

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

FORM 10-Q

[mark one]

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

For the quarterly period ended: September 30, 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 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: 64,215,727 shares of common stock, \$.00001 par value per share, as of November 12, 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.**

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# **PART I. FINANCIAL INFORMATION**

## *Item 1. Financial Statements*

### **NOVELOS THERAPEUTICS, INC. BALANCE SHEETS**

|                                                                                                                                                                                                                                                                            | <b>September 30,<br/>2009<br/>(unaudited)</b> | <b>December 31,<br/>2008</b> |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------|------------------------------|
| <b>ASSETS</b>                                                                                                                                                                                                                                                              |                                               |                              |
| <b>CURRENT ASSETS:</b>                                                                                                                                                                                                                                                     |                                               |                              |
| Cash and equivalents                                                                                                                                                                                                                                                       | \$ 5,567,114                                  | \$ 1,262,452                 |
| Prepaid expenses and other current assets                                                                                                                                                                                                                                  | 359,969                                       | 129,785                      |
| Total current assets                                                                                                                                                                                                                                                       | 5,927,083                                     | 1,392,237                    |
| <b>FIXED ASSETS, NET</b>                                                                                                                                                                                                                                                   | 54,028                                        | 58,451                       |
| <b>DEPOSITS</b>                                                                                                                                                                                                                                                            | 15,350                                        | 15,350                       |
| <b>TOTAL ASSETS</b>                                                                                                                                                                                                                                                        | <u>\$ 5,996,461</u>                           | <u>\$ 1,466,038</u>          |
| <b>LIABILITIES, REDEEMABLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIENCY</b>                                                                                                                                                                                                |                                               |                              |
| <b>CURRENT LIABILITIES:</b>                                                                                                                                                                                                                                                |                                               |                              |
| Accounts payable and accrued liabilities                                                                                                                                                                                                                                   | \$ 2,688,469                                  | \$ 4,653,912                 |
| Accrued compensation                                                                                                                                                                                                                                                       | 187,264                                       | 240,639                      |
| Accrued dividends                                                                                                                                                                                                                                                          | 2,411,558                                     | 1,689,322                    |
| Derivative liability                                                                                                                                                                                                                                                       | 2,088,176                                     | —                            |
| Deferred revenue – current                                                                                                                                                                                                                                                 | 33,333                                        | 33,333                       |
| Total current liabilities                                                                                                                                                                                                                                                  | 7,408,800                                     | 6,617,206                    |
| <b>DEFERRED REVENUE – NONCURRENT</b>                                                                                                                                                                                                                                       | 408,334                                       | 433,333                      |
| <b>COMMITMENTS AND CONTINGENCIES</b>                                                                                                                                                                                                                                       |                                               |                              |
| <b>REDEEMABLE PREFERRED STOCK:</b>                                                                                                                                                                                                                                         |                                               |                              |
| Series D convertible preferred stock, \$0.00001 par value; 420 shares designated; no shares and 413.5 shares issued and outstanding at September 30, 2009 and December 31, 2008, respectively                                                                              | —                                             | 13,904,100                   |
| Series E convertible preferred stock, \$0.00001 par value; 735 shares designated; 606.399338125 shares and no shares issued and outstanding at September 30, 2009 and December 31, 2008, respectively (Note 5) (liquidation preference \$32,063,367 at September 30, 2009) | 20,381,810                                    | —                            |
|                                                                                                                                                                                                                                                                            | <u>20,381,810</u>                             | <u>13,904,100</u>            |
| <b>STOCKHOLDERS' DEFICIENCY:</b>                                                                                                                                                                                                                                           |                                               |                              |
| Preferred stock, \$0.00001 par value; 7,000 shares authorized:                                                                                                                                                                                                             |                                               |                              |
| Series C cumulative convertible preferred stock; 232 shares issued and outstanding at September 30, 2009 and 272 shares issued and outstanding at December 31, 2008 (liquidation preference \$3,452,160 at September 30, 2009)                                             | —                                             | —                            |
| Common stock, \$0.00001 par value; 150,000,000 shares authorized; 55,455,394 shares issued and outstanding at September 30, 2009 and 43,975,656 shares issued and outstanding at December 31, 2008                                                                         | 555                                           | 440                          |
| Additional paid-in capital                                                                                                                                                                                                                                                 | 41,008,571                                    | 40,204,112                   |
| Accumulated deficit                                                                                                                                                                                                                                                        | (63,211,609)                                  | (59,693,153)                 |
| Total stockholders' deficiency                                                                                                                                                                                                                                             | (22,202,483)                                  | (19,488,601)                 |
| <b>TOTAL LIABILITIES, REDEEMABLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIENCY</b>                                                                                                                                                                                          | <u>\$ 5,996,461</u>                           | <u>\$ 1,466,038</u>          |

*See notes to financial statements.*

**NOVELOS THERAPEUTICS, INC.**  
**STATEMENTS OF OPERATIONS**  
(Unaudited)

|                                                                                                                 | <b>Three Months Ended September 30,</b> | <b>2008</b>           | <b>Nine Months Ended September 30,</b> | <b>2008</b>            |
|-----------------------------------------------------------------------------------------------------------------|-----------------------------------------|-----------------------|----------------------------------------|------------------------|
|                                                                                                                 | <b>2009</b>                             |                       | <b>2009</b>                            |                        |
| REVENUE                                                                                                         | \$ 13,702                               | \$ 35,513             | \$ 76,983                              | \$ 89,523              |
| <b>COSTS AND EXPENSES:</b>                                                                                      |                                         |                       |                                        |                        |
| Research and development                                                                                        | 1,765,664                               | 1,971,501             | 5,137,955                              | 12,929,184             |
| General and administrative                                                                                      | 545,883                                 | 622,347               | 1,528,826                              | 1,602,120              |
| Total costs and expenses                                                                                        | <u>2,311,547</u>                        | <u>2,593,848</u>      | <u>6,666,781</u>                       | <u>14,531,304</u>      |
| LOSS FROM OPERATIONS                                                                                            | <u>(2,297,845)</u>                      | <u>(2,558,335)</u>    | <u>(6,589,798)</u>                     | <u>(14,441,781)</u>    |
| <b>OTHER INCOME (EXPENSE):</b>                                                                                  |                                         |                       |                                        |                        |
| Interest income                                                                                                 | —                                       | 21,344                | 1,012                                  | 122,556                |
| Loss on derivatives (Notes 1 and 2)                                                                             | (446,685)                               | —                     | (2,830,274)                            | —                      |
| Miscellaneous                                                                                                   | 1,500                                   | 2,250                 | 6,233                                  | 6,750                  |
| Total other income (expense)                                                                                    | <u>(445,185)</u>                        | <u>23,594</u>         | <u>(2,823,029)</u>                     | <u>129,306</u>         |
| NET LOSS                                                                                                        | <u>(2,743,030)</u>                      | <u>(2,534,741)</u>    | <u>(9,412,827)</u>                     | <u>(14,312,475)</u>    |
| PREFERRED STOCK DIVIDENDS                                                                                       | (842,996)                               | (530,467)             | (2,495,902)                            | (1,463,715)            |
| PREFERRED STOCK DEEMED DIVIDENDS                                                                                | —                                       | —                     | (714,031)                              | (4,417,315)            |
| NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS                                                                    | <u>\$ (3,586,026)</u>                   | <u>\$ (3,065,208)</u> | <u>\$ (12,622,760)</u>                 | <u>\$ (20,193,505)</u> |
| <b>BASIC AND DILUTED NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS PER COMMON SHARE</b>                          | <u>\$ (0.07)</u>                        | <u>\$ (0.07)</u>      | <u>\$ (0.27)</u>                       | <u>\$ (0.50)</u>       |
| <b>SHARES USED IN COMPUTING BASIC AND DILUTED NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS PER COMMON SHARE</b> | <u>49,653,675</u>                       | <u>41,667,964</u>     | <u>45,944,799</u>                      | <u>40,132,085</u>      |

