

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

**FORM 10-QSB/A**  
**Amendment No. 1**

[mark one]

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

For the quarterly period ended: September 30, 2005

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: 27,911,199 shares of common stock, \$.00001 par value per share, as of November 4, 2005.

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

**NOVELOS THERAPEUTICS, INC.**

**10-QSB/A INDEX**

<b>EXPLANATORY NOTE</b>	2
<b>PART I. FINANCIAL INFORMATION</b>	
Item 1. Financial Statements	3
Item 2. Management's Discussion and Analysis or Plan of Operation	15
Item 3. Controls and Procedures	29
<b>PART II. OTHER INFORMATION</b>	
Item 1. Legal Proceedings	31
Item 2. Unregistered Sales of Equity Securities and Use of Proceeds	31
Item 3. Defaults Upon Senior Securities	31
Item 4. Submission of Matters to a Vote of Security Holders	31

Item 5.	Other Information	31
Item 6.	Exhibits	31

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## EXPLANATORY NOTE

We are amending our quarterly report on Form 10-QSB for the quarter ended September 30, 2005 (the “Original Filing”) to reflect the restatement of our financial statements and the related disclosures for the quarter ended September 30, 2005. This amendment is being filed to correct an error in the Original Filing related to our accounting for the beneficial conversion feature associated with our Series A 8% Cumulative Convertible Preferred Stock and to correct the calculation of Net Loss Attributable to Common Stockholders and Basic and Diluted Net Loss Attributable to Common Stockholders Per Common Share. We have also filed an amendment on Form 10-KSB/A for the year ended December 31, 2005 to reflect the restatement as of that date.

This amendment restates the calculation of Net Loss Attributable to Common Stockholders and Basic and Diluted Net Loss Attributable to Common Stockholders Per Common Share by including in the respective calculations the deemed dividend associated with the beneficial conversion feature of the preferred stock in the Statements of Operations. The amendment also expands the related disclosures in the Statements of Cash Flows and Notes to Financial Statements (for additional information relating to the effect of the restatement, see Note 13 to our Financial Statements). Our Balance Sheets were not affected by this restatement. The deemed dividend associated with the beneficial conversion feature of the preferred stock is a non-cash item.

In connection with the discovery of this error as a result of an internal review, we reassessed our evaluation of our internal controls over financial reporting as of September 30, 2005 and have concluded that a material weakness existed in our internal controls over financial reporting with respect to the identification of and accounting for the beneficial conversion feature of the preferred stock financing transaction. For more information on our revised evaluation of our internal controls over financial reporting and the steps we have taken to remediate the weakness, see Item 3. Controls and Procedures.

Except for the sections of this Form 10-QSB/A listed below, all of the information in this amended Quarterly Report on Form 10-QSB/A is as of September 30, 2005 and does not reflect events occurring after the Original Filing. In addition, in accordance with applicable SEC rules, this amended Annual Report on Form 10-QSB/A includes currently dated certifications from our Chief Executive Officer and Chief Financial Officer as Exhibits 31.1, 31.2, 32.1 and 32.2. This Form 10-QSB/A should be read in conjunction with the Company’s filings made with the SEC subsequent to the Original Filing.

For the convenience of the reader, this amended Quarterly Report on Form 10-QSB/A sets forth the Original Filing in its entirety, as modified and superseded where necessary to reflect the restatement. The following items have been amended as a result of, and to reflect, the restatement described above and no other information in the Original Filing is amended hereby, as a result of the restatement:

### Part I

#### Item 1 – Financial Statements:

- Statements of Operations
- Statements of Cash Flows (Supplemental Disclosures of Non-Cash Activities)
- Notes to Financial Statements:
  - Note 3 – Stock-Based Compensation
  - Note 5 – Net Loss Per Share
  - Note 11 – Convertible Preferred Stock
  - Note 13 – Restatement of Previously Issued Financial Statements

#### Item 2 – Management’s Discussion and Analysis or Plan of Operation

#### Item 3 – Controls and Procedures

### Part II

#### Item 6 – Exhibits

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## PART I. FINANCIAL INFORMATION

### Item 1. Financial Statements

#### NOVELOS THERAPEUTICS, INC.

**BALANCE SHEETS**

	September 30, 2005 <u>(unaudited)</u>	December 31, 2004 <u>(audited)</u>
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and equivalents	\$ 4,830,451	\$ 10,356
Restricted cash	195,726	—
Accounts receivable	—	12,584
Prepaid expenses and other current assets	631,920	79,631
Total current assets	<u>5,658,097</u>	<u>102,571</u>
PROPERTY AND EQUIPMENT, NET	21,660	—
DEPOSITS	9,656	6,000
<b>TOTAL ASSETS</b>	<u>\$ 5,689,413</u>	<u>\$ 108,571</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable and accrued liabilities	\$ 689,869	\$ 2,026,171
Accrued interest	5,700	397,612
Notes payable to stockholders	—	2,017,931
Current portion of long-term debt	—	1,840
Total current liabilities	<u>695,569</u>	<u>4,443,554</u>
DEPOSIT ON CONVERTIBLE PREFERRED STOCK, SERIES B	—	1,142
DEFERRED REVENUE	—	12,584
DEFERRED RENT	—	250
Total liabilities	<u>695,569</u>	<u>4,457,530</u>
<b>COMMITMENTS AND CONTINGENCIES</b>		
<b>STOCKHOLDERS' EQUITY (DEFICIT):</b>		
Preferred stock, \$.00001 par value; 7,000 shares authorized:		
Series A 8% cumulative convertible preferred stock; 3,000 shares issued and outstanding at September 30, 2005	—	—
Common stock, \$.00001 par value; 100,000,000 shares authorized at September 30, 2005 and December 31, 2004; 27,818,700 and 4,426,126 shares issued and outstanding at September 30, 2005 and December 31, 2004, respectively	278	44
Additional paid-in capital	19,687,231	7,998,110
Accumulated deficit	(14,693,665)	(12,345,157)
Treasury stock (195,672 shares at December 31, 2004), at cost	—	(1,956)
Total stockholders' equity (deficit)	<u>4,993,844</u>	<u>(4,348,959)</u>
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)</b>	<u>\$ 5,689,413</u>	<u>\$ 108,571</u>

See notes to financial statements.

