Series E Preferred Stock.

Terms of Series E Preferred Stock

The shares of Series E Preferred Stock have a stated value of \$50,000 per share and 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 for an aggregate of 49,649,446 shares of common stock. If there is an effective registration statement covering the shares of common stock underlying the Series E Preferred Stock and the VWAP, as defined in the Series E Certificate of Designations, of Novelos common stock exceeds \$2.00 for 20 consecutive trading days, then the outstanding Series E 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 Series E 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, in shares of Series E Preferred Stock or in registered shares of Novelos common stock at the Company's option, subject to certain conditions.

For as long as any shares of Series E Preferred Stock remain outstanding, Novelos is prohibited from (i) paying dividends to its common stockholders, (ii) amending its certificate of incorporation or by-laws, (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 E Preferred Stock (except for certain exempted issuances), (iv) increasing the number of shares of Series E Preferred Stock or issuing any additional shares of Series E Preferred Stock, (v) selling or otherwise disposing of all or substantially all of its assets (or in the case of licensing, any material intellectual property) or entering into a merger or consolidation with another company unless Novelos is the surviving corporation, the Series E Preferred Stock remains outstanding and there are no changes to the rights and preferences of the Series E Preferred Stock, (vi) redeeming or repurchasing any capital stock other than the Series E Preferred Stock, (vii) incurring any new debt for borrowed money in excess of \$500,000 and (viii) changing the number of the Company's directors.

Registration Rights Agreement

Simultaneous with the execution of the Purchase Agreement, the Company entered into a registration rights agreement (the "Registration Rights Agreement") with Purdue and the Series D Investors. The Registration Rights Agreement requires Novelos to file with the Securities and Exchange Commission no later than 5 business days following the six-month anniversary of the execution of the Securities Purchase Agreement, 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 as described below that are included on a prior registration statement), (ii) 9,230,769 shares of common stock issuable upon exercise of the warrants issued to Purdue and (iii) 11,865,381 shares of common stock issuable upon exercise of warrants held by the Series D Investors. Novelos will be 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. In the event Novelos fails to file the registration statement within the timeframe specified by the Registration Rights Agreement, it will be required to pay to Purdue and the Series D Investors 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 E Preferred Stock and warrants until the delinquent registration statement is filed. Novelos will be 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 Rights Agreement replaces a prior agreement dated April 11, 2008 between Novelos and the Series D Investors.

The Company has an obligation to maintain an effective registration statement covering 12,000,000 shares of common stock issuable upon Series E Preferred Stock, pursuant to a registration rights agreement dated May 3, 2007, as amended. 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 this registration statement have been sold or May 3, 2010. 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 second post-effective amendment was declared effective on April 27, 2009. As of March 31, 2009, 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.

Advisor Fees

Ferghana Partners, Inc. ("Ferghana"), a New York consulting firm, received a cash fee for their services in connection with the negotiation and execution of the Collaboration Agreement equal to \$700,000 (or seven percent (7%) of the gross proceeds to the Company resulting from the sale of Series E Preferred Stock and Common Stock Purchase Warrants to Purdue in connection with the Collaboration Agreement). Ferghana will also receive cash fees equal to six percent (6%) of all payments to Novelos by Mundipharma under the Collaboration Agreement other than royalties on net sales.

The terms of the Series E Preferred Stock contain provisions that may require redemption 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 as of March 31, 2009. The gross proceeds of \$10,000,000 received in conjunction with the Series E Financing were allocated on a relative fair value basis between the Series E Preferred Stock and the warrants. The relative fair value of the warrants issued to investors of \$2,907,000 was recorded as additional paid-in capital while the relative fair value of the Series E Preferred Stock of \$7,093,000 was recorded as temporary equity. The carrying value of the Series E Preferred Stock was immediately adjusted to its fair value of \$7,385,000 based on the fair value of the as-converted common stock. The difference of \$292,000 represents a beneficial conversion feature and was recorded as a deemed dividend to preferred stockholders. Issuance costs related to the Series E Financing of \$795,000 were netted against temporary equity. The Series E Preferred Stock that was issued in payment of dividends was initially recorded in temporary equity at the value of the dividends that had accrued totaling \$1,597,000. This amount was then adjusted to the fair value of \$1,179,000 based on the fair value of the as-converted common stock. The difference of \$418,000 was recorded as an offset to the deemed dividends recorded. The Series E Preferred Stock that was issued in exchange for outstanding shares of Series D Preferred Stock was recorded at \$13,904,000, the carrying value of the shares of Series D Preferred Stock as of the date of the exchange.