*See notes to financial statements.*

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

|                                                                                                | <b>Nine Months Ended September 30,</b> |                     |
|------------------------------------------------------------------------------------------------|----------------------------------------|---------------------|
|                                                                                                | <b>2009</b>                            | <b>2008</b>         |
| <b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>                                                   |                                        |                     |
| Net loss                                                                                       | \$ (9,412,827)                         | \$ (14,312,475)     |
| Adjustments to reconcile net loss to cash used in operating activities:                        |                                        |                     |
| Depreciation and amortization                                                                  | 22,423                                 | 11,955              |
| Loss on disposal of fixed assets                                                               | —                                      | 6,472               |
| Stock-based compensation                                                                       | 503,161                                | 330,296             |
| Loss on derivatives                                                                            | 2,830,274                              | —                   |
| Changes in:                                                                                    |                                        |                     |
| Prepaid expenses and other current assets                                                      | (230,184)                              | (62,934)            |
| Accounts payable and accrued liabilities                                                       | (1,965,443)                            | (751,979)           |
| Accrued compensation                                                                           | (53,375)                               | (102,208)           |
| Deferred revenue                                                                               | (24,999)                               | 475,000             |
| Cash used in operating activities                                                              | <u>(8,330,970)</u>                     | <u>(14,405,873)</u> |
| <b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>                                                   |                                        |                     |
| Purchases of fixed assets                                                                      | (18,000)                               | (31,003)            |
| Change in restricted cash                                                                      | —                                      | 1,184,702           |
| Cash provided by (used in) investing activities                                                | <u>(18,000)</u>                        | <u>1,153,699</u>    |
| <b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>                                                   |                                        |                     |
| Proceeds from issuance of common stock, net                                                    | 3,449,101                              | 2,986,738           |
| Proceeds from the sale of preferred stock and warrants, net                                    | 9,204,531                              | 5,469,672           |
| Dividends paid to preferred stockholders                                                       | —                                      | (740,280)           |
| Proceeds from exercise of stock option                                                         | —                                      | 1,000               |
| Cash provided by financing activities                                                          | <u>12,653,632</u>                      | <u>7,717,130</u>    |
| INCREASE (DECREASE) IN CASH AND EQUIVALENTS                                                    | 4,304,662                              | (5,535,044)         |
| CASH AND EQUIVALENTS AT BEGINNING OF YEAR                                                      | <u>1,262,452</u>                       | <u>9,741,518</u>    |
| CASH AND EQUIVALENTS AT END OF PERIOD                                                          | <u>\$ 5,567,114</u>                    | <u>\$ 4,206,474</u> |
| <b>SUPPLEMENTAL DISCLOSURE OF NON-CASH INVESTING AND FINANCING ACTIVITIES</b>                  |                                        |                     |
| Deemed dividends on preferred stock                                                            | \$ 714,031                             | \$ 4,417,315        |
| Dividends accrued but not paid to preferred stockholders                                       | \$ 2,294,321                           | \$ 1,060,935        |
| Dividends paid to preferred stockholders in shares of Series E preferred stock                 | \$ 1,597,144                           | \$ —                |
| Relative fair value of warrants issued to stockholders                                         | \$ 3,659,692                           | \$ 1,302,592        |
| Issuance of common stock in exchange for tender of warrants                                    | \$ 1,625,760                           | \$ —                |
| Reclassification of derivative liability to paid-in capital upon cashless exercise of warrants | \$ 115,283                             | \$ —                |
| Exchange of Series B preferred stock for Series D preferred stock                              | \$ —                                   | \$ 9,918,666        |
| Exchange of Series D preferred stock for Series E preferred stock                              | \$ 13,904,100                          | \$ —                |
| Conversion of Series E preferred stock and accumulated dividends into common stock             | \$ 2,039,130                           | \$ —                |
| Conversion of Series C preferred stock and accumulated dividends into common stock             | \$ 569,566                             | \$ —                |

*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 (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 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 primary endpoint of the Company’s Phase 3 clinical trial for NOV-002 in non-small cell lung cancer is increased median overall survival, to be measured following the occurrence of 725 events (deaths). The Company anticipates that the results from this trial will be available in early 2010. On August 25, 2009, the Company entered into a Securities Purchase Agreement (the “August 2009 Purchase Agreement”) with Purdue Pharma L.P. (“Purdue”) contemplating the issuance and sale at two or more closings of up to 13,636,364 shares of Novelos common stock and warrants to purchase approximately 4,772,728 shares of Novelos common stock at an exercise price of \$0.66 per share, expiring December 31, 2015, for an aggregate purchase price of \$9,000,000. At the initial closing on August 25, 2009, the Company sold Purdue 5,303,030 shares of common stock and a warrant to purchase 1,856,062 shares of common stock for gross proceeds of \$3,500,000. At the final closing under the August 2009 Purchase Agreement on November 10, 2009, the Company sold Purdue 8,333,334 shares of Novelos common stock and a warrant to purchase 2,916,668 shares of Novelos common stock for gross proceeds of \$5,500,000. The August 2009 Purchase Agreement required the Company to adopt an expanded development and regulatory plan for NOV-002 (the “Plan”), which contemplates substantial expenditures through mid-2010 in addition to clinical development expenditures previously contemplated for the completion of the Phase 3 trial. The Company is required to use proceeds from the sale of securities under the August 2009 Purchase Agreement for the expenditures identified in the Plan. The Company believes that the available funds at September 30, 2009, plus the proceeds from the final closing under the August 2009 Purchase Agreement will allow it to operate beyond the conclusion of the Phase 3 trial and into the third quarter of 2010.