3

**NOVELOS THERAPEUTICS, INC.**

**STATEMENTS OF OPERATIONS**  
For the Three and Nine Month Periods Ended  
September 30, 2005 and September 30, 2004

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
	Restated (Note 13)		Restated (Note 13)	
	(unaudited)			
<b>REVENUES:</b>				
Sales of samples	\$ 12,584	—	\$ 12,584	—
Total revenues	<u>12,584</u>	<u>—</u>	<u>12,584</u>	<u>—</u>
<b>COSTS AND EXPENSES:</b>				

Research and development	360,628	\$ 48,511	813,716	\$ 223,588
General and administrative	612,696	142,178	1,018,677	370,017
Total costs and expenses	<u>973,324</u>	<u>190,689</u>	<u>1,832,393</u>	<u>593,605</u>
OTHER INCOME (EXPENSE):				
Consulting revenue	—	320	—	13,374
Interest income	8,077	—	9,693	95
Interest expense	(3,209)	(53,917)	(109,102)	(154,652)
Miscellaneous	1,000	2,040	4,297	3,708
Gain on forgiveness of debt	—	—	2,087,531	—
Restructuring expense	—	—	(2,521,118)	—
Total other income (expense)	<u>5,868</u>	<u>(51,557)</u>	<u>(528,699)</u>	<u>(137,475)</u>
NET LOSS	(954,872)	(242,246)	(2,348,508)	(731,080)
PREFERRED STOCK DEEMED DIVIDEND	(1,943,377)	—	(1,943,377)	—
ACCRETION ON CONVERTIBLE PREFERRED STOCK, SERIES A	—	—	—	(69,541)
ACCRETION ON CONVERTIBLE PREFERRED STOCK, SERIES B	—	—	—	(67,267)
NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS	<u>\$ (2,898,249)</u>	<u>\$ (242,246)</u>	<u>\$ (4,291,885)</u>	<u>\$ (867,888)</u>
BASIC AND DILUTED NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS PER COMMON SHARE	<u>\$ (0.11)</u>	<u>\$ (0.05)</u>	<u>\$ (0.22)</u>	<u>\$ (0.28)</u>
SHARES USED IN COMPUTING BASIC AND DILUTED NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS PER COMMON SHARE	<u>27,228,700</u>	<u>4,426,126</u>	<u>19,689,732</u>	<u>3,117,868</u>

See notes to financial statements.

4

**NOVELOS THERAPEUTICS, INC.**  
**STATEMENTS OF CASH FLOWS**  
**For the Nine Month Periods Ended**  
**September 30, 2005 and September 30, 2004**

	<u>Nine Months Ended September 30,</u>	
	<u>2005</u>	<u>2004</u>
	<u>(unaudited)</u>	<u>(unaudited)</u>
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$ (2,348,508)	\$ (731,080)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	1,303	2,448
Stock-based compensation	168,186	5,901
Gain on forgiveness of debt	(2,087,531)	—
Loss on cancellation of escrow agreement	—	1,957
Common stock issued for restructuring expense	2,521,118	—
Increase (decrease) in:		
Accounts receivable	12,584	—
Prepaid expenses and other current assets	(50,556)	(2,758)
Accounts payable and accrued expenses	(40,325)	327,580
Accrued interest	51,451	120,512
Deferred revenue	(12,584)	—
Deferred rent	250	500
Cash used in operating activities	<u>(1,784,612)</u>	<u>(274,940)</u>
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Purchases of property and equipment	(22,963)	—

Increase in restricted cash	(195,726)	—
Deposits	(4,798)	—
Cash used in investing activities	(223,487)	—
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Net proceeds from issuance of preferred stock	2,680,000	—
Net proceeds from issuance of common stock	3,819,034	—
Payments of long-term debt	(1,840)	(2,088)
Proceeds from issuance of promissory notes	850,000	100,000
Payment of promissory notes	(519,000)	—
Cash provided by financing activities	6,828,194	97,912
<b>INCREASE (DECREASE) IN CASH AND EQUIVALENTS</b>	<b>4,820,095</b>	<b>(177,028)</b>
<b>CASH AND EQUIVALENTS, BEGINNING OF YEAR</b>	<b>10,356</b>	<b>183,365</b>
<b>CASH AND EQUIVALENTS, END OF PERIOD</b>	<b>\$ 4,830,451</b>	<b>\$ 6,337</b>

See notes to financial statements.

5

**NOVELOS THERAPEUTICS, INC.**  
**STATEMENTS OF CASH FLOWS**  
**For the Nine Month Periods Ended**  
**September 30, 2005 and September 30, 2004**

	<b>Nine Months Ended September 30,</b>	
	<b>2005</b>	<b>2004</b>
	<b>Restated (Note 13)</b>	<b>(unaudited)</b>
	<b>(unaudited)</b>	
<b>SUPPLEMENTAL DISCLOSURES OF CASH FLOW</b>		
Cash paid during the period for:		
Interest	\$ 57,461	\$ 33,750
<b>SUPPLEMENTAL DISCLOSURES OF NON-CASH ACTIVITIES</b>		
Deemed dividend on preferred stock	\$ 1,943,377	\$ —
Common stock issued for services	\$ 156,250	\$ —
Common stock issued for accrued services	\$ 216,000	\$ —
Common stock issued on conversion of promissory notes	\$ 1,727,000	\$ —
Common stock issued in exchange for accounts payable	\$ 544,221	\$ —
Common stock issued for accrued interest	\$ 100,000	\$ —
Accounts payable forgiven	\$ 773,599	\$ —
Accrued compensation forgiven	\$ 360,357	\$ —
Accrued interest forgiven	\$ 343,363	\$ —
Accrued liability for amounts included in prepaid expenses	\$ 372,450	\$ —

See notes to financial statements.

6

**NOVELOS THERAPEUTICS, INC.**  
**NOTES TO FINANCIAL STATEMENTS**  
**(Unaudited)**

**1. BASIS OF PRESENTATION**

The accompanying unaudited financial statements of Novelos Therapeutics, Inc. ("Novelos" or on or after June 13, 2005, 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 the results for the interim periods 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 the entire fiscal year ending December 31, 2005. These unaudited financial statements should be read in conjunction with the audited financial statements and related notes thereto included in the Company's latest audited annual financial statements. Those audited financial statements are included in the Company's Current Report on Form 8-K, which was filed with the Securities and Exchange Commission ("SEC") on June 2, 2005.

The 2004 financial statements were prepared on a going-concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The opinion of the independent registered public accounting firm issued in connection with the audit of Novelos' financial statements for the year ended December 31, 2004 contained a qualification as to Novelos' ability to continue as a going concern. As discussed further in the "Liquidity and Capital Resources" section of "Management's Discussion and Analysis or Plan of Operation" below, Novelos has raised both debt and equity financing since January 1, 2005. At September 30, 2005, the Company had stockholders' equity of approximately \$5.0 million and unrestricted cash and equivalents of approximately \$4.8 million.

The Company's continuation as a going concern is dependent upon its ability to continue business development, obtain United States Food and Drug Administration ("FDA") approval to market its products, create sales, meet its obligations, raise additional capital financing and, ultimately, attain profitable operations. Management is continuing its efforts to obtain additional funds through registered or private placement offerings and possible collaborative arrangements so that the Company can continue to meet its obligations and sustain operations.

Restricted cash represents cash placed in escrow as contractually required under an employment agreement with an officer.