As a result of the modification to the warrants to extend the term by approximately 32 months that occurred in connection with the exchange of all outstanding shares of Series D Preferred Stock for shares of Series E Preferred Stock, in the quarter ended March 31, 2009, a deemed dividend of \$840,000 was recorded. This amount represents the incremental fair value of the warrants immediately before and after modification using the Black-Scholes option pricing model, volatility of 80%, discount rates of 1.54% and 2.17% and the remaining terms.

Since the Company has concluded it is not probable that an event will occur which would allow the holders of Series E 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 \$32,676,000 at March 31, 2009.

Common Stock Warrants — The following table summarizes information with regard to outstanding warrants issued in connection with equity and debt financings as of March 31, 2009.

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:			
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	12,379,848	\$ 1.82	March 7, 2011
Series B Preferred:			
Investors	7,500,000	\$ 0.65	December 31, 2015
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	December 31, 2015
Series E Preferred	9,230,769	\$ 0.65	December 31, 2015
Total	38,445,170		

No warrants have been exercised as of March 31, 2009.

6. 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 granted to non-employee consultants:

	Three months ended March 31,	
	2009	2008
Employee and director stock option grants:		
Research and development	\$ 36,260	\$ 28,330
General and administrative	82,015	58,887
	<u>118,275</u>	<u>87,217</u>
Non-employee consultants stock option grants and restricted stock awards:		
Research and development	3,329	70
General and administrative	4,983	402
	<u>8,312</u>	<u>472</u>
Total stock-based compensation	<u>\$ 126,587</u>	<u>\$ 87,689</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 March 31, 2008
Volatility	80%
Weighted-average volatility	80%
Risk-free interest rate	3.28%
Expected life (years)	5
Dividend	0
Weighted-average exercise price	\$ 0.60
Weighted-average grant-date fair value	\$ 0.40

There were no stock option grants during the three months ended March 31, 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 December 31, 2008	7,279,825	\$ 0.60	7.9	\$ 989,718
Options granted	—			
Outstanding at March 31, 2009	7,279,825	\$ 0.60	7.6	\$ 713,648
Exercisable at March 31, 2009	4,371,481	\$ 0.68	6.4	\$ 713,648

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 March 31, 2009, there was approximately \$723,000 of total unrecognized compensation cost related to unvested stock-based compensation arrangements. Of this total amount, 45%, 37% and 18% are expected to be recognized during 2009, 2010 and 2011, respectively. The Company expects 2,908,344 in unvested options to vest in the future. The weighted-average grant-date fair value of vested and unvested options outstanding at March 31, 2009 was \$0.41 and \$0.31, respectively.

In January 2009, the Company modified the terms of options to purchase 40,000 shares of common stock held by two employees to vest all unvested options and to extend the expiration dates of the options. The modification was made in connection with the termination of the two employees to reduce costs. During the three months ended March 31, 2009, incremental stock-based compensation expense of \$8,000 was recorded in connection with the modification of the option terms.

7. 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:

	Three Months Ended March 31,	
	2009	2008
Stock options	7,279,825	5,082,651
Warrants	38,445,170	26,873,047
Conversion of preferred stock	54,670,982	18,264,000

8. 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 three months ended March 31, 2009 because the Company has experienced losses since inception. The Company has not recorded deferred tax assets as their realization is uncertain.

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, 2008 on Form 10-K, which was filed with the Securities and Exchange Commission (“SEC”) on March 30, 2009. 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, is currently in Phase 3 development for non-small cell lung cancer. NOV-002 is intended for use in combination with chemotherapy to act as a chemoprotectant and a chemopotentiator. Three separate Phase 2 trials demonstrated clinical activity and safety of NOV-002 in combination with chemotherapy in non-small cell lung cancer. In May 2006, we finalized a Special Protocol Assessment (SPA) with the FDA for a single pivotal Phase 3 trial in advanced non-small cell lung cancer in combination with first-line chemotherapy, and received Fast Track designation in August 2006. Patient enrollment commenced in November 2006 and targeted enrollment was reached in March 2008. The primary endpoint of the Phase 3 trial is increased median overall survival, to be measured following the occurrence of 725 events (deaths). Based on evaluation of activity through April 2009, we now anticipate that results for this trial will be available in early 2010.

