

**Prospectus Supplement No. 2**  
**(To Prospectus dated September 6, 2007)**

**NOVELOS THERAPEUTICS, INC.**

**12,000,000 shares of common stock**

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This prospectus supplement supplements the Prospectus dated September 6, 2007, relating to the resale of 12,000,000 shares of our common stock. This prospectus supplement should be read in conjunction with the Prospectus.

**Quarterly Report on Form 10-QSB**

On November 13, 2007, we filed with the Securities and Exchange Commission our Quarterly Report on Form 10-QSB for the quarter ended September 30, 2007. The text of the Form 10-QSB is attached hereto.

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**Investing in our common stock involves a high degree of risk.**  
**See Risk Factors beginning on page 6 of the Prospectus.**

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

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The date of this prospectus supplement is November 14, 2007

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

FORM 10-QSB

[mark one]

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

For the quarterly period ended: September 30, 2007

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number 333-119366

**NOVELOS THERAPEUTICS, INC.**

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

**DELAWARE**

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

**04-3321804**

*(IRS Employer  
Identification No.)*

**One Gateway Center, Suite 504, Newton, Massachusetts 02458**

*(Address of principal executive offices)*

**(617) 244-1616**

*(Issuer's telephone number, including area code)*

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

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

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

Number of shares outstanding of the issuer's common stock as of the latest practicable date: 39,260,272 shares of common stock, \$.00001 par value per share, as of November 1, 2007.

Transitional Small Business Disclosure Format (check one): Yes ☐ No ☒

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NOVELOS THERAPEUTICS, INC.

10-QSB INDEX

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# PART I. FINANCIAL INFORMATION

## Item 1. Financial Statements

### NOVELOS THERAPEUTICS, INC. BALANCE SHEETS

|                                                                                                                                                                                                                                                                                                                                                                             | September 30,<br>2007<br>(unaudited) | December 31,<br>2006<br>(audited) |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|-----------------------------------|
| <b>ASSETS</b>                                                                                                                                                                                                                                                                                                                                                               |                                      |                                   |
| CURRENT ASSETS:                                                                                                                                                                                                                                                                                                                                                             |                                      |                                   |
| Cash and equivalents                                                                                                                                                                                                                                                                                                                                                        | \$ 15,271,151                        | \$ 9,938,428                      |
| Restricted cash                                                                                                                                                                                                                                                                                                                                                             | 148,000                              | 1,655,251                         |
| Prepaid expenses and other current assets                                                                                                                                                                                                                                                                                                                                   | 205,511                              | 294,995                           |
| Total current assets                                                                                                                                                                                                                                                                                                                                                        | 15,624,662                           | 11,888,674                        |
| FIXED ASSETS, NET                                                                                                                                                                                                                                                                                                                                                           | 36,469                               | 23,810                            |
| DEPOSITS                                                                                                                                                                                                                                                                                                                                                                    | 15,350                               | 10,875                            |
| <b>TOTAL ASSETS</b>                                                                                                                                                                                                                                                                                                                                                         | <b>\$ 15,676,481</b>                 | <b>\$ 11,923,359</b>              |
| <b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>                                                                                                                                                                                                                                                                                                                                 |                                      |                                   |
| CURRENT LIABILITIES:                                                                                                                                                                                                                                                                                                                                                        |                                      |                                   |
| Accounts payable and accrued liabilities                                                                                                                                                                                                                                                                                                                                    | \$ 4,546,087                         | \$ 1,088,041                      |
| Accrued compensation                                                                                                                                                                                                                                                                                                                                                        | 206,654                              | 225,384                           |
| Total current liabilities                                                                                                                                                                                                                                                                                                                                                   | 4,752,741                            | 1,313,425                         |
| COMMITMENTS AND CONTINGENCIES                                                                                                                                                                                                                                                                                                                                               |                                      |                                   |
| REDEEMABLE PREFERRED STOCK:                                                                                                                                                                                                                                                                                                                                                 |                                      |                                   |
| Series B convertible preferred stock, \$0.00001 par value; 400 shares designated; 300 shares issued and outstanding at September 30, 2007 (liquidation preference \$15,000,000) (Note 3)                                                                                                                                                                                    | 9,918,666                            | —                                 |
| STOCKHOLDERS' EQUITY:                                                                                                                                                                                                                                                                                                                                                       |                                      |                                   |
| Preferred Stock, \$0.00001 par value; 6,272 shares authorized: Series A 8% cumulative convertible preferred stock; 3,264 shares issued and outstanding at December 31, 2006 (liquidation preference \$3,264,000); Series C 8% cumulative convertible preferred stock; 272 shares issued and outstanding at September 30, 2007 (liquidation preference \$3,264,000) (Note 3) | —                                    | —                                 |
| Common stock, \$0.00001 par value; 150,000,000 shares authorized; 39,260,272 shares issued and outstanding at September 30, 2007; 39,235,272 shares issued and outstanding at December 31, 2006                                                                                                                                                                             | 393                                  | 392                               |
| Additional paid-in capital                                                                                                                                                                                                                                                                                                                                                  | 37,707,424                           | 34,294,154                        |
| Accumulated deficit                                                                                                                                                                                                                                                                                                                                                         | (36,702,743)                         | (23,684,612)                      |
| Total stockholders' equity                                                                                                                                                                                                                                                                                                                                                  | 1,005,074                            | 10,609,934                        |
| <b>TOTAL LIABILITIES, REDEEMABLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY</b>                                                                                                                                                                                                                                                                                               | <b>\$ 15,676,481</b>                 | <b>\$ 11,923,359</b>              |

See notes to financial statements.

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

|                                                                                                                 | Three Months Ended September 30, |                       | Nine Months Ended September 30, |                       |
|-----------------------------------------------------------------------------------------------------------------|----------------------------------|-----------------------|---------------------------------|-----------------------|
|                                                                                                                 | 2007                             | 2006                  | 2007                            | 2006                  |
| <b>COSTS AND EXPENSES:</b>                                                                                      |                                  |                       |                                 |                       |
| Research and development                                                                                        | \$ 5,910,849                     | \$ 2,408,658          | \$ 11,620,579                   | \$ 4,200,465          |
| General and administrative                                                                                      | 734,212                          | 586,452               | 1,978,184                       | 1,889,182             |
| Total costs and expenses                                                                                        | 6,645,061                        | 2,995,200             | 13,598,763                      | 6,089,647             |
| <b>OTHER INCOME:</b>                                                                                            |                                  |                       |                                 |                       |
| Interest income                                                                                                 | 228,368                          | 192,017               | 575,753                         | 472,023               |
| Miscellaneous                                                                                                   | 1,880                            | 1,500                 | 4,880                           | 4,500                 |
| Total other income                                                                                              | 230,248                          | 193,517               | 580,633                         | 476,523               |
| <b>NET LOSS</b>                                                                                                 | <b>(6,414,813)</b>               | <b>(2,801,683)</b>    | <b>(13,018,130)</b>             | <b>(5,613,124)</b>    |
| PREFERRED STOCK DIVIDENDS                                                                                       | (402,780)                        | (65,280)              | (758,340)                       | (195,840)             |
| PREFERRED STOCK DEEMED DIVIDENDS                                                                                | —                                | —                     | (9,003,083)                     | —                     |
| <b>NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS</b>                                                             | <b>\$ (6,817,593)</b>            | <b>\$ (2,866,963)</b> | <b>\$ (22,779,553)</b>          | <b>\$ (5,808,964)</b> |
| <b>BASIC AND DILUTED NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS PER COMMON SHARE</b>                          | <b>\$ (0.17)</b>                 | <b>\$ (0.07)</b>      | <b>\$ (0.58)</b>                | <b>\$ (0.16)</b>      |
| <b>SHARES USED IN COMPUTING BASIC AND DILUTED NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS PER COMMON SHARE</b> | <b>39,258,913</b>                | <b>39,226,250</b>     | <b>39,243,239</b>               | <b>36,487,218</b>     |