## **2. MERGER AND RESTRUCTURING**

On May 26, 2005, Nove Acquisition, Inc., a wholly-owned subsidiary of Common Horizons, Inc., a Nevada corporation ("Common Horizons"), merged with and into Novelos such that Novelos was the surviving corporation and became a wholly-owned subsidiary of Common Horizons. All outstanding shares of common stock of Novelos were converted into an equal number of shares of common stock of Common Horizons. In addition, each option and warrant to acquire shares of common stock of Novelos was converted into the right to acquire an equal number of shares of common stock of Common Horizons at the exercise price stated in the original option or warrant. All treasury stock (195,672 shares) was retired.

On May 26, 2005, indebtedness of Novelos in the amount of \$3,139,185 was exchanged for 586,352 shares of common stock of Novelos with an aggregate deemed value of \$732,940 and cash in the amount of \$318,714, which resulted in forgiveness of debt income of \$2,087,531. Also on May 26, 2005, holders of convertible notes of Novelos in the principal amount of \$1,100,000 converted their notes into 1,760,000 shares of common stock of Novelos at a price of \$0.625 per share. In addition,

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Novelos amended an arrangement for future royalty payments to a related party (see Note 10), which resulted in the issuance of 2,016,894 shares of its common stock with an aggregate deemed value of \$2,521,118. These amounts have been reflected in Novelos' Statements of Operations as "Gain on forgiveness of debt" and "Restructuring expense."

On May 27, 2005, Common Horizons sold 87 units, each unit consisting of 20,000 shares of common stock and warrants expiring on August 9, 2008 to purchase 10,000 shares of common stock at a purchase price of \$2.25 per share (a "Unit"), in a private placement transaction to accredited investors. Common Horizons received \$1,725,000 in cash as a result of such sale of Units. Holders of convertible debt of Common Horizons in the amount of \$450,000 converted the debt into 18 of the 87 Units. In connection with the closing, Common Horizons paid commissions and finders fees consisting of \$217,500 in cash and warrants expiring August 9, 2010 to purchase 152,000 shares of common stock of Common Horizons at a price of \$2.00 per share.

On May 27, 2005, there were approximately 25,458,700 shares of common stock of Common Horizons issued and outstanding and options and warrants to purchase up to 3,966,651 shares of common stock of Common Horizons issued and outstanding.

On June 13, 2005, Common Horizons merged with and into its wholly-owned subsidiary, Novelos. Each stockholder of Common Horizons received one share of common stock, par value \$0.00001 per share, of Novelos for each share of common stock, par value \$0.001 per share, of Common Horizons. In addition, each option and

warrant to acquire shares of common stock of Common Horizons was converted into the right to acquire an equal number of shares of common stock of Novelos at the exercise price stated in the original option or warrant.

On June 29, 2005, the Company completed a second closing of its private placement of Units. The Company sold 33 Units for aggregate gross proceeds of \$825,000. The Company issued to the accredited investors an aggregate of 660,000 shares of its common stock and warrants to purchase an aggregate of 330,000 shares of its common stock. In connection with this second closing, the Company paid commissions and finders fees consisting of \$80,500 and warrants expiring August 9, 2010 to purchase 64,000 shares of common stock of the Company at an exercise price of \$2.00 per share.

On July 29, 2005, the Company completed a third closing of its private placement of Units. The Company sold 46 Units, which resulted in aggregate gross proceeds to the Company of \$1,150,000. The Company issued to the accredited investors an aggregate of 920,000 shares of its common stock and warrants to purchase an aggregate of 460,000 shares of its common stock. In connection with this closing, the Company paid commissions and finders fees consisting of \$105,000 and warrants expiring August 9, 2010 to purchase 82,000 shares of common stock of the Company at a price of \$2.00 per share.

On August 9, 2005, the Company completed a fourth closing of its private placement of Units. The Company sold 34 Units, receiving \$750,000 in cash as a result of such sale, and converting accrued interest of \$100,000 into Units. The Company issued to the accredited investors an aggregate of 680,000 shares of its common stock and warrants to purchase an aggregate of 340,000 shares of its common stock. In connection with this closing, the Company paid finders fees consisting of \$58,000 and warrants expiring August 9, 2010 to purchase 42,000 shares of common stock of the Company at a price of \$2.00 per share.

On August 9, 2005, the Company repaid the stockholder notes described in Note 8 in the principal amount of \$500,000 with proceeds from the private placement of Units.

In connection with the private placement of Units, vFinance Investments, Inc. and Mercer Capital, Ltd. have acted as placement agents, on a best efforts basis. The placement agent agreement provides that the placement agents receive 8% of the gross proceeds of the units sold by or through the efforts of the placement agents, a nonaccountable expense allowance of 2% of the gross proceeds of all units sold in the offering, and reimbursement for additional expenses of up to \$40,000 to cover their due diligence investigation of the Company and their legal fees and expenses. In addition, the placement agents are entitled to warrants to purchase shares of common stock of the Company equal to 10% of the total number of shares of common stock of the Company sold by or through the efforts

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of the placement agents. These warrants have an exercise price of \$2.00 per share and expire on August 9, 2010. The placement agents also received 125,000 shares of common stock of Common Horizons upon the initial sale of Units. The Company also paid similar fees (cash and warrants) to finders who introduced the Company to certain investors.

The Company is obligated to file a registration statement covering the shares of common stock and common stock issuable in the private placement within 60 days (October 8, 2005) and to cause the registration statement to be declared effective within 180 days (February 5, 2006) following the last closing date of such sale of Units. The Company is obligated to pay the investors an amount equal to two percent (2%) of the purchase price of the Units purchased by them for each 30-day period following such date that the registration statement has not been filed or declared effective, as the case may be. The Company has not as yet filed the required registration statement and has recorded an accrued liability of \$200,000 as of September 30, 2005 for such payments. If the Company fails to pay any partial liquidated damages in full within seven days after the date payable, the Company will pay interest thereon at a rate of 15% per annum. The Company anticipates filing the required registration statement by mid-November 2005.

The sale of the Series A preferred stock and warrants described in Note 11, resulted in an anti-dilution adjustment to the exercise price of the outstanding warrants described above. Such adjustment reduced the exercise price of such warrants from \$2.00 and \$2.25 to \$1.65 per share of common stock.

### **3. STOCK-BASED COMPENSATION**

The Company accounts for stock option awards granted to directors and employees (collectively, employees) under the recognition and measurement principles of Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees*, (“APB 25”). For the three months ended September 30, 2005 and 2004, respectively, there is no stock-based employee compensation cost for options granted to employees under the plan as none have been granted at exercise prices below the fair market value of the underlying stock. For the nine months ended September 30, 2005 and 2004, respectively, there was no stock-based employee compensation cost for options granted to employees under the plan as none have been granted at exercise prices below the fair market value of the underlying stock. For those options granted at exercise prices equal to or greater than the fair market value of the underlying stock on the date of the grant, the Company applies the disclosure-only provision of Statement of Financial Accounting Standards (“SFAS”) No. 123, *Accounting for Stock-Based Compensation*, (“SFAS 123”), and SFAS No. 148, *Accounting for Stock-Based Compensation—Transition and Disclosure*. The table below illustrates the effect on net income (loss) and earnings (loss) per share if the Company had applied

the fair value recognition provisions of SFAS 123 to stock-based employee compensation. Common stock options granted have been valued using the Black-Scholes option pricing model prescribed by SFAS 123.