NOV-002 is also being developed to treat early-stage breast cancer. In June 2007 we commenced enrollment in a U.S. Phase 2 neoadjuvant breast trial, which is ongoing at The University of Miami and The Medical University of South Carolina to evaluate the ability of NOV-002 to enhance the effectiveness of chemotherapy. As presented at the San Antonio Breast Cancer Symposium (December 2008) six pathologic complete responses occurred in the first 15 women (40%) who have completed chemotherapy and undergone surgery, which is much greater than the historical control of less than 20% in HER-2 negative patients. Furthermore, patients experienced decreased hematologic toxicities.

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 (plus 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. These results were presented at the American Society of Clinical Oncology in May 2008.

Based on results to-date, in 2009 we intend to initiate several Phase 2 trials with NOV-002 in cancers. Our ability to initiate these trials, and the timing of such trials, will depend on available funding, principally from collaborative arrangements or the issuance of debt or equity securities.

NOV-205, our second compound, is intended for use as a hepatoprotective agent with immunomodulating and anti-inflammatory properties. 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 the event we obtain the additional funding necessary for that purpose. However, there can be no assurance that such funding will be available.

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.

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 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 March 31, 2009 and 2008

Revenue. During the three months ended March 31, 2009 and 2008 we recognized \$8,000 in license fees in connection with our collaboration with Lee's Pharmaceutical (HK) Ltd. ("Lee's Pharma"), which commenced in December 2007. Under the terms of our agreement with Lee's Pharma, 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 Pharma. The \$500,000 initial payment received is being amortized over the estimated term of the agreement, 15 years. During the three months ended March 31, 2009, we also recognized \$23,000 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.

Research and Development. Research and development expense for the three months ended March 31, 2009 was \$1,784,000, compared to \$6,912,000 for the same period in 2008. The \$5,128,000, or 74%, 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, and an increasing number of patients completed their treatment regimen throughout 2008. As a result, certain clinical costs have leveled out or declined. Contract research services such as those related to clinical research organizations and central laboratory services decreased by \$1,496,000. The cost of the chemotherapy drug to be provided to patients at clinical sites in Europe decreased by \$1,723,000. Clinical investigator expenses, which are affected by the number of patients that remain on treatment, decreased by \$1,388,000. Drug manufacturing and distribution costs (including storing and shipping chemotherapy drug) decreased by \$485,000. Salaries and overhead costs decreased by \$36,000.

General and Administrative. General and administrative expense for the three months ended March 31, 2009 was \$476,000, compared to \$263,000 for the same period in 2008. The \$213,000, 81%, increase was due principally to the fact that the first three months of 2008 included a \$404,000 credit that was recorded to reduce an accrual for potential liquidated damages associated with registration rights agreements. We had accrued an estimate for such damages in 2007 and those damages were then waived in connection with the sale of Series D Preferred Stock during 2008. Stock-based compensation also increased by \$28,000. These increases were partially offset by a \$122,000 decrease in professional fees and a \$97,000 decrease in salaries and overhead costs. These decreases were a result of actions taken to reduce discretionary spending in order to preserve cash.

Interest Income. Interest income for the three months ended March 31, 2009 was \$1,000 compared to \$63,000 for the same period in 2008. This decrease is a result of lower cash balances as well as a decline in prevailing interest rates.

Gain on derivatives – Effective January 1, 2009, we adopted EITF 07-5. As a result of the adoption of EITF 07-5, we recorded a gain on derivatives of \$412,000 during the three months ended March 31, 2009. This amount represents the decrease in fair value, during the three months ended March 31, 2009, of outstanding warrants which contain “down-round” anti-dilution provisions.

Preferred Stock Dividends. During the quarter ended March 31, 2009, we accrued \$768,000 in dividends with respect to our Series C, D and E preferred stockholders. 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 the three months ended March 31, 2009) were exchanged for Series E preferred stock. The remaining accrued dividends have not been paid. During the three months ended March 31, 2009, we also recorded deemed dividends to preferred stockholders 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, as described in Note 5 to the financial statements.