*See notes to financial statements.*

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

|                                                                             | <b>Nine Months Ended September 30,</b> |                      |
|-----------------------------------------------------------------------------|----------------------------------------|----------------------|
|                                                                             | <b>2007</b>                            | <b>2006</b>          |
| <b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>                                |                                        |                      |
| Net loss                                                                    | \$ (13,018,130)                        | \$ (5,613,124)       |
| Adjustments to reconcile net loss to cash used in operating activities:     |                                        |                      |
| Depreciation and amortization                                               | 10,015                                 | 7,192                |
| Stock-based compensation                                                    | 436,975                                | 462,492              |
| Increase (decrease) in:                                                     |                                        |                      |
| Prepaid expenses and other current assets                                   | 89,484                                 | 46,615               |
| Accounts payable and accrued liabilities                                    | 3,458,046                              | 743,751              |
| Accrued compensation                                                        | (18,730)                               | 146,860              |
| Cash used in operating activities                                           | <u>(9,042,340)</u>                     | <u>(4,206,214)</u>   |
| <b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>                                |                                        |                      |
| Purchases of property and equipment                                         | (22,674)                               | (10,716)             |
| Change in restricted cash                                                   | 1,507,251                              | (2,013,860)          |
| Deferred financing costs                                                    | —                                      | 24,612               |
| Deposits                                                                    | (4,475)                                | (1,219)              |
| Cash provided by (used in) investing activities                             | <u>1,480,102</u>                       | <u>(2,001,183)</u>   |
| <b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>                                |                                        |                      |
| Proceeds from issuance of Series B convertible preferred stock, net         | 13,693,051                             | —                    |
| Proceeds from issuance of common stock, net                                 | —                                      | 13,846,774           |
| Dividends paid to preferred stockholders                                    | (758,340)                              | (195,840)            |
| Payment to preferred stockholders in connection with exchange of shares (1) | (40,000)                               | —                    |
| Proceeds from exercise of stock option                                      | 250                                    | 750                  |
| Cash provided by financing activities                                       | <u>12,894,961</u>                      | <u>13,651,684</u>    |
| <b>INCREASE IN CASH AND EQUIVALENTS</b>                                     | <u>5,332,723</u>                       | <u>7,444,287</u>     |
| <b>CASH AND EQUIVALENTS AT BEGINNING OF YEAR</b>                            | <u>9,938,428</u>                       | <u>4,267,115</u>     |
| <b>CASH AND EQUIVALENTS AT END OF PERIOD</b>                                | <u>\$ 15,271,151</u>                   | <u>\$ 11,711,402</u> |
| <b>SUPPLEMENTAL DISCLOSURE OF NON-CASH ACTIVITIES</b>                       |                                        |                      |
| Deemed dividends on preferred stock                                         | \$ 8,963,083                           | \$ —                 |
| Issuance of warrants to Series B preferred stockholders                     | \$ 3,774,385                           | \$ —                 |
| Issuance of warrants to placement agents                                    | \$ 768,621                             | \$ —                 |
| Common stock issued for services                                            | \$ —                                   | \$ 144,850           |

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

*See notes to financial statements.*

**Novelos Therapeutics, Inc.**  
**Notes to Financial Statements**

**1. BASIS OF PRESENTATION**

The accompanying unaudited financial statements of Novelos Therapeutics, Inc. ("Novelos" or 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-QSB and Item 310 of Regulation S-B. 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, 2007. 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, 2006 on Form 10-KSB, which was filed with the Securities and Exchange Commission ("SEC") on March 21, 2007.

*Cash* – Restricted cash consists of cash pledged as security on a letter of credit agreement with a bank. See Note 8.

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

*Reclassifications* – Certain amounts in prior periods have been reclassified to conform to the current period presentation.

**2. REVERSE MERGER AND REORGANIZATION**

During May and June 2005, the Company completed a two-step reverse merger with Common Horizons, Inc. ("Common Horizons"), a Nevada-based developer of web portals, and its wholly-owned subsidiary Nove Acquisition, Inc. Following the reverse merger Novelos became the surviving corporation. Following these transactions, Novelos shareholders owned approximately 83% of the combined company on a fully diluted basis after giving effect to the transactions. The business of Common Horizons, which was insignificant, was abandoned and the business of Novelos was adopted. The transaction was therefore treated as a reverse acquisition recapitalization with Novelos as the acquiring party and Common Horizons as the acquired party for accounting purposes.

**3. STOCKHOLDERS' EQUITY**

*2005 PIPE* - From May 27, 2005 through August 9, 2005, the Company completed a private offering of securities structured as a "PIPE" (Private Investment in Public Equity), exempt from registration under the Securities Act of 1933, in which it sold to accredited investors 4,000,000 shares of common stock and issued 2,000,000 common stock warrants (initially exercisable at \$2.25 per share) for net cash proceeds of approximately \$3,715,000 (net of cash issuance costs of approximately \$735,000) and conversion of debt and accrued interest of \$550,000. In connection with the private placement, the Company also issued 125,000 shares of common stock to placement agents with a value of approximately \$156,000 and issued 340,000 common stock warrants to placement agents and finders at an initial exercise price of \$2.00 per share. Pursuant to anti-dilution provisions, the number of warrants issued to investors, placement agents and finders was subsequently increased to 3,139,312 and the exercise price of the warrants was reduced to \$1.65 per share as a result of the Series A Preferred financing described below. The 2006 PIPE transaction in March 2006 described below resulted in a further adjustment to the warrants, increasing the number of warrants to 3,836,967 and reducing the exercise price of the warrants to \$1.35 per share. The sale of Series B Preferred Stock described below resulted in a further adjustment to the warrants, increasing the number of warrants to 5,180,000 and reducing the exercise price of the warrants to \$1.00 per share.

*Series A Preferred* - On September 30, 2005 and October 3, 2005, the Company sold, in a private placement, a total of 3,200 shares of its Series A 8% Cumulative Convertible Preferred Stock ("Series A Preferred Stock") and 969,696 common stock warrants for net proceeds of \$2,864,000, net of issuance costs of \$336,000. The preferred shares were originally convertible at a price of \$1.65 per common share into 1,939,393 shares of common stock and the warrants were exercisable at \$2.00 per share. The Series A Preferred Stock and warrants had anti-dilution provisions that provided for adjustments to the conversion or exercise price, as applicable, upon the occurrence of certain events. Pursuant to these anti-dilution provisions, both the conversion price of the preferred stock and the exercise price of the warrants were subsequently adjusted to \$1.35 per share on March 7, 2006 in connection with a subsequent offering of common stock described below (2006 PIPE) and the preferred stock then outstanding became convertible into 2,417,774 shares of common stock. See "Series C Preferred" below for a description of the exchange of Series A Preferred Stock.

**2006 PIPE** - On March 7, 2006, the Company completed a private offering of securities structured as a PIPE, exempt from registration under the Securities Act of 1933, in which it sold to accredited investors 11,154,073 shares of common stock at \$1.35 per share and warrants to purchase 8,365,542 shares of its common stock exercisable at \$2.50 per share for net cash proceeds of approximately \$13,847,000 (net of issuance costs of approximately \$1,211,000, including placement agent fees of approximately \$1,054,000). In connection with the private placement, the Company issued 669,244 common stock warrants (exercisable at \$2.50 per share) to the placement agents. Pursuant to anti-dilution provisions, the number of warrants issued to investors and placement agents and finders was subsequently increased to 10,270,018 and the exercise price of the warrants was reduced to \$2.20 per share as a result of the sale of Series B preferred stock described below.

**Registration Rights, 2005 and 2006 Financings** – The shares of common stock sold in the 2005 PIPE and the 2006 PIPE and the shares of common stock issuable upon conversion of the Series C Preferred Stock and exercise of certain outstanding warrants have been registered for resale with the Securities and Exchange Commission. Pursuant to the registration rights associated with the financings, if the Company fails to maintain the effectiveness of the registration statements for the periods specified in the agreements, the Company may become obligated to pay liquidated damages to the selling stockholders. The Company believes that an investor claim for liquidated damages relating to these registration rights is not probable and therefore has not accrued for such a contingency at September 30, 2007.

**Series B Preferred** - On May 2, 2007, pursuant to a securities purchase agreement with accredited investors dated April 12, 2007 (the “Purchase Agreement”), as amended May 2, 2007, the Company sold 300 shares of a newly created series of preferred stock, designated “Series B Convertible Preferred Stock”, with a stated value of \$50,000 per share (the “Series B Preferred Stock”) and issued warrants to purchase 7,500,000 shares of common stock for an aggregate purchase price of \$15,000,000.