For purposes of pro forma disclosures, the estimated fair value of the stock options was amortized over the stock options' vesting periods. Had compensation expense for the Company's stock-based compensation plans been determined based on the fair market value on the grant dates for awards under those plans consistent with the method of SFAS 123, the Company's net loss attributed to common stockholders and net loss per share attributed to common stockholders would have been as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
	Restated (Note 13)		Restated (Note 13)	
Net loss attributed to common stockholders as reported	\$(2,898,249)	\$(242,246)	\$(4,291,885)	\$(867,888)
Deduct: Stock-based employee compensation expense determined under fair-value-based method	(45,915)	(1,318)	(50,244)	(3,954)
Pro forma net loss attributed to common stockholders	<u>\$(2,944,164)</u>	<u>\$(243,564)</u>	<u>\$(4,342,129)</u>	<u>\$(871,842)</u>
Basic and diluted net loss attributed to common stockholders per share:				
As reported	<u>\$ (0.11)</u>	<u>\$ (0.05)</u>	<u>\$ (0.22)</u>	<u>\$ (0.28)</u>
Pro forma	<u>\$ (0.11)</u>	<u>\$ (0.06)</u>	<u>\$ (0.22)</u>	<u>\$ (0.28)</u>

Stock or other equity-based compensation for non-employees is accounted for under the fair-value method as required by SFAS 123 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*. Under this method, the equity-based instrument is valued at either the fair value of the consideration received or the equity instrument issued on the date of vesting. The resulting compensation cost is recognized and charged to operations over the service period. The measurement date is generally the issuance date for employees and the vesting date for consultants. The resulting non-cash expense is recorded in the statement of operations over the vesting period of the stock option.

#### 4. COMPREHENSIVE INCOME (LOSS)

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

#### 5. NET LOSS PER SHARE (Restated, see Note 13)

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 and warrants. Since the Company has a net loss for all periods presented, the inclusion of stock options and warrants in the computation is antidilutive. Accordingly, basic and diluted net loss per share is the same.

For the three and nine months ended September 30, 2005 and 2004, options to purchase 2,627,651 and 952,651 shares of common stock, respectively, and warrants to purchase 4,768,402 and 0 shares of common stock, respectively, were not included in the computation of diluted net loss per share since their inclusion would be antidilutive. Also, for the three and nine months ended September 30, 2005 1,818,181 shares of common stock issuable upon the conversion of preferred stock were excluded from the computation of diluted net loss per share since their inclusion would be antidilutive.

#### 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 statements 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, 2005 and 2004, respectively, 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 PRONOUNCEMENT**

In December 2004, the Financial Accounting Standards Board issued SFAS No.123 (revised 2004), *Share-Based Payment*, ("SFAS 123R"), which will be effective for the year ending December 31, 2006. SFAS 123R will result in the recognition of substantial compensation expense relating to the Company's employee stock option plans. The Company currently uses the intrinsic value method to measure compensation expense for stock-based awards to its employees. Under this standard, the Company generally does not recognize any compensation expense related to stock option grants the Company issues to employees under its stock option plans. Under the new rules, the Company will be required to adopt a fair-value-based method for measuring the compensation expense related to employee stock awards; this will lead to additional compensation expense and therefore will have an adverse effect on the Company's reported results of operations. Note 3 above provides the pro forma net income (loss) and earnings (loss) per share as if the Company had used a fair-value-based method similar to the methods required under SFAS 123R to measure the compensation expense for employee stock awards during the three- and nine-month periods ended September 30, 2005 and 2004, respectively.

## **8. NOTES PAYABLE TO STOCKHOLDERS**

In December 2004, Novelos received \$100,000 in exchange for a demand secured note payable. In January 2005, Novelos received \$400,000 from the same individual in exchange for a demand secured note payable. The notes bore interest at 6% per annum and were repayable following the closing of one or more equity financings that resulted in aggregate gross proceeds of at least \$5,000,000 to Novelos. In exchange for these loans and the individual's commitment to provide additional financing of up to \$500,000 through August 2005, this individual received in January 2005, 10,000,000 shares of common stock of Novelos. These loans allowed Novelos to sustain its operations until permanent equity, as described in Note 2, was obtained. The Company closed equity financings by means of the private placements described in Note 2, which resulted in \$5,000,000 in aggregate gross proceeds to the Company. The Company repaid these notes on August 9, 2005 with proceeds from these equity financings.

## **9. COMMITMENTS**

On May 11, 2005, Novelos entered into a one-year lease for office space, commencing September 1, 2005, at an annual rent of \$58,000. Novelos was previously a tenant-at-will under a prior sublease agreement with a third party.

In connection with the restructuring of Novelos' debt described in Note 2, on May 6, 2005, Novelos agreed to reimburse a vendor, after the expiration of the 18-month holding period and the sale of its 50,000 shares of common stock of Novelos, the difference, if any, between the amount realized upon the sale of these shares and \$79,000.

## **10. RELATED-PARTY TRANSACTIONS AND COMMITMENTS**

One of the Company's directors is the majority shareholder of ZAO Bam. Pursuant to a royalty and technology transfer agreement between the Company and ZAO Bam, the Company is required to

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make royalty payments equal to 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.

The Company has also agreed to pay ZAO Bam 12% of all license revenues, as defined, in excess of the Company's expenditures associated therewith, 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, provided however that such payment be no less than 3% of all license revenues.

Pursuant to an agreement that became effective on May 26, 2005, the Company 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. One of the Company's directors is president of Oxford Group, Ltd. As described in Note 2, the Company revised an arrangement for future royalty payments to Oxford Group, Ltd., which resulted in the issuance of 2,016,894 shares of common stock, including 907,602 shares to each of two directors of the Company, with an aggregate deemed value of \$2,521,118.

The obligations of ZAO Bam and Oxford Group resulted from their assignment of the exclusive intellectual

property and marketing rights to a drug development platform technology, worldwide, excluding Russia and the Commonwealth of Independent States. The royalty payments will be recorded as royalty expense when the obligations are incurred.

The payment for any new technologies will be accounted for as purchased technology and either capitalized or expensed at the time of payment, depending on the stage of completion of the related products.

See Notes 8 and 11 in regard to transactions with certain stockholders.

## **11. CONVERTIBLE PREFERRED STOCK (Restated, see Note 13)**

On September 30, 2005, the Company sold a share of its Series A 8% cumulative convertible preferred stock, par value \$0.00001 per share, and warrants to purchase 303 shares of its common stock for a purchase price of \$1,000. The warrants expire in five years and have an exercise price of \$2.00 per share. The Company sold an aggregate of 3,000 shares of Series A preferred stock and warrants to purchase an aggregate of 909,090 shares of common stock to three institutional investors, one of which was a previous investor in the Company and the remaining two being related to that investor, for aggregate net proceeds of \$2,680,000.