The completion of the Phase 3 clinical trial is likely to significantly affect the Company’s ability to finance continued operations beyond the third quarter of 2010. If the results are favorable, the Company believes it will be able to obtain adequate funding to pursue its strategic objectives and clinical development programs longer term. If the results of the Phase 3 clinical trial are not favorable, the Company may be unable to obtain additional funding, and may be required to scale back administrative activities and clinical development programs, or cease its operations entirely. Furthermore, adverse conditions in the capital markets globally may impair the Company’s ability to obtain funding in a timely manner.

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.

*Recently Issued Accounting Standards* – In June 2009, the Financial Accounting Standards Board (“FASB”) issued FASB ASC 105, *Generally Accepted Accounting Principles*, which establishes the FASB Accounting Standards Codification (“ASC”) as the sole source of authoritative generally accepted accounting principles (“GAAP”). Pursuant to the provisions of FASB ASC 105, the Company has updated references to GAAP in its financial statements issued for the period ended September 30, 2009. The adoption of FASB ASC 105 did not impact the Company’s financial position or results of operations.

In May 2009, the FASB issued new authoritative guidance now codified as FASB ASC Topic 855 related to subsequent events, which establishes general standards of accounting for and disclosures of subsequent events that occur after the balance sheet date but prior to the issuance of financial statements. The guidance requires additional disclosure regarding the date through which subsequent events have been evaluated by the entity as well as whether that date is the date the financial statements were issued. This guidance became effective for the Company's financial statements as of June 30, 2009. The Company has evaluated subsequent events through November 16, 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 the Derivatives and Hedging Topic of the 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 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 issuances of stock at prices below the then-effective exercise price of the warrants. The number of such warrants was 14,003,319 at January 1, 2009 and 8,012,180 at September 30, 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 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, 2009, these warrants represent the only outstanding derivative instruments issued or held by the Company.

## **2. CHANGE IN ACCOUNTING PRINCIPLE**

Effective January 1, 2009, the Company adopted the guidance of FASB ASC 815-40, *Derivatives and Hedging*, 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 this adoption, 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 this guidance, in the first quarter of 2009, 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 increase in fair value of the warrants of \$447,000 during the three months ended September 30, 2009 and \$2,830,000 during the nine months ended September 30, 2009 has been included as a component of other income in the accompanying statements of operations for the respective period. Certain of the warrants that had been recorded as a derivative liability were exchanged for shares of the Company's common stock during the three months ended September 30, 2009. See Note 5 for a description of that transaction. The fair value of the warrants at September 30, 2009 of \$2,088,000 is included as a current liability in the accompanying balance sheet as of that date.

## **3. 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, 2009 |              |         | Fair Value   |
|---------------------|--------------------|--------------|---------|--------------|
|                     | Level 1            | Level 2      | Level 3 |              |
| <b>Liabilities:</b> |                    |              |         |              |
| Warrants            | \$ -               | \$ 2,088,000 | \$ -    | \$ 2,088,000 |

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 six to seventeen months and risk-free interest rates ranging from 0.18% to 0.68%.

#### 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, 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 Hong Kong, Macau, China and Taiwan, the “Chinese Territory”) and Australia (collectively referred to as the “Mundipharma 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 Mundipharma Territory. Novelos is responsible for the cost and execution of development, regulatory submissions and commercialization of NOV-002 outside the Mundipharma Territory, and Mundipharma is responsible for the cost and execution of certain development activities, all regulatory submissions and all commercialization within the Mundipharma 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 Mundipharma 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 Mundipharma Territory where Novelos held patents on the licensed technology as of the effective date of the agreement. Royalties in countries in the Mundipharma Territory where Novelos did not hold patents as of the effective date will be paid at 50% of the royalty rates in countries where patents were 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 Mundipharma 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 the Collaboration 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 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 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, 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 Pharm"). Pursuant to this agreement, Lee's Pharm obtained an exclusive license to develop, manufacture and commercialize NOV-002 and NOV-205 in the Chinese 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 Pharm. This initial \$500,000 payment received is being amortized over the estimated term of this agreement, 15 years. Accordingly, \$8,333 and \$25,000 of license revenue was recognized in each of the three and nine month periods, respectively, ended September 30, 2009 and 2008.

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

### **5. STOCKHOLDERS' DEFICIENCY**

#### ***August 2009 Common Stock Private Placement***

##### ***Securities Purchase Agreement***

On August 25, 2009, the Company entered into the August 2009 Purchase Agreement with Purdue to sell 13,636,364 shares of its common stock, \$0.00001 par value and warrants to purchase 4,772,728 shares of its common stock at an exercise price of \$0.66 per share, expiring December 31, 2015, for an aggregate purchase price of \$9,000,000. Concurrently with the execution and delivery of the August 2009 Purchase Agreement, the Company initially sold Purdue 5,303,030 shares of its common stock and a warrant to purchase 1,856,062 shares of its common stock at \$0.66 per share for approximately \$3,500,000 (the "Initial Closing"). The sale of the remaining common stock and warrants was completed on November 10, 2009. See Note 9.

Pursuant to the August 2009 Purchase Agreement, from the date of the Initial Closing until Purdue receives certain data related to the Company's Phase 3 clinical trial in non-small cell lung cancer (the "Exclusive Negotiation Period") Purdue has the exclusive right to negotiate with Novelos for the license or other acquisition of NOV-002 Rights (as defined in the August 2009 Purchase Agreement) in the United States (the "U.S. License"). If, during the Exclusive Negotiation Period, Purdue and Novelos agree on terms for a definitive agreement for the U.S. License, Novelos shall grant Purdue an option to enter into such definitive agreement within 30 days after the expiration of the Exclusive Negotiation Period. Purdue is entitled to a right of first refusal (the "Right of First Refusal") with respect to bona fide offers for a U.S. License received from third parties and approved by the Company's board of directors. Under the Right of First Refusal, Novelos will be required to communicate to Purdue the terms of any such third-party offers received and Purdue will have 30 days to enter into a definitive agreement with Novelos on substantially similar terms that provide no lesser economic benefit to Novelos as provided in the third-party offer. The Right of First Refusal terminates upon specified business combinations occurring after the Exclusive Negotiation Period. Novelos has separately entered into letter agreements with Mundipharma and its independent associated company providing for a conditional exclusive right to negotiate for, and a conditional right of first refusal with respect to, NOV-002 Rights for Latin America, Mexico and Canada.

Pursuant to the August 2009 Purchase Agreement, Purdue has the right to either designate one member to Novelos' board of directors (the "Board") or designate an observer to attend all meetings of the Board, committees thereof and access to all information made available to members of the Board. This right lasts until the later of such time as Purdue or its associated companies no longer hold at least one-half of the common stock purchased pursuant to the August 2009 Purchase Agreement and no longer hold at least one-half of the Series E Preferred Stock issued to them on February 11, 2009. The right to designate a board observer had previously been granted in connection with the financing that occurred on February 11, 2009 and Purdue appointed such an observer in February 2009. Purdue also has the right to participate in future equity financings in proportion to their pro rata ownership of common and preferred stock.