#### *Rights and Preferences*

The shares of Series B Preferred Stock issued to investors are convertible into shares of common stock at \$1.00 per share at any time after issuance at the option of the holder. If there is an effective registration statement covering the shares of common stock underlying the Series B Preferred Stock and the volume-weighted average price (“VWAP”), as defined in the Series B Certificate of Designations, of the Company’s common stock exceeds \$2.00 for 20 consecutive trading days, then the outstanding Series B Preferred Stock will automatically convert into common stock at the conversion price then in effect. The conversion price is subject to adjustment only for stock dividends, stock splits or similar capital reorganizations. The Series B Preferred Stock has an annual dividend rate of 9%, payable semi-annually on September 30 and March 31. Such dividends may be paid in cash or in registered shares of the Company’s common stock at the Company’s option. The Series B Preferred Stock ranks senior to all other outstanding series of preferred stock and common stock as to the payment of dividends and the distribution of assets upon voluntary or involuntary liquidation, dissolution or winding up of the Company’s affairs. The Series B preferred stockholders will be entitled to receive first, \$50,000 per share and all accrued and unpaid dividends. They are then entitled to participate with the holders of the remaining classes of common stock in the distribution of remaining assets on a pro rata basis. If, upon any winding up of the Company’s affairs, assets available to pay the holders of Series B Preferred Stock are not sufficient to permit the payment in full, then all assets will be distributed to the holders of Series B Preferred Stock on a pro rata basis. If the Company sells, leases or otherwise transfers substantially all of its assets, consummates a business combination in which the Company is not the surviving corporation or, if the Company is the surviving corporation, if the holders of a majority of the common stock immediately before the transaction do not hold a majority of common stock immediately after the transaction, in one or a series of events, change the majority of the members of the board of directors, or if any person or entity (other than the holders of Series B Preferred Stock) acquires more than 50% of the Company’s outstanding stock, then the holders of Series B Preferred Stock are entitled to receive the same liquidation preference as described above, except that after receiving \$50,000 per preferred share and any accrued but unpaid dividends, they are not entitled to participate with other classes or common stock in a distribution of the remaining assets.

For as long as any shares of Series B Preferred Stock remain outstanding, the Company is prohibited from (i) paying dividends to common stockholders, (ii) amending the Company’s certificate of incorporation, (iii) issuing any equity security or any security convertible into or exercisable for any equity security at a price of \$1.00 or less or with rights senior to the Series B Preferred Stock (except for certain exempted issuances), (iv) increasing the number of shares of Series B Preferred Stock or issuing any additional shares of Series B Preferred Stock other than the 400 shares designated in the Series B Certificate of Designations, (v) selling or otherwise disposing of all or substantially all of the Company’s assets or intellectual property or entering into a merger or consolidation with another company unless Novelos is the surviving corporation, the Series B Preferred Stock remains outstanding and there are no changes to the rights and preferences of the Series B Preferred Stock, (vi) redeeming or repurchasing any capital stock other than Series B Preferred Stock, (vii) incurring any new debt for borrowed money and (viii) changing the number of the Company’s directors. The Company is required to reserve, out of authorized shares of common stock, 125% of the number of shares of common stock into which Series B Preferred Stock is convertible.



### *Board and Observer Rights*

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

Pursuant to the Purchase Agreement, from and after the closing of the sale of the Series B Preferred Stock, Xmark Opportunity Fund, Ltd. and its affiliates (the "Xmark Entities"), will have the right to designate one member to the Company's Board of Directors. This right shall last until such time as the Xmark Entities no longer hold at least one-third of the Series B Preferred Stock issued to them at closing. In addition, the Xmark Entities and Caduceus Capital Master Fund Limited and its affiliates (together with the Xmark Entities, the "Lead Investors") will have the right to designate one observer to attend all meetings of the Company's Board of Directors, committees thereof and access to all information made available to members of the Board. This right shall last until such time as the Lead Investors no longer hold at least one-third of the Series B Preferred Stock issued to them. To date, a board member and board observer have not been designated. Pursuant to the agreement by holders of Series A Preferred to exchange their shares for shares of Series C Preferred Stock, as described above, the holders of the new Series C preferred stock gave up the right to nominate one person to the Company's Board of Directors, which right they previously held as holders of Series A preferred stock.

### *Common Stock Purchase Warrants*

The common stock purchase warrants issued to investors are exercisable for an aggregate of 7,500,000 shares of the Company's common stock at an exercise price of \$1.25 per share and expire in May 2012. If after the first anniversary of the date of issuance of the warrant there is no effective registration statement registering, or no current prospectus available for, the resale of the shares issuable upon the exercise of the warrants, the holder may conduct a cashless exercise whereby the holder may elect to pay the exercise price by having the Company withhold, upon exercise, shares having a fair market value equal to the applicable aggregate exercise price. The warrant exercise price and/or number of warrants is subject to adjustment only for stock dividends, stock splits or similar capital reorganizations so that the rights of the warrant holders after such event will be equivalent to the rights of warrant holders prior to such event. If there is an effective registration statement covering the shares underlying the warrants and the VWAP, as defined in the warrant, of the Company's common stock exceeds \$2.25 for 20 consecutive trading days, then on the 31<sup>st</sup> day following the end of such period any remaining warrants for which a notice of exercise was not delivered shall no longer be exercisable and shall be converted into a right to receive \$.01 per share.

### *Registration Rights Agreement*

The Company and the investors entered into a registration rights agreement which required the Company to file with the SEC no later June 1, 2007, a registration statement covering the resale of a number of shares of common stock equal to 100% of the shares issuable upon conversion of the preferred stock and exercise of the warrants as of the date of filing of the registration statement. The registration rights agreement also required the registration statement to be declared effective by August 30, 2007 and requires the Company to use its best efforts to keep the registration statement continuously effective under the Securities Act until the earlier of the date when all securities covered by the registration statement have been sold or the second anniversary of the closing. In the event the registration statement was not declared effective within the timeframe specified by the Registration Rights Agreement or not maintained effective, the Company is required to pay to the investors liquidated damages equal to 1.5% per month (prorated on a daily basis for any period of less than a full month) of the aggregate purchase price of the preferred stock and warrants until the registration statement is declared effective. The Company is allowed to suspend the use of the registration statement for not more than 15 consecutive days or for a total of not more than 30 days in any 12-month period without incurring liability for the liquidated damages in certain circumstances.

The Company filed a registration statement covering 100% of the shares of common stock issuable on conversion of the preferred stock and exercise of the warrants (23,400,000 shares, including 900,000 shares underlying the common stock purchase warrants issued to placement agents) on May 25, 2007. The registration statement was thereafter amended to reduce the number of shares of common stock that may be resold under the registration statement to 80% of the shares issuable upon conversion of the preferred stock and none of the shares of common stock issuable upon exercise of the warrants. The holders of the Series B Preferred Stock consented to the filing of the amendment to the registration statement by which the number of shares of common stock covered by the registration statement was reduced from 23,400,000 shares to 12,000,000 shares. The holders of the Series B Preferred Stock also waived any liquidated damages arising under the registration rights agreement through September 7, 2007, as a result of such reduction in the number of shares registered, and by any failure to have the registration statement declared effective by the SEC prior to September 7, 2007. The registration statement, as amended, was declared effective on September 6, 2007.

After September 7, 2007 the Company may be required to pay to the investors any liquidated damages due as a result of the failure to (i) register 100% of the shares of common stock issuable upon conversion of the preferred stock and exercise of the warrants and (ii) keep the registration statement continuously effective. In the quarter ended September 30, 2007, the Company accrued \$80,500 for potential liquidated damages, representing an estimate of the pro rata portion due to investors as a result of registering 53%, instead of 100%, of the total shares underlying the preferred stock and warrants held by the investors. As of the date of this filing, no claim has been made for payment of any liquidated damages.

#### *Placement Agent Agreement*

Upon the closing of the preferred stock and warrant financing the Company paid a cash placement agent fee to Rodman & Renshaw LLC ("Rodman") and Rodman's subagent totaling \$1,050,000 and issued Rodman and the subagent warrants to purchase a total of 900,000 shares of common stock with the same terms as the warrants issued to the investors.

The Company has agreed to indemnify Rodman from claims arising in relation to the services it provided to the Company in connection with this agreement.