The fair value of the 909,090 warrants, determined on a relative fair value basis, was \$736,623, which is included in additional paid-in capital. Since the initial \$1.65 conversion price of the preferred stock was less than the market value at the time of the closing, the Company determined that this represents a beneficial conversion feature. After allocating the value of the warrants, the intrinsic value of the beneficial conversion feature was determined to be \$4,100,257. However, there were not sufficient net proceeds remaining to allocate the full intrinsic value to the beneficial conversion feature. Therefore, the remaining net proceeds of \$1,943,377 were allocated to the beneficial conversion feature and that amount was recorded as a deemed dividend in the quarter ended September 30, 2005.

The Series A preferred stock has a dividend rate of 8% per annum, payable quarterly, which rate increases to 20% per annum on the second anniversary of the issuance. Such dividends may be paid in cash or in shares of Series A preferred stock. Each share of Series A preferred stock is initially convertible into 606 shares of common stock.

The Company has agreed to file a registration statement with the SEC to register 175% of the shares of common stock issuable upon conversion of the Series A preferred stock and 100% of the common stock issuable upon exercise of the warrants within 30 days of the date of issuance of the Series A preferred stock and cause it to become effective within 120 days of the date of such issuance. The Company is obligated to pay such investors two percent (2%) in cash of the purchase price of any

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Series A preferred stock not yet converted and the purchase price of shares issued upon conversion of the Series A preferred stock for each month or portion of a month during which the Company is delinquent with respect to these registration obligations. The Company has obtained a waiver of this requirement provided that the required registration statement is filed on or before November 16, 2005. If the registration statement is not filed by that date, the Company will be obligated to pay such investors two and one-half percent (2.5%) in cash of the purchase price of any Series A preferred stock not yet converted and the purchase price of shares issued upon conversion of the Series A preferred stock up and until December 1, 2005.

The Series A preferred stock is not redeemable at the option of the holder. However, the Company may redeem the Series A preferred stock for \$1,200 per share plus any accrued but unpaid dividends upon 30 days' prior written notice if a registration statement has been filed with the SEC and declared effective by the SEC covering the shares of common stock of the Company issuable upon conversion of the Series A preferred stock and exercise of the warrants.

In connection with the sale of the Series A preferred stock and warrants, a stockholder, Margie Chassman, provided a financial enhancement to the investors in the form of an escrow of 2,000,000 shares of her common stock, to be drawn upon by the investors if their investment in the equity securities of the Company fail to provide a specified yield. The Company paid \$150,000 to Ms. Chassman and her designee, for providing such financial enhancement.

The Company anticipates that its aggregate fees and expenses in connection with the sale of the Series A preferred stock and warrants will be approximately \$320,000 (including the \$150,000 fee payable to the stockholders).

The sale of the Series A preferred stock and warrants led to an anti-dilution adjustment to the exercise price of the outstanding warrants of the Company. The exercise price per share was reduced from \$2.00 and \$2.25 to \$1.65 per share.

## **12. SUBSEQUENT EVENT**

On October 3, 2005, the Company completed a second closing of its sale of Series A preferred stock and common stock purchase warrants. The Company sold an aggregate of 200 shares of its Series A preferred stock and 60,606 common stock purchase warrants pursuant to the same terms and conditions as described in Note 11

for net proceeds of \$184,000.

In connection with the sale of the Series A preferred stock and warrants, Ms. Chassman provided a financial enhancement to the investors in the form of an escrow of 133,000 shares of her common stock, to be drawn upon by the investors if their investment in the equity securities of the Company fail to provide a specified yield. The Company paid \$16,000 to Ms. Chassman and her designee, for providing such financial enhancement.

The Company is obligated to file a registration statement covering the shares of common stock and common stock issuable in the private placement within 60 days (October 8, 2005) and to cause the registration statement to be declared effective within 180 days (February 5, 2006) following the last closing date of such sale of Units. The Company is obligated to pay the investors an amount equal to two percent (2%) of the purchase price of the Units purchased by them for each 30-day period following such date that the registration statement has not been filed or declared effective, as the case may be. The Company has not as yet filed the required registration statement and has recorded an accrued liability of \$200,000 as of September 30, 2005 for such payments. If the Company fails to pay any partial liquidated damages in full within seven days after the date payable, the Company will pay interest thereon at a rate of 15% per annum. The Company anticipates filing the required registration statement by mid-November 2005.

### 13. RESTATEMENT OF PREVIOUSLY ISSUED FINANCIAL STATEMENTS

Subsequent to the initial filing of the Company's quarterly report on Form 10-QSB for the quarter ended September 30, 2005 and in connection with an internal review of the terms associated with the Company's historical financing transactions, the Company determined that the intrinsic value

13

associated with the beneficial conversion feature ("BCF") of the Company's Series A 8% Cumulative Convertible Preferred Stock had not been properly presented as a deemed (non-cash) dividend nor deducted from net loss in determining net loss attributable to common stockholders in the quarter and nine months ended September 30, 2005. In accordance with Emerging Issues Task Force Issue ("EITF") No. 98-5, *Accounting for Convertible Securities with Beneficial Conversion Features or Contingently Adjustable Conversion Ratios*, and EITF No. 00-27, *Application of Issue No. 98-5 to Certain Convertible Instruments*, a conversion feature that is "in-the-money" based on the market price of a company's common stock at the commitment date is considered a BCF. As the terms of the Series A 8% Cumulative Convertible Preferred Stock allowed immediate conversion, the deemed (non-cash) dividend related to the BCF should have been recorded upon issuance.

The following table sets forth the effects of the restatement on certain line items within the Company's Statements of Operations for the three and nine months ended September 30, 2005:

	<u>As Previously Reported</u>	<u>Revision</u>	<u>As Restated</u>
<b>Quarter Ended September 30, 2005:</b>			
Net Loss	\$ (954,872)	\$ —	\$ (954,872)
Preferred Stock Deemed (Non-cash) Dividend	—	(1,943,377)	(1,943,377)
Net Loss Attributable to Common Stockholders	<u>\$ (954,872)</u>	<u>\$(1,943,377)</u>	<u>\$(2,898,249)</u>
Basic and Diluted Net Loss Attributable to Common Stockholders Per Common Share	<u>\$ (0.04)</u>	<u>\$ (0.07)</u>	<u>\$ (0.11)</u>
<b>Nine Months Ended September 30, 2005:</b>			
Net Loss	\$(2,348,508)	\$ —	\$(2,348,508)
Preferred Stock Deemed (Non-cash) Dividend	—	(1,943,377)	(1,943,377)
Net Loss Attributable to Common Stockholders	<u>\$(2,348,508)</u>	<u>\$(1,943,377)</u>	<u>\$(4,291,885)</u>
Basic and Diluted Net Loss Attributable to Common Stockholders Per Common Share	<u>\$ (0.12)</u>	<u>\$ (0.10)</u>	<u>\$ (0.22)</u>

14

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

### Forward-Looking Statements

This quarterly report on Form 10-QSB/A 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 were established in 1996 to commercialize two promising oxidized glutathione-based compounds, NOV-002 and NOV-205, for the treatment of cancer and hepatitis. Both compounds have completed clinical trials in humans and have been approved for use in the Russian Federation where they were developed. NOV-002, marketed in Russia by an unrelated entity under the trade name GLUTOXIM®, has been administered to over 5,000 patients, demonstrating clinical efficacy and excellent safety data. The U.S.-based Phase 1/2 clinical study of NOV-002 in combination with chemotherapy for lung cancer has been completed, with positive results. A Phase 2B/3 study is expected to commence in 2006. The Company plans to file an IND with the FDA for NOV-205 as a mono-therapy for hepatitis C by year-end 2005.