#### *Common Stock Purchase Warrant*

The common stock purchase warrant has an exercise price of \$0.66 per share and expires on December 31, 2015. The warrant exercise price and/or the number of shares of common stock issuable pursuant to such warrant will be 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. The relative fair value of the warrant issued to Purdue at the Initial Closing of \$752,000 was recorded as a component of additional paid-in capital. The fair value of the warrant was determined using the Black-Scholes method of valuation, estimated volatility of 90%, a risk-free interest rate of 2.02% and a term equal to the term of the warrant.

#### *Registration Rights Agreement*

As part of this transaction, the Company entered into a registration rights agreement with Purdue. The registration rights agreement requires the Company to file with the Securities and Exchange Commission no later than 5 business days following the earlier of the six-month anniversary of (i) the Final Subsequent Closing (as defined in the August 2009 Purchase Agreement) or (ii) the end of the Exclusive Negotiation, 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 keep the registration statement continuously effective under the Securities Act until the earlier of the date when all the registrable securities covered by the registration statement have been sold or the second anniversary of the closing. In the event the Company fails to file the registration statement timely, it will be required to pay Purdue 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 and until the delinquent registration statement is filed. 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. In the event that any sale or issuances of common stock and warrants pursuant to the Purchase Agreement occur after this filing deadline, the Company will be required to file a registration statement covering the registrable securities issued within 5 business days following the three-month anniversary of such sale or issuance. As of September 30, 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.

#### *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").

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. 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 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 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. Purdue and the Series D Investors consented to extend the Filing Deadline to September 15, 2009. The registration statement was filed on that date, but has not yet been declared effective. 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 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 September 30, 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.

#### *Accounting Treatment of Series E Financing*

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 September 30, 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 (determined using the Black-Scholes option pricing model, estimated volatility of 80%, a risk-free interest rate of 2.17% and a term equal to the term of the warrant) 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 their expiration 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 nine months ended September 30, 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 warrant term.

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 \$32,063,000 at September 30, 2009.

**Conversions of Preferred Stock** – During the three and nine months ended September 30, 2009, 39,043,493.75 shares of the Company's Series E preferred stock, having an aggregate stated value of \$1,952,000, and accumulated dividends thereon, were converted into 3,137,119 shares of common stock. The associated carrying value of the converted shares totaling approximately \$1,291,000 was reclassified to permanent equity from temporary equity. See Note 9 for a description of a conversion of Series E preferred stock which occurred in November 2009.

During the three months ended September 30, 2009, 5 shares of the Company's Series C preferred stock, having an aggregate stated value of \$60,000, and accumulated dividends thereon were converted into 114,410 shares of the Company's common stock. During the nine months ended September 30, 2009, 40 shares of the Company's Series C preferred stock, having an aggregate stated value of \$480,000, and accumulated dividends thereon were converted into 876,253 shares of the Company's common stock.

**Warrant Exchange** – On August 21, 2009, the Company entered into exchange agreements with certain accredited investors who held warrants to purchase 6,947,728 shares of its common stock. Pursuant to the exchange agreements, an aggregate of 2,084,308 shares of the Company's common stock with a fair value of \$1,626,000 were issued in exchange for these warrants. The holders agreed not to transfer or dispose of the shares of common stock until February 18, 2010. The warrants had been recorded as a derivative liability on the Company's balance sheet at their estimated fair value of \$1,109,000 at the date of exchange. The difference of \$517,000 between the estimated fair value of the warrants at the date of exchange and the common stock issued to settle the derivative liability has been included as a component of the loss on derivatives for the three and nine months ended September 30, 2009.

These warrants had been issued in March 2006 in connection with a private placement of Novelos common stock, had an expiration date of March 7, 2011 and were exercisable at a price of \$1.82 per share. Following the exchange, warrants expiring on March 7, 2011 to purchase a total of 5,432,120 shares of common stock at \$1.82 per share remained outstanding. Following the August 2009 Private Placement, the number of these outstanding warrants was increased to 5,559,674 and the exercise price was reduced to \$1.78, as a result of anti-dilution provisions in the warrants.

**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, 2009.

| <b>Offering</b>                            | <b>Outstanding<br/>(as adjusted)</b> | <b>Exercise<br/>Price<br/>(as adjusted)</b> | <b>Expiration Date</b> |
|--------------------------------------------|--------------------------------------|---------------------------------------------|------------------------|
| 2005 Bridge Loans                          | 720,000                              | \$ 0.625                                    | April 1, 2010          |
| 2005 PIPE - Placement agents and finders   | 762,810                              | \$ 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 | 5,559,674                            | \$ 1.78                                     | 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      |
| August 2009 Private Placement              | 1,856,062                            | \$ 0.66                                     | December 31, 2015      |
| <b>Total</b>                               | <b>33,197,725</b>                    |                                             |                        |

During the nine months ended September 30, 2009, the Company issued 79,028 shares of common stock in connection with the cashless exercise of warrants to purchase 283,333 shares of the Company's common stock. The warrants had an expiration date of August 9, 2010 and an exercise price of \$0.65 per share. The warrants had been recorded as a derivative liability. Upon exercise, \$115,000 was reclassified from derivative liability to paid-in capital.

Other than those described above, there have been no warrant exercises through September 30, 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<br>September 30, |                  | Nine months ended<br>September 30, |                   |
|---------------------------------------------------------------------------|-------------------------------------|------------------|------------------------------------|-------------------|
|                                                                           | 2009                                | 2008             | 2009                               | 2008              |
| Employee and director stock option grants:                                |                                     |                  |                                    |                   |
| Research and development                                                  | \$ 34,953                           | \$ 21,049        | \$ 106,500                         | \$ 135,333        |
| General and administrative                                                | 62,130                              | 57,476           | 219,449                            | 174,028           |
|                                                                           | 97,083                              | 78,525           | 325,949                            | 309,361           |
| Non-employee consultants stock option grants and restricted stock awards: |                                     |                  |                                    |                   |
| Research and development                                                  | 32,825                              | (4,976)          | 111,658                            | 4,339             |
| General and administrative                                                | 13,163                              | (288)            | 65,554                             | 16,596            |
|                                                                           | 45,988                              | (5,264)          | 177,212                            | 20,935            |
| Total stock-based compensation                                            | <u>\$ 143,071</u>                   | <u>\$ 73,261</u> | <u>\$ 503,161</u>                  | <u>\$ 330,296</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:

|                                        | Nine Months<br>Ended<br>September 30,<br>2008 |
|----------------------------------------|-----------------------------------------------|
| Volatility                             | 80%                                           |
| Weighted-average volatility            | 80%                                           |
| Risk-free interest rate                | 3.14%                                         |
| Expected life (years)                  | 5                                             |
| Dividend                               | 0                                             |
| Weighted-average exercise price        | \$ 0.60                                       |
| Weighted-average grant-date fair value | \$ 0.39                                       |

There were no stock option grants during the nine months ended September 30, 2009 or the three months ended September 30, 2008.