#### *Accounting Treatment*

Since the terms of the Series B Preferred Stock contain provisions that may require redemption in circumstances that are beyond the Company's control, the shares have been recorded outside of permanent equity in the balance sheet as of September 30, 2007. Furthermore, since the conversion price of the preferred stock was less than the market value of the Company's common stock at the time of the closing, the Company determined that there was a beneficial conversion feature ("BCF"). After allocating the relative fair value of the warrants issued to investors of \$3,774,385 to paid-in-capital, the intrinsic value of the BCF was determined to be \$7,824,385. Since the Series B Preferred Stock was immediately convertible, the BCF was recorded as a deemed dividend in the quarter ended June 30, 2007. The fair value of the warrants issued to placement agents at the date of issuance, calculated using the Black-Scholes valuation method, was \$1,138,698 and was recorded as a component of permanent equity with a subsequent reduction in permanent equity to record the issuance cost. The valuation was based on estimated volatility of 80%, a discount rate of 4.55%, and a term of 5 years.

**Series C Preferred** - As a condition to closing of the sale of Series B Preferred Stock described above, the Company entered into an agreement to exchange and consent with the holders of the Series A Preferred Stock. Pursuant to that agreement, the holders of the Series A Preferred Stock exchanged their 3,264 shares of Series A Preferred Stock for 272 shares of a new Series C convertible preferred stock ("Series C Preferred Stock"), which are subordinated to the Series B Preferred Stock as set forth in the Series C Certificate of Designations. The Series C Preferred Stock is convertible at \$1.00 per share into 3,264,000 shares of common stock. As part of the exchange, the Company issued to the holders of the Series A Preferred Stock warrants to purchase 1,333,333 shares of common stock expiring on May 2, 2012 at a price of \$1.25 per share; paid them a cash allowance to defray expenses totaling \$40,000; and paid them an amount equal to unpaid dividends accumulated through the date of the exchange. The fair value of the warrants at the date of issuance calculated using the Black-Scholes valuation method was \$1,138,698. The valuation was based on estimated volatility of 80%, a discount rate of 4.55%, and a term of 5 years. The total of the fair value of the warrants and the cash payment of \$40,000 has been reflected as a deemed dividend to preferred stockholders in the statement of operations. Pursuant to the exchange agreement, the holders of the Series C Preferred Stock retained registration and related rights substantially identical to the rights that they had as holders of the Series A Preferred Stock. Pursuant to the anti-dilution provisions contained in the warrants issued to the holders of the Series A Preferred Stock during 2005, the exercise price of the warrants was reduced to \$1.00 in connection with the sale of the Series B Preferred Stock.

The Series C Preferred Stock has an annual dividend rate of 8% until October 1, 2008 and thereafter has an annual dividend rate of 20%. The dividend rate also increases to 20% upon certain events of default as defined in the Series C Certificate of Designations. The dividends are payable quarterly commencing on June 30, 2007. Such dividends shall be paid only after all outstanding dividends on the Series B Preferred Stock (with respect to the current fiscal year and all prior fiscal years) shall have been paid to the holders of the Series B Preferred Stock. The conversion price is subject to adjustment for stock dividends, stock splits or similar capital reorganizations.

**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, 2007:

| <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:                             |                                      |                                             |                        |
| Investors                              | 4,500,000                            | \$ 1.00                                     | August 9, 2008         |
| Placement agents and finders           | 680,000                              | \$ 1.00                                     | August 9, 2010         |
| Series A Preferred (1):                |                                      |                                             |                        |
| Investors - September 30, 2005 closing | 909,090                              | \$ 1.00                                     | September 30, 2010     |
| Investors - October 3, 2005 closing    | 60,606                               | \$ 1.00                                     | October 3, 2010        |
| 2006 PIPE:                             |                                      |                                             |                        |
| Investors                              | 9,509,275                            | \$ 2.20                                     | March 7, 2011          |
| Placement agents                       | 760,743                              | \$ 2.20                                     | March 7, 2011          |
| Series B Preferred:                    |                                      |                                             |                        |
| Investors                              | 7,500,000                            | \$ 1.25                                     | May 2, 2012            |
| Placement agents                       | 900,000                              | \$ 1.25                                     | May 2, 2012            |
| Series C Exchange                      | 1,333,333                            | \$ 1.25                                     | May 2, 2012            |
| Total                                  | 26,873,047                           |                                             |                        |

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

On April 1, 2005, in connection with the issuance of \$450,000 bridge notes payable, the Company issued warrants to purchase 720,000 shares of Novelos stock at \$0.625 per share that are exercisable through April 1, 2010.

No warrants have been exercised as of September 30, 2007.

**Reserved Shares** — At September 30, 2007 the following shares were reserved for future issuance upon exercise of stock options or warrants or conversion of preferred stock:

|                                            |            |
|--------------------------------------------|------------|
| 2000 Stock Option Plan                     | 73,873     |
| 2006 Stock Incentive Plan                  | 1,290,000  |
| Options issued outside of formalized plans | 2,553,778  |
| Warrants (1)                               | 28,973,047 |
| Preferred stock (1)                        | 22,014,000 |
| Total shares reserved for future issuance  | 54,904,698 |

(1) The amount of reserved shares includes shares reserved in excess of the number currently exercisable or convertible in accordance with the related financing agreements.

**Authorized Shares**— On July 16, 2007, the Company's shareholders approved and the Company filed an amendment to the articles of incorporation to increase the authorized shares of common stock from 100,000,000 to 150,000,000.

#### 4. STOCK-BASED COMPENSATION

The Company accounts for stock-based compensation in accordance with the provisions of Statement of Financial Accounting Standards (SFAS) 123R *Share-Based Payment* (SFAS 123R), using the modified-prospective-transition method. SFAS 123R requires all share-based payments to employees, including grants of employee stock options, to be recognized in the financial statements based on their fair values. SFAS 123R did not change the accounting guidance for share-based payments granted to non-employees provided in SFAS No. 123, *Accounting for Stock-Based Compensation* (SFAS 123), as originally issued and Emerging Issues Task Force (EITF) No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*. EITF 96-18 requires that companies recognize compensation expense based on the estimated fair value of options granted to non-employees over their vesting period, which is generally the period during which services are rendered by such non-employees. Under the modified-prospective-transition method, compensation cost recognized for all periods presented includes: (a) compensation cost for all stock-based payments granted, but not yet vested as of January 1, 2006, based on the grant-date fair value estimated in accordance with the original provisions of SFAS 123, and (b) compensation cost for all stock-based payments granted subsequent to January 1, 2006, based on the grant-date fair value estimated in accordance with the provisions of SFAS 123R.

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

|                                                                           | Three months ended<br>September 30, |            | Nine months ended<br>September 30, |            |
|---------------------------------------------------------------------------|-------------------------------------|------------|------------------------------------|------------|
|                                                                           | 2007                                | 2006       | 2007                               | 2006       |
| Employee and director stock option grants:                                |                                     |            |                                    |            |
| Research and development                                                  | \$ 17,928                           | \$ 47,820  | \$ 144,307                         | \$ 139,050 |
| General and administrative                                                | 53,054                              | 22,702     | 136,515                            | 52,924     |
|                                                                           | 70,982                              | 70,522     | 280,822                            | 191,974    |
| Non-employee consultants stock option grants and restricted stock awards: |                                     |            |                                    |            |
| Research and development                                                  | (3,134)                             | 3,969      | 18,787                             | 3,969      |
| General and administrative                                                | 45,743                              | 47,723     | 137,366                            | 266,549    |
|                                                                           | 42,609                              | 51,692     | 156,153                            | 270,518    |
| Total stock-based compensation                                            | \$ 113,591                          | \$ 122,214 | \$ 436,975                         | \$ 462,492 |