During the quarter ended March 31, 2008, \$403,000 in dividends were accrued with respect to Series B and C preferred stock. These dividends were paid in April following the closing of the sale of Series D Preferred Stock.

The deemed dividends, cash dividends and accrued dividends have been included in the calculation of net loss attributable to common stockholders of \$3,296,000, or \$0.07 per share, for the three months ended March 31, 2009 and \$7,504,000 or \$0.19 per share, for the three months ended March 31, 2008. The deemed dividends and cash dividends are excluded from our net loss (from operating activities) of \$1,813,000 or \$0.04 per share, for the three months ended March 31, 2009 and \$7,101,000 or \$0.18 per share for the three months ended March 31, 2008.

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 March 31, 2009, we had \$6,974,000 in cash and equivalents.

During the three months ended March 31, 2009, approximately \$3,493,000 in cash was used in operations, primarily due to a net loss of \$1,813,000 and a net decrease of \$1,433,000 in accounts payable and accrued liabilities. Other changes in working capital provided cash of \$32,000. The cash impact of the loss was increased by a \$412,000 non-cash gain on derivatives and reduced by non-cash stock-based compensation expense of \$127,000 and depreciation and amortization of fixed assets totaling \$6,000.

During the three months ended March 31, 2009, we received net proceeds of \$9,205,000 from the sale of our Series E Preferred stock (see Note 5 to the financial statements).

We believe that our funds at March 31, 2009 will allow us to continue operations at budgeted levels into late 2009, which is when we previously expected the results of our Phase 3 clinical trial in non-small cell lung would be available. The primary endpoint of our Phase 3 trial is increased median overall survival, to be measured following the occurrence of 725 events (deaths), and based on evaluation of activity through April 2009, we now anticipate that the results from this trial will be available in early 2010. Our ability to execute our operating plan beyond late 2009 is dependent on our ability to obtain additional capital (including through the sale of equity and debt securities at any time and by entering into collaborative arrangements for licensing rights in North America, which is not likely to occur before 2010) to fund our development activities. We plan to pursue these alternatives during 2009 and 2010, but there can be no assurance that we will obtain the additional capital necessary to fund our business beyond late 2009. The timing and content of the Phase 3 clinical trial results may impact our projected cash requirements and our ability to obtain capital. Furthermore, continuing adverse conditions in the capital markets globally may affect our ability to obtain funding in a timely manner. We are continuously evaluating measures to further reduce our costs to preserve existing capital. If we are unable to obtain sufficient additional funding, we will be required, beginning in late 2009, to scale back our administrative activities and clinical development programs, including the Phase 3 clinical development of our lead drug candidate, NOV-002, or we may be required to cease operations entirely.

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 March 31, 2009. 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 March 31, 2009, 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 first quarter of 2009 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-K 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-K indicates that factors exist that raise substantial doubt about our ability to continue as a going concern. We believe that our funds at March 31, 2009 will allow us to continue operations at budgeted levels into late 2009, which is when we previously anticipated that the results of our Phase 3 clinical trial in non-small cell lung cancer would be available. The primary endpoint of our Phase 3 trial is increased median overall survival, to be measured following the occurrence of 725 events (deaths), and based on evaluation of activity through April 2009, we now anticipate that the results from this trial will be available in early 2010. Our ability to execute our operating plan beyond late 2009 is dependent on our ability to obtain additional capital (including through the sale of equity and debt securities at any time and by entering into collaborative arrangements for licensing rights in North America, which is not likely to occur before 2010) to fund our development activities. We plan to pursue these alternatives during 2009, but there can be no assurance that we will obtain the additional capital necessary to fund our business beyond late 2009. The timing and content of the Phase 3 clinical trial results may affect our projected cash requirements and our ability to obtain capital. Furthermore, continuing adverse conditions in the capital markets globally may impair our ability to obtain funding in a timely manner. We are continuously evaluating measures to further reduce our costs to preserve existing capital. If we are unable to obtain sufficient additional funding, we will be required, beginning in late 2009, to scale back our administrative activities and clinical development programs, including the Phase 3 clinical development of our lead drug candidate, NOV-002, or we may have to cease our operations entirely.