A summary of stock option activity is as follows:

|                                   | Options<br>Outstanding | Weighted<br>Average<br>Exercise Price | Weighted<br>Average<br>Remaining<br>Contracted<br>Term in<br>Years | Aggregate<br>Intrinsic<br>Value |
|-----------------------------------|------------------------|---------------------------------------|--------------------------------------------------------------------|---------------------------------|
| Outstanding at December 31, 2008  | 7,279,825              | \$ 0.60                               | 7.9                                                                | \$ 989,718                      |
| Options granted                   | —                      |                                       |                                                                    |                                 |
| Outstanding at September 30, 2009 | 7,279,825              | \$ 0.60                               | 7.1                                                                | \$ 3,333,459                    |
| Exercisable at September 30, 2009 | 4,692,732              | \$ 0.67                               | 6.1                                                                | \$ 2,213,727                    |

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

As of September 30, 2009, there was approximately \$554,000 of total unrecognized compensation cost related to unvested stock-based compensation arrangements. Of this total amount, 19%, 54% and 27% are expected to be recognized during 2009, 2010 and 2011, respectively. The Company expects 2,587,093 in unvested options to vest in the future. The weighted-average grant-date fair value of vested and unvested options outstanding at September 30, 2009 was \$0.41 and \$0.30, 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 nine months ended September 30, 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 and accumulated dividends. 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<br>September 30, |            | Nine Months Ended<br>September 30, |            |
|-------------------------------|-------------------------------------|------------|------------------------------------|------------|
|                               | 2009                                | 2008       | 2009                               | 2008       |
| Stock options                 | 7,279,825                           | 5,154,825  | 7,279,825                          | 5,154,825  |
| Warrants                      | 33,197,725                          | 28,102,033 | 33,197,725                         | 28,102,033 |
| Conversion of preferred stock | 53,589,726                          | 36,829,192 | 53,589,726                         | 36,829,192 |

## 8. 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, 2009 because the Company has experienced losses since inception. The Company has not recorded deferred tax assets as their realization is uncertain.

## 9. SUBSEQUENT EVENTS

### *Results of Special Meeting of Shareholders*

#### *Increase in Authorized Shares of Common Stock*

On November 3, 2009, 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 75 million shares, from 150 million to 225 million. Following the adjournment of the meeting, the amendment was filed with the Secretary of State of Delaware, and it went into effect on November 3, 2009.

#### *Re-Election of Directors; Amendment to 2006 Stock Option Plan*

In addition to the approval of the amendment of the certificate of incorporation as described above, the Company's stockholders re-elected each incumbent member of the board of directors and approved an amendment to the Company's 2006 Stock Incentive Plan to increase the shares of common stock authorized under the plan by 5 million, from 5 million to 10 million. The amendment to the 2006 Stock Incentive Plan became effective immediately upon its approval by the stockholders.

### ***Conversion of Preferred Stock***

On November 10, 2009, 5.2 shares of the Company's Series E preferred stock, having an aggregate stated value of \$260,000, and accumulated dividends thereon, were converted into 426,999 shares of common stock.

### ***Final Closing on August 2009 Private Placement***

On November 10, 2009, the Company completed the final closing under the August 2009 Purchase Agreement and sold Purdue 8,333,334 shares of Novelos common stock and warrants to purchase 2,916,668 shares of Novelos common stock for gross proceeds of \$5,500,000. The terms of the August 2009 Purchase Agreement are described in Note 5.

The issuance of shares in the final closing resulted in anti-dilution adjustments to certain warrants. Pursuant to their terms, the outstanding warrants were increased by a total of 191,018 shares and their exercise price was decreased to \$1.72 from \$1.78.

## ***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 chemopotentiator and chemoprotectant. 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 the enrollment target 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). We 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 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, we intend to initiate several Phase 2 trials with NOV-002 in these and possibly other cancer indications. 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 first half of 2010 provided that 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 the Russian Territory, 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 to develop, manufacture and commercialize NOV-002 in Europe (other than the Russian Territory), Asia (other than the Chinese Territory) and Australia. We have a collaboration agreement with Lee's Pharm to develop, manufacture and commercialize NOV-002 and NOV-205 in the Chinese Territory.

## **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, nearly all of our research and development costs have been associated with our NOV-002 compound.

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

### **Three Months Ended September 30, 2009 and 2008**

**Revenue.** During the three months ended September 30, 2009 and 2008 we recognized \$8,000 in license fees in connection with our collaboration with Lee's Pharm, which commenced in December 2007. Under the terms of our agreement with Lee's Pharm, 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. The \$500,000 initial payment received is being amortized over the estimated term of the agreement, 15 years. During the three months ended September 30, 2009 and 2008, we also recognized \$5,000 and \$27,000, respectively, 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 September 30, 2009 was \$1,766,000, compared to \$1,972,000 for the same period in 2008. The \$206,000, or 10%, 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 off or further declined. Contract research services and other clinical activities such as those related to clinical research organizations, consultants and central laboratory services and investigator payments decreased by \$244,000. Salaries and overhead costs decreased by \$58,000. These decreases were offset by a \$52,000 increase in stock compensation expense and a \$44,000 increase in drug manufacturing and distribution costs as the Company prepares for expanded manufacturing activities associated with possible regulatory filings in 2010.

**General and Administrative.** General and administrative expense for the three months ended September 30, 2009 was \$546,000, compared to \$622,000 for the same period in 2008. The \$76,000, or 12%, decrease was due to a \$55,000 decrease in salaries and overhead and a \$39,000 decrease in professional fees. These decreases were a result of actions taken to reduce discretionary spending in order to conserve cash. These decreases were offset by a \$18,000 increase in stock-based compensation.

**Interest Income.** Interest income for the three months ended September 30, 2009 was \$0 compared to \$21,000 for the same period in 2008. During the three months ended September 30, 2009, our cash was on deposit in a non-interest bearing transactions account that is fully insured by the FDIC.

*Loss on Derivatives* – Effective January 1, 2009, we adopted the guidance of FASB ASC 815-40, *Derivatives and Hedging*. As a result of this adoption, we recorded a loss on derivatives of \$447,000 during the three months ended September 30, 2009. This amount represents the increase in fair value, during the three months ended September 30, 2009, 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. During the three months ended September 30, 2009, an aggregate of 2,084,308 shares of the Company’s common stock with a fair value of \$1,626,000 were issued in exchange for the tender of certain of these warrants. The difference of \$517,000 between the fair value of the warrants at the date of exchange and the fair value of the common stock issued to settle the derivative liability has been included as a component of the loss on derivatives in the three months ended September 30, 2009.

*Preferred Stock Dividends.* During the quarter ended September 30, 2009, we accrued \$843,000 in dividends with respect to our Series C and E preferred stock. During the three months ended September 30, 2009, preferred stock dividends accrued on shares of Series E preferred stock totaling \$87,000 and preferred stock dividends accrued on shares of Series C preferred stock totaling \$14,000 were converted into shares of common stock. At September 30, 2009, accrued dividends totaling \$2,412,000 remain unpaid.