#### Determining Fair Value

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

|                                        | Three Months Ended<br>September 30, |             | Nine Months Ended<br>September 30, |             |
|----------------------------------------|-------------------------------------|-------------|------------------------------------|-------------|
|                                        | 2007                                | 2006        | 2007                               | 2006        |
| Volatility                             | 80%                                 | 80%         | 80%                                | 80%         |
| Weighted-average volatility            | 80%                                 | 80%         | 80%                                | 80%         |
| Risk-free interest rate                | 4.18%-4.51%                         | 4.59%-5.05% | 4.18%-4.66%                        | 4.59%-5.05% |
| Expected life (years)                  | 5                                   | 5           | 5                                  | 5           |
| Dividend                               | 0                                   | 0           | 0                                  | 0           |
| Weighted-average exercise price        | \$ 0.64                             | \$ 1.23     | \$ 0.82                            | \$ 1.23     |
| Weighted-average grant-date fair value | \$ 0.43                             | \$ 0.56     | \$ 0.55                            | \$ 0.56     |

A summary of stock option activity under the 2000 Plan, the 2006 Plan and outside of any formalized plan is as follows:

|                                   | <b>Options<br/>Outstanding</b> | <b>Weighted<br/>Average<br/>Exercise Price</b> | <b>Weighted<br/>Average<br/>Remaining<br/>Contracted<br/>Term in<br/>Years</b> | <b>Aggregate<br/>Intrinsic<br/>Value</b> |
|-----------------------------------|--------------------------------|------------------------------------------------|--------------------------------------------------------------------------------|------------------------------------------|
| Outstanding at January 1, 2007    | 3,492,651                      | \$ 0.70                                        |                                                                                |                                          |
| Options granted                   | 450,000                        | \$ 0.82                                        |                                                                                |                                          |
| Options exercised                 | (25,000)                       | \$ 0.01                                        |                                                                                |                                          |
| Outstanding at September 30, 2007 | 3,917,651                      | \$ 0.72                                        | 7.9                                                                            | \$ 1,328,706                             |
| Exercisable at September 30, 2007 | 2,821,399                      | \$ 0.64                                        | 7.3                                                                            | \$ 1,318,706                             |

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, 2007, there was approximately \$445,000 of total unrecognized compensation cost related to unvested share-based compensation arrangements. Of this total amount, 14%, 53% and 33% are expected to be recognized during 2007, 2008 and 2009, respectively. The Company expects 1,096,252 in unvested options to vest in the future. The weighted-average grant-date fair value of vested and unvested options outstanding at September 30, 2007 was \$0.37 and \$0.58, respectively.

## 5. NET LOSS PER SHARE

Basic net loss per share is computed by dividing net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding during the period. Diluted net loss per share is computed by dividing net loss attributable to common stockholders by the weighted-average number of shares of common stock and the dilutive potential common stock equivalents then outstanding. Potential common stock equivalents consist of stock options, warrants and convertible preferred stock. Since the Company has a net loss for all periods presented, the inclusion of potential 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:

|                               | <b>Three Months Ended<br/>September 30,</b> |             | <b>Nine Months Ended<br/>September 30,</b> |             |
|-------------------------------|---------------------------------------------|-------------|--------------------------------------------|-------------|
|                               | <b>2007</b>                                 | <b>2006</b> | <b>2007</b>                                | <b>2006</b> |
| Stock options                 | 3,917,651                                   | 2,862,651   | 3,917,651                                  | 2,862,651   |
| Warrants                      | 26,873,047                                  | 14,561,449  | 26,873,047                                 | 14,561,449  |
| Conversion of preferred stock | 18,264,000                                  | 2,417,774   | 18,264,000                                 | 2,417,774   |

## 6. INCOME TAXES

The Company accounts for income taxes in accordance with SFAS No. 109, *Accounting for Income Taxes* (SFAS 109). Under SFAS 109, deferred tax assets or liabilities are computed based on the difference between the financial-statement and income-tax basis of assets and liabilities, and net operating loss carryforwards, using the enacted tax rates. Deferred income tax expense or benefit is based on changes in the asset or liability from period to period. The Company did not record a provision for federal, state or foreign income taxes for the three and nine months ended September 30, 2007 and 2006 because the Company has experienced losses since inception. The Company has not recorded a benefit for deferred tax assets as their realizability is uncertain.

## 7. NEW ACCOUNTING PRONOUNCEMENTS

In June 2007, the Emerging Issues Task Force reached a consensus on Issue No. 07-3 Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities (EITF 07-3). EITF 07-3 requires that nonrefundable advance payments for goods or services used or rendered for future research and development activities should be deferred and capitalized and subsequently recognized as an expense as the goods are delivered or the related services are performed. EITF 07-3 is effective for fiscal years beginning after December 15, 2007 and interim periods within those fiscal years with no earlier application permitted. The Company is currently evaluating the effect of this consensus on its future reported financial position and results of operations.

In February 2007, the Financial Accounting Standards Board (FASB) issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities - Including an Amendment to FASB Statement No. 115* (SFAS 159). SFAS 159 permits entities to choose to measure many financial instruments and certain other items at fair value. SFAS 159 is effective for financial statements issued for fiscal years beginning after November 15, 2007. Earlier adoption is permitted as of the beginning of a fiscal year that begins on or before November 15, 2007, provided that the entity also elects to apply the provisions of SFAS 157. The Company is currently evaluating the effect of this standard on its future reported financial position and results of operations.

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements* (SFAS 157), to define fair value, establish a framework for measuring fair value in generally accepted accounting principles and expand disclosures about fair-value measurements. SFAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007 and interim periods within those fiscal years, with earlier application allowed. The Company is currently evaluating the effect of this standard on its future reported financial position and results of operations.

## **8. COMMITMENTS AND RELATED PARTY TRANSACTIONS**

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

If a royalty is not being paid to ZAO BAM on net sales of oxidized glutathione products, then the Company is required to pay ZAO BAM 3% of all license revenues. If license revenues exceed the Company's cumulative expenditures including, but not limited to, preclinical and clinical studies, testing, FDA and other regulatory agency submission and approval costs, general and administrative costs, and patent expenses, then the Company would be required to pay ZAO Bam an additional 9% of the amount by which license revenues exceed the Company's cumulative expenditures.

As a result of the assignment to Novelos of the exclusive worldwide intellectual property and marketing rights of oxidized glutathione (excluding Russia and the other states of the former Soviet Union), Novelos is obligated to the Oxford Group, Ltd. for future royalties. One of the Company's directors is president of Oxford Group, Ltd. Pursuant to the agreement, as revised May 26, 2005, Novelos is required to pay Oxford Group, Ltd. a royalty in the amount of 0.8% of the Company's net sales of oxidized glutathione-based products.

In July, 2006, the Company entered into a contract with a supplier of pharmaceutical products that will provide chemotherapy drugs to be used in connection with Phase 3 clinical trial activities outside of the United States. Pursuant to the contract, the Company was obligated to purchase a minimum of approximately \$2,600,000 of chemotherapy drugs at specified intervals through March 2008. As of September 30, 2007, approximately \$135,000 is remaining under that commitment. In connection with that agreement, the Company was required to enter into a standby letter of credit arrangement with a bank, originally expiring in August 2007 and renewed through March 2008. The balance on the standby letter of credit at September 30, 2007 equals the remaining purchase commitment of \$135,000. In connection with the letter of credit, the Company has pledged cash of approximately \$148,000 to the bank as collateral on the letter of credit. The pledged cash is reflected as restricted cash on the balance sheet. In October 2007, the Company amended the contract to increase its remaining purchase commitment from \$135,000 to approximately \$2,000,000 through January 2008. Accordingly, the standby letter of credit was increased to the amount of the remaining commitment and the collateral was increased to approximately \$2,100,000.

## ***Item 2. Management's Discussion and Analysis or Plan of Operation***

### **Forward-Looking Statements**

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

### **Overview**

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

NOV-002, our lead compound currently in Phase 3 development for non-small cell lung cancer (NSCLC), acts together with chemotherapy as a chemoprotectant and an immunomodulator. In May 2006, we finalized a Special Protocol Assessment (SPA) with the FDA for a single pivotal Phase 3 trial in advanced NSCLC in combination with first-line chemotherapy, and received Fast Track designation in August 2006. The primary endpoint of this trial is improvement in median overall survival. Patient enrollment commenced in November 2006 and is ongoing. NOV-002 is also in Phase 2 development for chemotherapy-resistant ovarian cancer and early-stage breast cancer and, in addition, is being developed for treatment of acute radiation injury.