NOV-002, our lead compound, is being developed to treat non-small cell lung cancer (NSCLC). NOV-002 is also being developed to treat refractory (that is, not responsive to chemotherapy) ovarian cancer. NOV-205 is being developed to treat chronic hepatitis C in the U.S.

We own all intellectual property rights worldwide (excluding Russia and other states of the former Soviet Union) related to both clinical compounds and other pre-clinical compounds based on oxidized glutathione.

We have devoted substantially all of our efforts towards the research and development of our product candidates. As of September 30, 2005, we have incurred approximately \$4.6 million in research and development expense since our inception. We have had no revenue from product sales to date and have funded our operations through the sale of equity securities and debt financings. From our inception through September 30, 2005, we have raised approximately \$12.7 million in equity and debt financings. We have never been profitable and have incurred an accumulated deficit of \$14.7 million as of September 30, 2005.

On May 26, 2005, we restructured certain of our indebtedness. We exchanged indebtedness of \$3,139,185 for 586,352 shares of our common stock with an aggregate deemed value of \$732,940, \$318,714 in cash and forgiveness of debt of \$2,087,531. Also on May 26, 2005, holders of \$1,100,000 of convertible notes payable exercised their option to convert their notes into 1,760,000 shares of common stock at a price of \$0.625 per share. On May 26, 2005, we also revised certain of our royalty obligations. As a result, we issued 2,016,894 shares of our common stock with an aggregate deemed value of \$2,521,118.

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On September 30, 2005, we sold in a private placement 3,000 shares of Series A preferred stock and warrants to purchase 909,090 shares of common stock for aggregate net proceeds of \$2,680,000 and on October 3, 2005, we sold 200 shares of Series A preferred stock and warrants to purchase 60,606 shares of common stock for aggregate net proceeds of \$184,000.

## Critical Accounting Policies

Our financial statements are prepared in accordance with accounting principles generally accepted in the United States. These accounting principles require us to make certain estimates, judgments and assumptions. We believe that the estimates, judgments and assumptions upon which we rely are reasonable based upon information available to us at the time that these estimates, judgments and assumptions are made. These estimates, judgments and assumptions can affect the reported amounts of assets and liabilities as of the date of the financial statements, as well as the reported amounts of revenues and expenses during the periods presented. Those estimates and judgments are based on management's historical experience, the terms of existing agreements, our observation of trends in the industry, information that we obtain from our customers and outside sources, and on various other assumptions that management believes to be reasonable and appropriate under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. To the extent there are material differences between these estimates, judgments or assumptions and actual results, our financial statements will be affected.

We believe that the following accounting policies affect our more significant judgments and estimates used in the preparation of our financial statements.

*Accrued Expenses.* As part of the process of preparing financial statements, we are required to estimate

accrued expenses. This process involves identifying services that have been performed on our behalf, and estimating the level of service performed and the associated cost incurred for such service as of each balance sheet date in our financial statements. Examples of estimated expenses for which we accrue include: contract service fees such as amounts paid to clinical monitors; data management organizations and investigators in conjunction with clinical trials; fees paid to contract manufacturers in conjunction with the production of clinical materials; marketing; consulting fees; and professional service fees, such as lawyers and accountants. In connection with such service fees, our estimates are most affected by our understanding of the status and timing of services provided relative to the actual levels of services incurred by such service providers. The majority of our service providers invoice us monthly in arrears for services performed. In the event that we do not identify certain costs that have begun to be incurred, or we over- or underestimate the level of services performed or the costs of such services, our reported expenses for such period would be too low or too high. The date on which certain services commence, the level of services performed on or before a given date and the cost of such services are often determined based on subjective judgments. We make these judgments based upon the facts and circumstances known to us in accordance with generally accepted accounting principles.

*Stock-Based Compensation.* We have elected to follow Accounting Principles Board (APB), Opinion No. 25, *Accounting for Stock Issued to Employees*, or APB 25, and related interpretations, in accounting for our stock-based compensation plans, rather than the alternative fair-value method provided for under Statement of Financial Accounting Standards (SFAS) No. 123, *Accounting for Stock-Based Compensation*, or SFAS 123. In the notes to our financial statements, we provide pro forma disclosures in accordance with SFAS 123. We account for transactions in which services are received from non-employees in exchange for equity instruments based on the fair value of such services received or of the equity instruments issued, whichever is more reliably measured, in accordance with SFAS 123 and the Emerging Issues Task Force, (EITF) Issue 96-18, *Accounting for Equity Instruments That Are Issued to Other than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*, or EITF 96-18.

Accounting for equity instruments granted or sold by us under APB 25, SFAS 123 and EITF 96-18 requires fair-value estimates of the equity instrument granted or sold. If our estimates of the fair value of these equity instruments are too high or too low, our expenses may be over- or understated.

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For equity instruments granted or sold in exchange for the receipt of goods or services, we estimate the fair value of the equity instruments based upon consideration of factors that we deem to be relevant at that time. Because shares of our common stock were not publicly traded prior to the corporate restructuring described in Note 2 to the financial statements above, market factors historically considered in valuing stock and stock option grants included comparative values of public companies discounted for the risk and limited liquidity provided for in the shares we are issuing; pricing of private sales of our convertible preferred stock; prior valuations of stock grants and the effect of events that occurred between the time of such grants; economic trends; and the comparative rights and preferences of the security being granted compared to the rights and preferences of our other outstanding equity.

Prior to our corporate restructuring, the fair value of our common stock was determined by our board of directors contemporaneously with the grant. In the absence of a public trading market for our common stock, our board of directors considered numerous objective and subjective factors in determining the fair value of our common stock. At the time of option grants and other stock issuances, our board of directors considered the liquidation preferences, dividend rights, voting control and anti-dilution protection attributable to our then-outstanding convertible preferred stock; the status of private and public financial markets; valuations of comparable private and public companies; the likelihood of achieving a liquidity event such as an initial public offering; our existing financial resources; our anticipated continuing operating losses and increased spending levels required to complete our clinical trials; dilution to common stockholders from anticipated future financings; and a general assessment of future business risks.