During the three months ended September 30, 2008 we accrued \$465,000 of dividends due to our Series D preferred stockholders and accrued \$65,000 in dividends due to our Series C preferred stockholders.

The deemed dividends, cash dividends and accrued dividends have been included in the calculation of net loss attributable to common stockholders of \$3,586,000, or \$0.07 per share, for the three months ended September 30, 2009 and \$3,065,000 or \$0.07 per share, for the three months ended September 30, 2008. The deemed dividends and cash dividends are excluded from our net loss (from operating activities) of \$2,743,000, or \$0.06 per share, for the three months ended September 30, 2009 and \$2,535,000, or \$0.06 per share, for the three months ended September 30, 2008.

#### ***Nine Months Ended September 30, 2009 and 2008***

*Revenue.* During the nine months ended September 30, 2009 and 2008, 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 and 2008, we also recognized \$52,000 and \$65,000, respectively, 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 nine months ended September 30, 2009 was \$5,138,000, compared to \$12,929,000 for the same period in 2008. The \$7,791,000, or 60%, 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 off or declined. Contract research services such as those related to clinical research organizations, consultants and central laboratory services decreased by \$3,115,000. Clinical investigator expenses, which are affected by the number of patients that remain on treatment, decreased by \$2,406,000. The cost of chemotherapy drug to be provided to patients in Europe decreased by \$1,728,000 and drug manufacturing and distribution costs (including storing and shipping chemotherapy drug) decreased by \$416,000. Salaries and overhead costs decreased by \$204,000. These decreases were offset by a \$78,000 increase in stock compensation expense.

*General and Administrative.* General and administrative expense for the nine months ended September 30, 2009 was \$1,529,000. We recorded general and administrative expense of \$1,602,000 for the same period in 2008. However, during the nine months ended September 30, 2008 we recorded a \$404,000 credit to account for a waiver of potential liquidated damages associated with registration rights agreements. We had previously accrued an estimate for such damages in 2007. Without this \$404,000 credit, general and administrative expense during the nine months ended September 30, 2009 would have been \$2,006,000, representing a decrease of \$477,000, or 24%, during the nine months ended September 30, 2009 compared to the same period in the prior year. This decrease is due principally to a \$303,000 decrease in professional fees and a \$268,000 decrease in salaries and overhead costs, which were a result of actions taken to reduce discretionary spending in order to conserve cash. The decrease was partially offset by an increase in stock-based compensation of \$94,000.

*Interest Income.* Interest income for the nine months ended September 30, 2009 was \$1,000 compared to \$123,000 for the same period in 2008. Beginning in March 2009, our cash was on deposit in a non-interest bearing account that is fully insured by the FDIC.

*Loss on Derivatives.* Effective January 1, 2009, we adopted the guidance of FASB ASC 815-40, *Derivatives and Hedging* and, as a result, we recorded a loss on derivatives of \$2,830,000 during the nine months ended September 30, 2009. This amount represents the increase in fair value, during the nine months ended September 30, 2009, 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. During the nine months ended September 30, 2009, an aggregate of 2,084,308 shares of the Company’s common stock with a fair value of \$1,626,000 were issued in exchange for the tender of certain of these warrants. The difference of \$517,000 between the fair value of the warrants at the date of exchange and the fair value of the common stock issued to settle the derivative liability has been included as a component of the loss on derivatives in the nine months ended September 30, 2009.

*Preferred Stock Dividends.* During the nine months ended September 30, 2009, we accrued \$2,496,000 in dividends with respect to our Series C, D and E preferred stock. 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. The remaining accrued dividends have not been paid. 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, as described in Note 5 to the financial statements.

During the nine months ended September 30, 2008, we paid cash dividends to Series B and Series C preferred stockholders of \$740,000 and accrued \$1,060,000 of dividends due to our Series B, C and D preferred stockholders. During the nine months ended September 30, 2008 we also recorded deemed dividends to preferred stockholders totaling \$4,417,000. This amount represents the value attributed to the reduction in exercise and conversion prices of the warrants and preferred stock issued in May 2007 in connection with the financing that occurred in April 2008.

The deemed dividends, cash dividends and accrued dividends have been included in the calculation of net loss attributable to common stockholders of \$12,623,000, or \$0.27 per share, for the nine months ended September 30, 2009 and \$20,194,000, or \$0.50 per share, for the nine months ended September 30, 2008. The deemed dividends and cash dividends are excluded from our net loss (from operating activities) of \$9,413,000, or \$0.20 per share, for the nine months ended September 30, 2009 and \$14,312,000, or \$0.36 per share, for the nine months ended September 30, 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 September 30, 2009, we had \$5,567,000 in cash and equivalents.

During the nine months ended September 30, 2009, approximately \$8,331,000 in cash was used in operations, primarily due to a net loss of \$9,413,000, a net decrease of \$1,965,000 in accounts payable and accrued liabilities and an increase in prepaid expenses of \$230,000. Other changes in working capital used cash of \$78,000. The cash impact of the net loss was reduced by a \$2,830,000 non-cash loss on derivatives, non-cash stock-based compensation expense of \$503,000 and depreciation and amortization of fixed assets totaling \$22,000.

During the nine months ended September 30, 2009, we purchased \$18,000 in fixed assets. We received net proceeds of \$9,205,000 from the sale of our Series E preferred stock and received net proceeds of \$3,449,000 from the sale of common stock.

The primary endpoint of our Phase 3 clinical trial for NOV-002 in non-small cell lung cancer is increased median overall survival, to be measured following the occurrence of 725 events (deaths). We anticipate that the results from this trial will be available in early 2010. On August 25, 2009, we entered into the August 2009 Purchase Agreement with Purdue contemplating the issuance and sale at two or more closings of up to 13,636,364 shares of our common stock and warrants to purchase 4,772,728 shares of our common stock at an exercise price of \$0.66 per share, expiring December 31, 2015, for an aggregate purchase price of \$9,000,000.

At the initial closing on August 25, 2009, the Company sold Purdue 5,303,030 shares of common stock and a warrant to purchase 1,856,062 shares of common stock for gross proceeds of \$3,500,000. At the final closing under the August 2009 Purchase Agreement on November 10, 2009, the Company sold Purdue 8,333,334 shares of Novelos common stock and warrants to purchase 2,916,668 shares of Novelos common stock for gross proceeds of \$5,500,000. The August 2009 Purchase Agreement required us to adopt an expanded development and regulatory plan for NOV-002 (the "Plan") which contemplates substantial expenditures through mid-2010 in addition to clinical development expenditures previously contemplated for the completion of the Phase 3 trial. We are required to use proceeds from the sale of securities under the August 2009 Purchase Agreement for the expenditures identified in the Plan. We believe that the available funds at September 30, 2009, plus the proceeds from the final closing under the August 2009 Purchase Agreement, will allow us to operate beyond the conclusion of the Phase 3 trial and into the third quarter of 2010.