NOV-205, our second compound, acts as a hepatoprotective agent with immunomodulating and anti-inflammatory properties. Our Investigational New Drug Application for NOV-205 as monotherapy for chronic hepatitis C has been accepted by the FDA, and a U.S. Phase 1b clinical trial in patients who previously failed treatment with pegylated interferon plus ribavirin is ongoing.

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

### **Plan of Operation**

Our plan of operation for the next twelve months is to continue the clinical development of our two product candidates. We expect our principal expenditures during those 12 months to include the costs associated with clinical trials. We will continue to maintain a low number of permanent employees and utilize senior advisors, consultants, contract research and manufacturing organizations and third parties to perform certain aspects of product development, including clinical and non-clinical development, manufacturing and, in some cases, regulatory and quality assurance functions. On May 2, 2007 we completed a private placement of our Series B Preferred Stock and warrants with net proceeds of approximately \$13,693,000 (net of issuance costs). Based on our current and anticipated spending, we expect that we will be able to fund these activities with existing working capital into the middle of 2008.

### **Capital Structure and Financings**

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

During 2005 and 2006 we completed various private placements of securities. In May through August of 2005 we sold an aggregate of 4,000,000 shares of common stock and warrants to purchase 2,000,000 shares of common stock for net cash proceeds of \$3,715,000 and the conversion of \$550,000 of convertible debt and accrued interest. In September and October 2005, we sold in a private placement 3,200 shares of Series A preferred stock and warrants to purchase 969,696 shares of common stock for aggregate net proceeds of \$2,864,000. On March 7, 2006, we sold 11,154,073 shares of our common stock and warrants to purchase 8,365,542 shares of our common stock for net proceeds of \$13,847,000. On May 2, 2007, we sold 300 shares of our Series B preferred stock and warrants to purchase 7,500,000 shares of our common stock for net proceeds of \$13,693,000 (net of issuance costs). The shares of Series B Preferred Stock are convertible into 15,000,000 shares of common stock. In connection with that financing, the holders of the existing Series A preferred stock exchanged their 3,264 shares of Series A preferred stock for 272 shares of a new Series C convertible preferred stock which are convertible into 3,264,000 shares of common stock.

## **Results of Operations**

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

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

### **Three Months Ended September 30, 2007 and 2006**

**Research and Development.** Research and development expense for the three months ended September 30, 2007 was \$5,911,000 compared to \$2,409,000 for the three months ended September 30, 2006. The \$3,502,000, or 145%, increase in research and development expense was due to increased funding of our clinical, contract manufacturing and non-clinical activities. The overall increase resulted principally from expanded activities relating to our pivotal Phase 3 clinical trial of NOV-002 for non-small cell lung cancer. The increase includes \$1,176,000 in additional contract research and consulting services, an increase of \$1,196,000 in clinical site expenses, an increase of \$159,000 in drug manufacturing costs and an increase of \$57,000 related to salaries and overhead costs such as travel and related expenses. We also purchased \$1,814,000 of chemotherapy drugs during the third quarter of 2007 (an increase of \$950,000 over the third quarter of 2006) to be used in the Phase 3 clinical trial, specifically for clinical sites in Eastern and Western Europe. Since we do not anticipate recovering any of the costs of the chemotherapy and we do not have a reliable method for tracking the drugs that have been administered to patients or evaluating any losses associated with spoilage, we recorded the entire amount as an expense in the period purchased. As disclosed in Note 8, we have a commitment, as amended in October 2007, to purchase an additional \$2,000,000 of chemotherapy drugs at specified intervals through January 2008. The increased costs were offset by a \$36,000 decrease in stock compensation expense during the third quarter of 2007 as compared to the third quarter of 2006, principally resulting from the expiration of vesting periods for certain option grants.

**General and Administrative.** General and administrative expense for the three months ended September 30, 2007 was \$734,000 compared to \$587,000 for the three months ended September 30, 2006. The \$147,000, or 25%, increase in general and administrative expense was primarily due to four factors. First, we recorded \$81,000 in potential liquidated damages associated with the registration of less than 100% of the securities required by the registration rights agreements with investors in our Series B Preferred Stock. Second, professional fees increased \$46,000 as a result of increases in legal and accounting services. Third, compensation and related costs and fees to directors increased \$42,000 as a result of salary increases to administrative personnel, increases to director fees and the hiring of additional personnel. Fourth, stock compensation increased by \$36,000 due to new option grants during 2006 to employees, directors and consultants. These increases were offset by a \$49,000 decrease in the cost associated with investor relations professional services as we increased our use of internal resources to perform those functions as well as a decrease of \$9,000 in overhead and miscellaneous costs.



*Interest Income.* Interest income for the three months ended September 30, 2007 was \$228,000 compared to \$192,000 for the three months ended September 30, 2006. The increase in interest income during 2007 related to higher average cash balances in 2007 as a result of the net proceeds received from the sale of Series B preferred stock on May 2, 2007.

*Preferred Stock Dividends and Deemed Dividends.* During the quarter ended September 30, 2007 we paid cash dividends to Series B and C preferred stockholders of \$562,500 and \$65,280, respectively. Of the amount paid to Series B preferred stockholders, \$225,000 had been accrued in the quarter ended June 30, 2007. The dividends related to the third quarter have been included in the calculation of net loss attributable to common stockholders of \$6,818,000, or \$0.17 per share, for the quarter ended September 30, 2007. These dividends are excluded from our net loss (from operating activities) of \$6,415,000, or \$0.16 per share, for the quarter ended September 30, 2007. The net loss attributable to common stockholders for the quarter ended September 30, 2006 included \$65,280 of dividends paid to the former Series A preferred stockholders.

#### ***Nine Months Ended September 30, 2007 and 2006***

*Research and Development.* Research and development expense for the nine months ended September 30, 2007 was \$11,621,000 compared to \$4,200,000 for the nine months ended September 30, 2006. The \$7,421,000, or 177%, increase in research and development expense was due to increased funding of our clinical, contract manufacturing and non-clinical activities. The overall increase resulted principally from expanded activities relating to our pivotal Phase 3 clinical trial of NOV-002 for non-small cell lung cancer. The increase includes \$3,239,000 in additional contract research and consulting services, an increase of \$2,151,000 in clinical site expenses, an increase of \$421,000 in drug manufacturing costs and an increase of \$167,000 related to salaries and overhead costs such as travel and related expenses. Additionally, stock compensation expense increased \$20,000 during the first nine months of 2007 as compared to the first nine months of 2006, principally resulting from additional option grants in December 2006. We also purchased \$2,319,000 of chemotherapy drugs during the first half of 2007 (an increase of \$1,455,000 over the first nine months of 2006) to be used in the Phase 3 clinical trial, specifically for clinical sites in Eastern and Western Europe. Since we do not anticipate recovering any of the costs of the chemotherapy and we do not have a reliable method for tracking the drugs that have been administered to patients or evaluating any losses associated with spoilage, we recorded the entire amount as an expense in the period purchased. As disclosed in Note 8, we have a commitment, as amended in October 2007, to purchase an additional \$2,000,000 of chemotherapy drugs at specified intervals through January 2008. The increases discussed above were offset by a \$32,000 reduction in patent costs.

*General and Administrative.* General and administrative expense for the nine months ended September 30, 2007 was \$1,978,000 compared to \$1,889,000 for the nine months ended September 30, 2006. The \$89,000, or 5%, increase in general and administrative expense was due to four factors. First, we recorded \$81,000 in potential liquidated damages associated with the registration of less than 100% of the securities required by the registration rights agreements with investors in our Series B Preferred Stock. This represents a \$106,000 increase over the first nine months of 2006, which included a credit of \$25,000 for potential liquidated damages associated with a previous financing. Second, compensation and related costs and fees to directors increased \$102,000 as a result of the hiring of a full-time director of finance in mid-2006, salary increases to administrative personnel, and increases to director fees. Third, overhead costs increased \$74,000 due principally to increases in insurance and travel costs. Lastly, stock compensation increased by \$98,000 due to new option grants during 2006 to employees, directors and consultants. These increases were offset by a decrease of \$291,000 in professional and consulting costs associated with legal, accounting and investor-relations professional services as we increased our use of internal resources to perform those functions.

*Interest Income.* Interest income for the nine months ended September 30, 2007 was \$576,000 compared to \$472,000 for the nine months ended September 30, 2006. The increase in interest income during 2007 related to higher average cash balances in 2007 as a result of the net proceeds received from 2006 and 2007 financing transactions.