## **Results of Operations**

### *Three Months Ended September 30, 2005 and 2004*

*Revenue.* Revenue for the three months ended September 30, 2005 was \$12,584 compared to \$0 for the three months ended September 30, 2004 and represented the recognition of a prior year's deferred revenue on sales of bulk drug samples to facilitate research activities. This revenue represents recognition of the remaining installment due on bulk drug sample sales. In lieu of cash, we accepted research and development services as final payment.

*Research and Development.* Research and development expense for the three months ended September 30, 2005 was \$360,628 compared to \$48,511 for the three months ended September 30, 2004. Research and development expense consists of expenses 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 of facilities. The \$312,117, or 643%, increase in research and development expense was primarily due to increased funding of our preclinical, clinical and contract manufacturing activities, an increase in compensation costs due to an increase in headcount, and an increase in stock-based compensation. The closings of the private

placement transaction during the quarters ended June 30, 2005 and September 30, 2005 and the corporate restructuring that occurred during the quarter ended June 30, 2005 allowed us to engage outside consultants and organizations to further research, develop and test our product candidates.

*General and Administrative.* General and administrative expense for the three months ended September 30, 2005 was \$612,696 compared to \$142,178 for the three months ended September 30, 2004. General and administrative expense consists primarily of salaries and other related costs for personnel in executive, finance, investor relations, accounting, business development, and human resource functions. Other costs include facility costs not otherwise included in research and development expense, insurance, costs for public and investor relations and professional fees for legal and accounting services. The \$470,518, or 331%, increase in general and administrative expense was primarily due to increased costs associated with our periodic filing requirements and increases related to professional and consulting fees, public and investor relations and public company recordkeeping. As described in Note 2, we also recorded a \$200,000 expense during the three months ended September 30, 2005 relating to the late filing provision of the registration rights agreement associated with the sale of Units.

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*Interest Income.* Interest income for the three months ended September 30, 2005 was \$8,077 compared to \$0 for the three months ended September 30, 2004. The increase in interest income during the three months ended September 30, 2005 related to higher average cash balances in 2005, as a result of the financings described in Note 2, being placed in interest-bearing accounts.

*Interest Expense.* Interest expense for the three months ended September 30, 2005 was \$3,209 compared to \$53,917 for the three months ended September 30, 2004. The \$50,708, or 94%, decrease was due to lower average debt balances.

*Preferred Stock Deemed Dividend.* In the three months ended September 30, 2005 we recorded a deemed dividend to preferred stockholders of \$1,943,377. This amount represents the value attributed to the beneficial conversion feature of the Series A 8% Cumulative Convertible Preferred Stock issued during that period. The amount has been included in the calculation of net loss attributable to common stockholders for the three months ended September 30, 2005. There were no deemed dividends in the three months ended September 30, 2004.

*Nine Months Ended September 30, 2005 and 2004*

*Revenue.* Revenue for the nine months ended September 30, 2005 was \$12,584 compared to \$0 for the nine months ended September 30, 2004 and represented the recognition of a prior year's deferred revenue on sales of bulk drug samples to facilitate research activities. This revenue represents recognition of the remaining installment due on bulk drug sample sales. In lieu of cash, we accepted research and development services as final payment.

*Research and Development.* Research and development expense for the nine months ended September 30, 2005 was \$813,716 compared to \$223,588 for the nine months ended September 30, 2004. Research and development expense consists of expenses 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 of facilities. The \$590,128, or 264%, increase in research and development expense was primarily due to increased funding of our preclinical, clinical and contract manufacturing activities, an increase in compensation costs due to an increase in headcount, and an increase in stock-based compensation. The private placement transactions, corporate restructuring and issuance of promissory notes during the nine months ended September 30, 2005 allowed us to engage outside consultants and organizations to further research, develop and test our product candidates.

*General and Administrative.* General and administrative expense for the nine months ended September 30, 2005 was \$1,018,677 compared to \$370,017 for the nine months ended September 30, 2004. General and administrative expense consists primarily of salaries and other related costs for personnel in executive, finance, investor relations, accounting, business development, and human resource functions. Other costs include facility costs not otherwise included in research and development expense, insurance, costs for public and investor relations and professional fees for legal and accounting services. The \$648,660, or 175%, increase in general and administrative expense was primarily due to our periodic filing obligations and increases in professional and consulting fees, public and investor relations and public company recordkeeping. We also incurred additional legal and consulting costs during the nine months ended September 30, 2005 in translating and filing our European patent applications. As described in Note 2, we also recorded a \$200,000 expense during the nine months ended September 30, 2005 relating to the late filing provision of the registration rights agreement associated with the sale of Units.

*Consulting Revenue.* Consulting revenue for the nine months ended September 30, 2005 was \$0 compared to \$13,374 for the nine months ended September 30, 2004. Consulting revenue recorded during the nine months ended September 30, 2004 primarily related to one consulting engagement that ended during the quarter ended June 30, 2004.

*Interest Income.* Interest income for the nine months ended September 30, 2005 was \$9,693 compared to \$95 for the nine months ended September 30, 2004. The increase in interest income

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during the nine months ended September 30, 2005 over the comparable period in 2004 related to higher average cash balances in 2005, as a result of the financings described in Note 2, being placed in interest-bearing accounts.

*Interest Expense.* Interest expense for the nine months ended September 30, 2005 was \$109,102 compared to \$154,652 for the nine months ended September 30, 2004. The \$45,550, or 29%, decrease was due to lower average debt balances during the 2005 period.

*Gain on Forgiveness of Debt.* Gain on forgiveness of debt for the nine months ended September 30, 2005 was \$2,087,531 compared to \$0 for the nine months ended September 30, 2004. On May 26, 2005, we exchanged indebtedness of \$3,139,185 for 586,352 shares of our common stock with an aggregate deemed value of \$732,940 and \$318,714 in cash, which resulted in forgiveness of debt income of \$2,087,531.

*Restructuring Expense.* Restructuring expense for the nine months ended September 30, 2005 was \$2,521,118 compared to \$0 for the nine months ended September 30, 2004. On May 26, 2005, we revised an arrangement that requires us to pay future royalties, which resulted in the issuance of 2,016,894 shares of our common stock with an aggregate deemed value of \$2,521,118.

*Preferred Stock Deemed Dividend.* In the nine months ended September 30, 2005 we recorded a deemed dividend to preferred stockholders of \$1,943,377. This amount represents the value attributed to the beneficial conversion feature of the Series A 8% Cumulative Convertible Preferred Stock issued during that period. The amount has been included in the calculation of net loss attributable to common stockholders for the nine months ended September 30, 2005. There were no deemed dividends in the nine months ended September 30, 2004.

### **Liquidity and Capital Resources**

We have financed our operations since inception through the sale of equity securities and the issuance of debt. As of September 30, 2005, we had approximately \$4,830,000 in unrestricted cash and equivalents.