We are prohibited from taking certain actions and entering into certain transactions without the consent of holders of our Series E preferred stock.

For as long as any shares of Series E Preferred Stock remain outstanding we are prohibited from taking certain actions or entering into certain transactions without the prior consent of specific holders of outstanding shares of Series E preferred stock (currently consisting of Xmark Opportunity Partners, OrbiMed Advisors LLC and Purdue Pharma L.P.). 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 E Preferred Stock (except for certain exempted issuances), increasing the number of shares of Series E Preferred Stock or issuing any additional shares of Series E Preferred Stock other than the 735 shares designated in the Series E 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 (and in the case of licensing, any material intellectual property) or entering into a merger or consolidation with another company unless we are the surviving corporation, the Series E Preferred Stock remains outstanding and there are no changes to the rights and preferences of the Series E Preferred Stock;
- redeeming or repurchasing any capital stock other than Series E Preferred Stock; or
- incurring any new debt for borrowed money in excess of \$500,000.

Eventhough our board of directors may determine 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 specific holders of the outstanding shares of Series E Preferred Stock. The interests of the holders of Series E preferred stock may differ from those of stockholders generally. Moreover, the relationship of Purdue Pharma with Mundipharma (our collaborator on most non-U.S. development, manufacturing and commercialization of NOV-002) has the potential of creating situations where the interests of the Company and those of Purdue Pharma may conflict. If we are unable to obtain consent from each of the holders identified above, we may be unable to complete actions or transactions that our board of directors has determined are in the best interest of the Company and its shareholders.

We have not paid dividends to preferred stockholders totaling \$860,000 as of March 31, 2009 and we may be unable to pay dividends to preferred stockholders when due in future periods.

Our ability to pay cash 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. We anticipate that future dividends on Series E preferred stock will be paid by issuing shares of common stock or additional shares of Series E preferred stock, which will result in additional dilution to existing shareholders. We anticipate that the accrued unpaid dividend on our Series C preferred stock (\$457,000 at March 31, 2009) will continue to accumulate.

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

On February 11, 2009, we sold 200 shares of our Series E convertible preferred stock and warrants to purchase 9,230,769 shares of common stock, receiving gross proceeds of \$10,000,000 and paid approximately \$795,000 in fees and expenses. In addition, 413.5 shares of Series D convertible preferred stock and accumulated dividends thereon were exchanged for 445.442875 shares of Series E convertible preferred stock.

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
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	By-Laws		8-K	June 17, 2005	2
10.1	Securities Purchase Agreement dated February 11, 2009		8-K	February 18, 2009	10.1
10.2	Registration Rights Agreement dated February 11, 2009		8-K	February 18, 2009	10.2
10.3	Series D Preferred Stock Consent and Agreement to Exchange dated February 10, 2009		8-K	February 18, 2009	10.3
10.4	Warrant Amendment Agreements dated February 11, 2009		8-K	February 18, 2009	10.4
10.5	Amendment No. 2 to Registration Rights Agreement dated February 11, 2009		8-K	February 18, 2009	10.5
10.6	Collaboration Agreement dated February 11, 2009		10-K	March 30, 2009	10.39
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: May 15, 2009

By: /s/ Harry S. Palmin

Harry S. Palmin

President and Chief Executive Officer

EXHIBIT INDEX

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	By-Laws		8-K	June 17, 2005	2
10.1	Securities Purchase Agreement dated February 11, 2009		8-K	February 18, 2009	10.1
10.2	Registration Rights Agreement dated February 11, 2009		8-K	February 18, 2009	10.2
10.3	Series D Preferred Stock Consent and Agreement to Exchange dated February 10, 2009		8-K	February 18, 2009	10.3
10.4	Warrant Amendment Agreements dated February 11, 2009		8-K	February 18, 2009	10.4
10.5	Amendment No. 2 to Registration Rights Agreement dated February 11, 2009		8-K	February 18, 2009	10.5
10.6	Collaboration Agreement dated February 11, 2009		10-K	March 30, 2009	10.39
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			

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: May 15, 2009

/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: May 15, 2009

/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 March 31, 2009, 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: May 15, 2009

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

Date: May 15, 2009