*Preferred Stock Dividends and Deemed Dividends.* During the nine months ended September 30, 2007 we paid cash dividends to Series A and C preferred stockholders of \$195,840 and dividends totaling \$562,500 to our Series B preferred stockholders. During the nine months ended September 30, 2007 we also recorded deemed dividends to preferred stockholders totaling \$9,003,000. This amount represents the value attributed to the beneficial conversion feature of the Series B convertible preferred stock of \$7,824,000 and the fair value of warrants and cash totaling \$1,179,000 transferred to the former Series A preferred stockholders in connection with the exchange of their shares for shares of Series C preferred stock that were subordinated to the Series B shares. The deemed dividends and cash dividends have been included in the calculation of net loss attributable to common stockholders of \$22,780,000, or \$0.58 per share, for the nine months ended September 30, 2007. The deemed dividends and cash dividends are excluded from our net loss (from operating activities) of \$13,018,000, or \$0.33 per share, for the nine months ended September 30, 2007. There were no deemed dividends in the first nine months of 2006.

## Liquidity and Capital Resources

We have financed our operations since inception through the sale of equity securities and the issuance of debt (which was subsequently paid off or converted into equity). As of September 30, 2007, we had \$15,419,000 in cash and equivalents, including \$148,000 of restricted cash that is reserved for research and development activities.

During the nine months ended September 30, 2007, cash of approximately \$9,042,000 was used in operations, primarily due to a net loss of \$13,018,000 and net payment of accrued compensation of \$19,000, offset by non-cash stock-based compensation expense of \$437,000, depreciation and amortization of \$10,000, a decrease in prepaid expenses of \$90,000 and an increase in accounts payable and accrued expenses of \$3,458,000. The significant increase in accounts payable and accrued expenses is a result of greater than expected delays in invoicing from clinical research organizations. During the nine months ended September 30, 2007, cash of approximately \$1,480,000 was provided by investing activities resulting from the release of restrictions on \$1,507,000 of cash that had been previously restricted, offset by payments of \$23,000 to purchase fixed assets and \$4,000 for a lease deposit.

During the nine months ended September 30, 2007, cash of approximately \$12,895,000 was provided by financing activities as a result of the net proceeds of \$13,693,000 from the sale of our Series B preferred stock. This was offset by the payment of cash dividends on the Series A, B and C convertible preferred stock totaling \$758,000 and a \$40,000 payment made in connection with the exchange of Series A preferred shares for Series C preferred shares.

Based on our current and anticipated spending, we believe that our available cash and equivalents, including the net proceeds from the Series B financing, will be sufficient to meet our working capital requirements, including operating losses and capital expenditure requirements, into the middle of 2008, assuming that our business plan is implemented successfully.

We believe, however, that we will need to raise additional capital in order to complete the pivotal Phase 3 clinical trial for NOV-002 in NSCLC and other research and development activities. Furthermore, we may license or acquire other compounds that will require capital for development. We may seek additional funding through collaborative arrangements and public or private financings. Additional funding may not be available to us on acceptable terms or at all. In addition, the terms of any financing may adversely affect the holdings or the rights of our stockholders. For example, if we raise additional funds by issuing equity securities, further dilution to our existing stockholders may result. If we are unable to obtain funding on a timely basis, we may be required to significantly curtail one or more of our research or development programs. We also could be required to seek funds through arrangements with collaborators or others that may require us to relinquish rights to some of our technologies, product candidates, or products which we would otherwise pursue on our own.

Even if we are able to raise additional funds in a timely manner, our future capital requirements may vary from what we expect and will depend on many factors, including the following:

- the resources required to successfully complete our clinical trials;
- the time and costs involved in obtaining regulatory approvals;
- continued progress in our research and development programs, as well as the magnitude of these programs;
- the cost of manufacturing activities;
- the costs involved in preparing, filing, prosecuting, maintaining, and enforcing patent claims;
- the timing, receipt, and amount of milestone and other payments, if any, from collaborators; and
- fluctuations in foreign exchange rates.

## Commitments

In July 2006, we entered into a contract with a supplier of pharmaceutical products that will provide chemotherapy drugs to be used in connection with Phase 3 clinical trial activities in certain locations outside of the United States. Payments under the contract will be made in Euros and will be funded with available working capital. The minimum remaining commitment under the contract is approximately as follows as of September 30, 2007:

|                                  | Payments Due by Period |             |             |             |               |
|----------------------------------|------------------------|-------------|-------------|-------------|---------------|
|                                  | Total                  | 0-12 Months | 1 - 3 Years | 3 - 5 Years | After 5 Years |
| Chemotherapy purchase commitment | \$ 135,000             | \$ 135,000  | \$ -        | \$ -        | \$ -          |

In October 2007, the contract was amended to increase the remaining purchase commitment from \$135,000 to approximately \$2,000,000 through January 2008.

## Factors Affecting Future Performance

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

We currently generate no revenue from our proposed products or otherwise. We do not know when this will change. We have expended and will continue to expend substantial funds in the research, development and clinical and pre-clinical testing of our drug compounds. We will require additional funds to conduct research and development, establish and conduct clinical and pre-clinical trials, establish commercial-scale manufacturing arrangements and provide for the marketing and distribution of our products. Additional funds may not be available on acceptable terms, if at all. If adequate funding is not available to us, we may have to delay, reduce the scope of or eliminate one or more of our research or development programs or product launches or marketing efforts, which may materially harm our business, financial condition and results of operations.

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

- the number of potential products and technologies in development;
- continued progress and cost of our research and development programs;
- progress with pre-clinical studies and clinical trials;
- the time and costs involved in obtaining regulatory clearance;
- costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims;
- costs of developing sales, marketing and distribution channels and our ability to sell our drugs;
- costs involved in establishing manufacturing capabilities for clinical trial and commercial quantities of our drugs;
- competing technological and market developments;
- market acceptance of our products;
- costs for recruiting and retaining management, employees and consultants;
- costs for training physicians;
- our status as a bulletin-board listed company and the prospects for our stock to be listed on a national exchange; and

- uncertainty and economic instability resulting from terrorist acts and other acts of violence or war.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

A U.S.-based Phase 1/2 clinical trial of NOV-002 involving 44 non-small cell lung cancer patients provided what we believe to be a favorable outcome. As a result, we enrolled the first patient in the pivotal Phase 3 trial of NOV-002 for non-small cell lung cancer in November 2006 and are continuing to enroll patients. We expect full enrollment in March 2008 and trial conclusion mid-2009. We enrolled the first patient in the Phase 2 clinical study for NOV-002 for chemotherapy-resistant ovarian cancer in July 2006 and announced what we believe to be encouraging results from this ongoing study in June 2007. We enrolled the first patient in the Phase 1b clinical study for NOV-205 for chronic hepatitis C in September 2006 and we anticipate completing that study by the end of 2007. We also commenced a Phase 2 clinical study for NOV-002 for early-stage breast cancer and expect interim results in mid-2008. There can be no assurance that we can demonstrate that these products are safe or effective in advanced clinical trials. We are also not able to give assurances that the results of the tests already conducted can be repeated or that further testing will support our applications for regulatory approval. As a result, our drug and technology research program may be curtailed, redirected or eliminated at any time.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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



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

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

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

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

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

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

We have initiated a portion of our clinical trial activities in both Western and Eastern Europe. We anticipate that approximately 40% of the overall Phase 3 clinical trial budget of approximately \$35 million will be incurred in Euros. Significant depreciation in the value of the U.S. Dollar against principally the Euro could adversely affect our ability to complete the trials, particularly if we are unable to redirect funding or raise additional funds. Since the timing and amount of foreign-denominated payments are uncertain and dependent on a number of factors, it is difficult to cost-effectively hedge the potential exposure. Therefore, to date, we have not entered into any foreign currency hedges to mitigate the potential exposure.