The completion of the Phase 3 clinical trial is likely to significantly affect our ability to finance continued operations beyond the third quarter of 2010. If the results are favorable, we believe we will be able to obtain adequate funding to pursue its strategic objectives and clinical development programs longer term. If the results of the Phase 3 clinical trial are not favorable, we may be unable to obtain additional funding and may be required to scale back administrative activities and clinical development programs, or cease our operations entirely. Furthermore, adverse conditions in the capital markets globally may impair our ability to obtain capital in a timely manner.

#### **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, 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 September 30, 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 third 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**

#### **We will require additional capital to continue operations beyond the third quarter of 2010.**

The report from our independent registered public accounting firm dated March 17, 2009 and included with our annual report on Form 10-K indicated that factors existed that raised substantial doubt about our ability to continue as a going concern.

The primary endpoint of our Phase 3 clinical trial for NOV-002 in non-small cell lung cancer is increased median overall survival, to be measured following the occurrence of 725 events (deaths). We anticipate that the results from this trial will be available in early 2010. On August 25, 2009, we entered into a Securities Purchase Agreement (the "August 2009 Purchase Agreement") with Purdue Pharma L.P. ("Purdue") contemplating the issuance and sale at two or more closings of up to 13,636,364 shares of our common stock and warrants to purchase approximately 4,772,728 shares of our common stock at an exercise price of \$0.66 per share, expiring December 31, 2015, for an aggregate purchase price of \$9,000,000. At the initial closing on August 25, 2009, we sold Purdue 5,303,030 shares of common stock and a warrant to purchase 1,856,062 shares of common stock for gross proceeds of \$3,500,000. At the final closing under the August 2009 Purchase Agreement on November 10, 2009, we sold Purdue 8,333,334 shares of our common stock and warrants to purchase 2,916,668 shares of our common stock for gross proceeds of \$5,500,000. The August 2009 Purchase Agreement required us to adopt an expanded development and regulatory plan for NOV-002 (the "Plan"), which contemplates substantial expenditures through mid-2010 in addition to clinical development expenditures previously contemplated for the completion of the Phase 3 trial. We are required to use proceeds from the sale of securities under the August 2009 Purchase Agreement for the expenditures identified in the Plan. We believe that the available funds at September 30, 2009, plus the proceeds from the final closing under the August 2009 Purchase Agreement, will allow us to operate beyond the conclusion of the Phase 3 trial and into the third quarter of 2010, as set forth in the Plan.

Our ability to execute our operating plan beyond the third quarter of 2010 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) to fund our development activities. We plan to pursue these alternatives, but there can be no assurance that we will obtain the additional capital necessary to fund our business beyond the third quarter of 2010. The timing and content of the Phase 3 clinical trial results will affect our projected cash requirements and our ability to obtain capital. If the results are favorable, we believe we will be able to obtain adequate funding to pursue our strategic objectives and clinical development programs longer term. If the results of our Phase 3 clinical trial are not favorable, we may be unable to obtain additional funding, and we may be required to scale back our administrative activities and clinical development programs, or cease our operations entirely. Furthermore, adverse conditions in the capital markets globally may impair our ability to obtain funding in a timely manner.

#### **Purdue has obtained certain rights that may discourage third parties from entering into discussions with us to acquire rights to NOV-002 for the United States.**

Until Purdue receives certain information related to our Phase 3 clinical trial in non-small cell lung cancer, Novelos is prohibited from negotiating with any party other than Purdue for the license or other acquisition of rights to register, develop, make, have made, use, warehouse, promote, market, sell, have sold, import, distribute and offer for sale NOV-002 (collectively "NOV-002 Rights") in the United States. Purdue has been granted a right of first refusal on bona fide offers to obtain NOV-002 Rights in the United States received from third parties and approved by our board of directors. Under Purdue's right of first refusal, Purdue will have 30 days to enter into a definitive agreement with Novelos on terms representing the same economic benefit for Novelos as in the third-party offer. The right of first refusal terminates upon specified business combinations. Novelos has entered into separate letter agreements with Mundipharma and an independent associated company providing for a conditional exclusive right to negotiate for, and a conditional right of first refusal with respect to third party offers to obtain NOV-002 Rights (i) for Mexico, Central America, South America and the Caribbean and (ii) for Canada, respectively. The existence of these rights may discourage other possible strategic partners from entering into discussions with us to obtain NOV-002 Rights in North and South America.

**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 the Xmark affiliated funds, the OrbiMed affiliated funds and Purdue). We are prohibited from paying dividends to common stockholders, amending our certificate of incorporation or by-laws, 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 the related warrants; or
- incurring any new debt for borrowed money in excess of \$500,000.

Even though 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 rights of first refusal and the exclusive negotiation rights granted to Purdue and its independent associated companies under the August 2009 Purchase Agreement and the collaboration agreement with Mundipharma (our collaborator on most non-U.S. development, manufacturing and commercialization of NOV-002) have the potential of creating situations where the interests of the Company and those of Purdue 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 \$2,412,000 as of September 30, 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 (\$668,000 at September 30, 2009) will continue to accumulate.

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

On September 30, 2009, we issued 114,410 shares of our common stock upon conversion of 5 shares of our Series C preferred stock, having an aggregate stated value of \$60,000, and accumulated undeclared dividends thereon

On September 29, 2009 we issued 755,809 shares of our common stock upon conversion of 9.29349375 shares of our Series E preferred stock, having an aggregate stated value of \$464,674, and accumulated undeclared dividends thereon.

On August 25, 2009, we sold 5,303,030 shares of our common stock and warrants to purchase 1,856,062 shares of common stock at an exercise price of \$0.66 per share, receiving gross proceeds of approximately \$3,500,000.

On August 21, 2009, we issued 2,084,308 shares of common stock to holders of common stock warrants issued in a March 2006 financing transaction in exchange for outstanding warrants to purchase 6,947,728 shares of common stock at an exercise price of \$1.82 per share. The issuance was made pursuant to an exchange agreement with each warrant holder and was exempt from registration under Section 3(a)(9) of the Securities Act.

On August 4, 2009, we issued 1,684,845 shares of our common stock upon conversion of 21 shares of our Series E preferred stock, having an aggregate stated value of \$1,050,000 and accumulated undeclared dividends thereon.

On July 2, 2009, we issued 72,916 shares of our common stock in connection with the cashless exercise of warrants to purchase an aggregate of 262,503 shares of our common stock. The warrants had an expiration date of August 2, 2010 and an exercise price of \$0.65 per share.

On July 1, 2009, we issued 696,465 shares of our common stock upon conversion of 8.75 shares of our Series E preferred stock, having an aggregate stated value of \$437,500, and accumulated undeclared dividends thereon.

***Item 3. Defaults Upon Senior Securities***

None.

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

None.