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

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

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

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

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

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

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

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

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

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

Keeping abreast of, and in compliance with, changing laws, regulations and standards relating to corporate governance, public disclosure and internal controls, including the Sarbanes-Oxley Act of 2002, new SEC regulations and, in the event we seek and are approved for listing on a registered national securities exchange, the stock exchange rules will require an increased amount of management attention and external resources. We intend to continue to invest all reasonably necessary resources to comply with evolving standards, which may result in increased general and administrative expense and a diversion of management time and attention from revenue-generating activities to compliance activities. Beginning with our annual report for the fiscal year ending December 31, 2007 we will be required to include a report of our management on internal control over financial reporting. Further, in our annual report for the fiscal year ending December 31, 2008 we will be required to include an attestation report of our independent registered public accounting firm on internal control over financial reporting.

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

Our directors, officers and holders of our Series B preferred stock beneficially own, in the aggregate, approximately 35% of our outstanding voting shares. The interests of our current officers, directors and Series B investors may differ from the interests of other stockholders. Further, our current officers, directors and Series B investors may have the ability to significantly affect the outcome of all corporate actions requiring stockholder approval, including the following actions:

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

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

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

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

For as long as any shares of Series B Preferred Stock remain outstanding we are prohibited from taking certain actions or entering into certain transactions without the prior consent of the holders of outstanding shares of Series B preferred stock. We are prohibited from paying dividends to common stockholders, amending our certificate of incorporation, issuing any equity security or any security convertible into or exercisable for any equity security at a price of \$1.00 or less or with rights senior to the Series B Preferred Stock (except for certain exempted issuances), increasing the number of shares of Series B Preferred Stock or issuing any additional shares of Series B Preferred Stock other than the 400 shares designated in the Series B Certificate of Designations, or changing the number of our directors. We are also prohibited from entering into certain transactions such as selling or otherwise disposing of all or substantially all of our assets or intellectual property or entering into a merger or consolidation with another company unless we are the surviving corporation, the Series B Preferred Stock remains outstanding and there are no changes to the rights and preferences of the Series B Preferred Stock, redeeming or repurchasing any capital stock other than Series B Preferred Stock, or incurring any new debt for borrowed money.

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

**We have failed to register 100% of the securities that were required to be registered in accordance with the Series B Preferred Stock financing agreements.**

In connection with the private placement of Series B Preferred Stock and warrants that closed on May 2, 2007, we entered into a registration rights agreement with the investors that required the Company to file with the SEC no later than June 1, 2007, a registration statement covering the resale of a number of shares of common stock equal to 100% of the shares issuable upon conversion of the preferred stock and exercise of the warrants as of the date of filing of the registration statement (23,400,000 shares). The Registration Statement on Form SB-2 covering the resale of 23,400,000 shares of common stock was filed on May 25, 2007. As a result of comments received from the Securities and Exchange Commission we subsequently amended the registration statement to reduce the size of the offering from 23,400,000 shares to 12,000,000 shares. The holders of Series B Preferred Stock consented to the reduction of shares being covered by the registration statement from 23,400,000 to 12,000,000. Additionally, the investors agreed to extend the date by which the registration statement must be declared effective until September 7, 2007. Furthermore, the holders of Series B Preferred Stock have waived, through September 7, 2007, any liquidated damages arising as a result of the reduction in the number of shares being registered and by any failure to have the registration statement declared effective prior to September 7, 2007. The registration statement, as amended, was declared effective on September 6, 2007.

If the holders of Series B Preferred Stock do not waive liquidated damages for periods subsequent to September 7, 2007, we may become liable for liquidated damages equal to 1.5% per month (pro-rated on a daily basis for any period of less than a full month) of the aggregate purchase price of the Series B Preferred Stock until May 2, 2009. In the quarter ended September 30, 2007, the Company accrued \$80,500 for potential liquidated damages, representing an estimate of the pro rata portion due to investors as a result of registering 53%, instead of 100%, of the total shares underlying the preferred stock and warrants held by the investors. As of the date of this filing, no claim has been made for payment of any liquidated damages.

### ***Item 3. 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, 2007. 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, 2007, 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 fiscal quarter of 2007 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 2. Unregistered Sales of Equity Securities and Use of Proceeds*

On July 6, 2007 we issued 25,000 shares of our common stock to Dr. Kenneth Tew, the chairman of our Scientific Advisory Board, upon exercise of his stock option at a price per share of \$0.01 for total consideration of \$250, pursuant to an option granted in April 2004.

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

None.

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

We held our Annual Meeting of Stockholders at the offices of Foley Hoag LLP, 155 Seaport Boulevard, Boston, Massachusetts on July 16, 2007.

(i) The stockholders elected six directors to serve until the next Annual Meeting of Stockholders. The stockholders present in person or by proxy cast the following numbers of votes in connection with the election of directors, resulting in the election of all nominees:

| <b>Nominee</b>      | <b>Votes For</b> | <b>Votes Withheld</b> |
|---------------------|------------------|-----------------------|
| Simyon Palmin       | 30,194,875       | 148,810               |
| Harry S. Palmin     | 30,190,675       | 153,010               |
| Michael J. Doyle    | 30,194,875       | 148,810               |
| Sim Fass            | 30,192,875       | 150,810               |
| David B. McWilliams | 30,194,875       | 148,810               |
| Howard M. Schneider | 30,192,875       | 150,810               |

(ii) The stockholders approved an amendment to our Certificate of Incorporation to increase the number of shares of authorized common stock from 100,000,000 to 150,000,000. There were 29,414,346 votes cast for the proposal; 921,639 votes were cast against the proposal; 7,700 votes abstained; and there were no broker non-votes.

### *Item 5. Other Information*

None.

### *Item 6. Exhibits*

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



| Exhibit<br>No. | Description                                                                                                                        | Filed<br>with<br>this<br>Form<br>10-QSB | Incorporated by Reference |                 | Exhibit<br>No. |
|----------------|------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------|---------------------------|-----------------|----------------|
|                |                                                                                                                                    |                                         | Form                      | Filing Date     |                |
| 3.2            | Certificate of Merger merging Common Horizons, Inc. with and into Novelos Therapeutics, Inc. dated June 13, 2005                   |                                         | 10-QSB                    | August 10, 2007 | 3.2            |
| 3.3            | Certificate of Correction dated March 3, 2006                                                                                      |                                         | 10-QSB                    | August 10, 2007 | 3.3            |
| 3.4            | Certificate of Amendment to Amended and Restated Certificate of Incorporation dated July 16, 2007                                  |                                         | 10-QSB                    | August 10, 2007 | 3.4            |
| 3.5            | Certificate of Designations of Series B convertible preferred stock                                                                |                                         | 10-QSB                    | August 10, 2007 | 3.5            |
| 3.6            | Certificate of Designations of Series C cumulative convertible preferred stock                                                     |                                         | 10-QSB                    | August 10, 2007 | 3.6            |
| 3.7            | By-Laws                                                                                                                            |                                         | 8-K                       | June 17, 2005   | 2              |
| 4.1            | Form of Common Stock Purchase Warrant dated May 2, 2007 issued pursuant to the Securities Purchase Agreement dated April 12, 2007  |                                         | 10-QSB                    | May 8, 2007     | 4.1            |
| 4.2            | Form of Common Stock Purchase Warrant dated May 2, 2007 issued pursuant to the Agreement to Exchange and Consent dated May 2, 2007 |                                         | 10-QSB                    | May 8, 2007     | 4.2            |
| 10.1           | Securities Purchase Agreement dated April 12, 2007                                                                                 |                                         | 10-QSB                    | May 8, 2007     | 10.1           |
| 10.2           | Letter Amendment dated May 2, 2007 to the Securities Purchase Agreement                                                            |                                         | 10-QSB                    | May 8, 2007     | 10.2           |
| 10.3           | Registration Rights Agreement dated May 2, 2007                                                                                    |                                         | 10-QSB                    | May 8, 2007     | 10.3           |
| 10.4           | Placement Agent Agreement with Rodman & Renshaw, LLC dated February 12, 2007                                                       |                                         | 10-QSB                    | May 8, 2007     | 10.4           |
| 10.5           | Agreement to Exchange and Consent dated May 1, 2007                                                                                |                                         | 10-QSB                    | May 8, 2007     | 10.5           |
| 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           | Certificate pursuant to 18 U.S.C. Section 1350 of the chief executive officer                                                      | X                                       |                           |                 |                |
| 32.2           | Certificate pursuant to 18 U.S.C. Section 1350 of the chief financial officer                                                      | 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 13, 2007

By: /s/ Harry S. Palmin

Harry S. Palmin

President, Chief Executive Officer