***Item 5. Other Information***

*Amendment to By-laws*

Effective August 20, 2009, our by-laws were amended in order to implement required notice periods and a protocol for calling shareholder meetings and addressing shareholder proposals. Among other things, the amendment to our by-laws established a procedure that a stockholder of Novelos must follow in order to nominate a candidate for election to our board of directors. Under our by-laws, as amended, in order to make a nomination, a stockholder must be a record holder entitled to vote on the election to which such nomination pertains, and must also provide advance notice to our corporate secretary not less than 90 days nor more than 120 days prior to the anniversary of the last annual meeting (subject to the limited exceptions set forth in the bylaws). This summary of the notice provisions of our by-laws relating to the nomination of directors is only a summary and is qualified in its entirety by reference to our amended by-laws, which are filed as Exhibit 3.8 to this quarterly report and are incorporated herein by reference.

*Final Closing on August 2009 Private Placement*

On November 10, 2009, we completed the final closing under the August 2009 Purchase Agreement with Purdue and sold Purdue 8,333,334 shares of our common stock and warrants to purchase 2,916,668 shares of our common stock at an exercise price of \$0.66 per share, expiring December 31, 2015, for gross proceeds of \$5,500,000. This sale was exempt from registration under the Securities Act of 1933 by virtue of Section 4(2) thereof. The terms of the August 2009 Purchase Agreement are described in Note 5 to the financial statements.

**Item 6. Exhibits**

| Exhibit No. | Description                                                                                                                                                                                  | Filed with this Form 10-Q | Incorporated by Reference |                    | Exhibit No. |
|-------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|---------------------------|--------------------|-------------|
|             |                                                                                                                                                                                              |                           | Form                      | Filing Date        |             |
| 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                                                                                         | X                         |                           |                    |             |
| 3.8         | Amended and Restated By-Laws                                                                                                                                                                 |                           | 8-K                       | August 26, 2009    | 3.1         |
| 10.1        | Form of Warrant Exchange Agreement dated August 21, 2009                                                                                                                                     |                           | 8-K                       | August 26, 2009    | 10.5        |
| 10.2        | Securities Purchase Agreement dated August 25, 2009                                                                                                                                          |                           | S-1                       | September 15, 2009 | 10.41       |
| 10.3        | Registration Rights Agreement dated August 25, 2009                                                                                                                                          |                           | S-1                       | September 15, 2009 | 10.42       |
| 10.4        | Common Stock Purchase Warrant dated August 25, 2009                                                                                                                                          |                           | S-1                       | September 15, 2009 | 10.43       |
| 10.5        | Letter Agreement with LP Clover Limited dated August 25, 2009                                                                                                                                |                           | S-1                       | September 15, 2009 | 10.44       |
| 10.6        | Letter Agreement with Mundipharma International Corporation Limited dated August 25, 2009                                                                                                    |                           | S-1                       | September 15, 2009 | 10.45       |
| 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 16, 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 |                    | Exhibit No. |
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| 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                                                                                         | X                         |                           |                    |             |
| 3.8         | Amended and Restated By-Laws                                                                                                                                                                 |                           | 8-K                       | August 26, 2009    | 3.1         |
| 10.1        | Form of Warrant Exchange Agreement dated August 21, 2009                                                                                                                                     |                           | 8-K                       | August 26, 2009    | 10.5        |
| 10.2        | Securities Purchase Agreement dated August 25, 2009                                                                                                                                          |                           | S-1                       | September 15, 2009 | 10.41       |
| 10.3        | Registration Rights Agreement dated August 25, 2009                                                                                                                                          |                           | S-1                       | September 15, 2009 | 10.42       |
| 10.4        | Common Stock Purchase Warrant dated August 25, 2009                                                                                                                                          |                           | S-1                       | September 15, 2009 | 10.43       |
| 10.5        | Letter Agreement with LP Clover Limited dated August 25, 2009                                                                                                                                |                           | S-1                       | September 15, 2009 | 10.44       |
| 10.6        | Letter Agreement with Mundipharma International Corporation Limited dated August 25, 2009                                                                                                    |                           | S-1                       | September 15, 2009 | 10.45       |
| 31.1        | Certification of the chief executive officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002                                                                                       | X                         |                           |                    |             |

| <b>Exhibit<br/>No.</b> | <b>Description</b>                                                                                                     | <b>Filed<br/>with<br/>this<br/>Form<br/>10-Q</b> | <b>Incorporated by Reference</b> |                    | <b>Exhibit<br/>No.</b> |
|------------------------|------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------|----------------------------------|--------------------|------------------------|
|                        |                                                                                                                        |                                                  | <b>Form</b>                      | <b>Filing Date</b> |                        |
| 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                                                |                                  |                    |                        |

**CERTIFICATE OF AMENDMENT  
TO  
THE AMENDED AND RESTATED CERTIFICATE OF INCORPORATION  
OF  
NOVELOS THERAPEUTICS, INC.**

**NOVELOS THERAPEUTICS, INC.** (the “Corporation”), a corporation organized and existing under of the General Corporation Law of the State of Delaware, does hereby certify:

**FIRST:** That the board of directors of the Corporation (the “Board of Directors”), at a duly convened meeting of the Board of Directors, duly adopted a resolution declaring advisable the amendment of the Amended and Restated Certificate of Incorporation of the Corporation, and submitted the same to the stockholders of the Corporation for approval. The resolution setting forth the proposed amendments is as follows:

**RESOLVED,** that the first paragraph of Article FOURTH, be amended and restated in its entirety as follows:

**“Fourth.** The aggregate number of shares of stock that the Corporation shall have authority to issue is two hundred twenty-five million and seven thousand (225,007,000), of which two hundred twenty-five million (225,000,000) shares shall be designated “Common Stock” and seven thousand (7,000) shares shall be designated “Preferred Stock.” Shares of Common Stock and Preferred Stock shall have a par value of \$.00001 per share.”

The remainder of Article FOURTH shall remain unchanged.

**SECOND:** That the stockholders of the Corporation have duly approved the aforesaid amendment in accordance with the provisions of Sections 211 and 242 of the General Corporation Law of the State of Delaware.

*[Remainder of page intentionally left blank]*

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IN WITNESS WHEREOF, the Company has caused this Certificate of Amendment to the Amended and Restated Certificate of Incorporation to be signed by Harry S. Palmin, its Chief Executive Officer and President, thereto duly authorized, this 3<sup>rd</sup> day of November, 2009.

NOVELOS THERAPEUTICS, INC.

By: /s/ Harry S. Palmin

Harry S. Palmin

Chief Executive Officer and President

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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 16, 2009

/s/ Harry S. Palmin

Harry S. Palmin

President and Chief Executive Officer (Principal Executive Officer)

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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 16, 2009

/s/ Joanne M. Protano

Joanne M. Protano

Chief Financial Officer (Principal Financial and Accounting Officer)

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**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, 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: November 16, 2009

/s/ Joanne M. Protano

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

Date: November 16, 2009

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