During the nine months ended September 30, 2005, cash of \$1,785,000 was used in operations, primarily due to a net loss of \$2,149,000, a \$2,088,000 non-cash gain attributable to the forgiveness of debt, a decrease in prepaid expenses and other current assets of \$51,000, and a decrease in accounts payable and accrued expenses of \$40,000, offset by stock-based compensation expense of \$168,000 and non-cash restructuring expenses of \$2,521,000.

During the nine months ended September 30, 2005, cash of \$223,000 was used in investing activities due to \$23,000 in purchases of property and equipment, an increase in restricted cash of \$195,000 and an increase in deposits of \$5,000.

During the nine months ended September 30, 2005, financing activities provided cash of \$6,828,000 consisting of net proceeds of \$2,680,000 from the sale of preferred stock, net proceeds of \$3,819,000 from the sale of units (each unit consisting of 20,000 shares of common stock and a warrant to purchase 10,000 shares of common stock), and \$850,000 from the issuance of promissory notes, partially offset by \$521,000 in payments on notes payable to stockholders and long-term debt. On October 3, 2005, we completed a second closing of our preferred stock financing and received net proceeds of \$184,000 from the sale of our preferred stock.

We believe that our available cash and cash equivalents will be sufficient to meet our working capital requirements, including operating losses, and capital expenditure requirements until September 2006, assuming that our business plan is implemented successfully.

However, we believe that we will need to raise additional capital within the next twelve months in order to support the planned growth of our business. 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

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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 timing, receipt, and amount of milestone and other payments, if any, from collaborators;

- 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; and
- our ability to establish and maintain additional collaborative arrangements.

### **Recently Issued Accounting Pronouncement**

On December 16, 2004, the Financial Accounting Standards Board issued SFAS 123 (revised 2004), referred to as SFAS 123R, *Share-Based Payment*, which is a revision of SFAS 123 (“SFAS 123R”). SFAS 123R supersedes APB 25 and amends SFAS No. 95, *Statement of Cash Flows*. Generally, the approach in SFAS 123R is similar to the approach described in SFAS 123, detailed below. However, SFAS 123R requires all share-based payments to employees, including grants of employee stock options, to be recognized in the statement of operations based on their fair values at the date of grant. Pro forma disclosure is no longer an alternative. In April 2005, the SEC delayed the effective date for adoption to no later than the beginning of the first fiscal year beginning after December 15, 2005. Early adoption will be permitted in periods in which financial statements have not yet been issued. We expect to adopt SFAS 123R on January 1, 2006, the commencement of our first quarter of fiscal 2006.

SFAS 123R permits public companies to adopt its requirements using one of two methods. A “modified prospective” is a method in which compensation cost is recognized beginning with the effective date (a) based on the requirements of SFAS 123R for all share-based payments granted after the effective date and (b) based on the requirements of SFAS 123 for all awards granted to employees prior to the effective date of SFAS 123R that remain unvested on the effective date. A “modified retrospective” is a method which includes the requirements of the modified prospective method described above, but also permits entities to restate based on the amounts previously recognized under SFAS 123 for purposes of pro forma disclosures either (a) all prior periods presented or (b) prior interim periods of the year of adoption. We have yet to determine which method to use in adopting SFAS 123R.

As permitted by SFAS 123, we currently account for share-based payments to employees using APB 25's intrinsic value method and, as such, generally recognize no compensation cost for employee stock options. Accordingly, the adoption of SFAS 123R's fair-value method may have a significant impact on our reported results of operations, although it will have no impact on our overall financial position. The impact of adoption of SFAS 123R cannot be predicted at this time because it will depend on levels of share-based payments granted in the future. However, had we adopted SFAS 123R in prior periods, the impact of that standard would have approximated the impact of SFAS 123 as described in the disclosure of pro forma net loss and net loss per share in Note 3 to our financial statements. We are currently evaluating the impact of the adoption of SFAS 123R on our financial position and results of operations, including the valuation methods and support for the assumptions that underlie the valuation of the awards.

### **Factors That May Affect Future Results**

*Our business involves a high degree of risk. If any of these risks, or other risks not presently known to us or that we currently believe are not significant, develops into an actual event, then our business, financial condition and results of operations could be adversely affected. If that happens, the market price of our common stock could decline.*

### **The Company may not have adequate funds to sustain its operations.**

The Company's independent registered public accounting firm has issued an opinion on the financial statements of the Company for the year ended December 31, 2004, which includes an explanatory paragraph expressing substantial doubt about the Company's ability to continue as a going concern. As of August 9, 2005, the Company had restructured or repaid substantially all of its debt and closed private placements of common stock and common stock purchase warrants that resulted in aggregate net proceeds of \$3,819,034 to the Company. On September 30, 2005, the Company sold 3,000 shares of its Series A 8% Cumulative Convertible Preferred Stock resulting in net proceeds of \$2,680,000. On October 3, 2005 the Company sold 200 shares of its Series A 8% Cumulative Convertible Preferred Stock resulting in net proceeds of \$184,000. Currently, the Company believes that it has available cash sufficient to meet its working capital requirements until September 2006, assuming its expense levels do not exceed its current plan. However, if the Company does not generate revenues or raise additional capital, it will not be able to sustain its operations at current levels beyond that date or earlier if expense levels increase.

**The failure to complete development of the Company's therapeutic technology, obtain government approvals, including required 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 the Company's ongoing business.**

The Company's research and development activities and the manufacture and marketing of the Company's 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 the Company's proposed products, the Company will have to demonstrate that the Company's 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, manufacture, 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, the Company must successfully research, develop, obtain regulatory approval for, manufacture, introduce, market and distribute the Company's technologies. For each drug utilizing oxidized glutathione-based compounds, including NOV-002 and NOV-205, the Company must successfully meet a number of critical developmental milestones including:

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

The time-frame necessary to achieve these developmental milestones may be long and uncertain, and the Company may not successfully complete these milestones for any of the Company's intended products in development.

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

- the uncertainties arising from the rapidly growing scientific aspects of drug therapies and potential treatments;

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- 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 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 the Company or the Company's clinical investigators do not follow the FDA's requirements for conducting clinical trials. If the Company is unable to receive clearance to conduct clinical trials or the trials are halted by the FDA, the Company would not be able to achieve any revenue from such product, as it is illegal to sell any drug or medical device for human consumption 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 the Company's business. The Company's clinical trials may not demonstrate sufficient levels of safety and efficacy necessary to obtain the requisite regulatory approvals for the Company's drugs, and thus the Company's proposed drugs may not be approved for marketing.

The Company may encounter delays or rejections based upon 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. The Company may encounter similar delays in foreign countries. Sales of the Company's 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. The Company 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 the Company requests.

Even if the Company does ultimately receive FDA approval for any of its 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 the Company from developing and commercializing its drugs and subject it to enforcement action.

**The Company's drugs or technology may not gain FDA approval in clinical trials or be effective as a therapeutic agent which could affect the Company's future profitability and prospects.**

In order to obtain regulatory approvals, the Company must demonstrate that each drug is safe and effective for use in humans and functions as a therapeutic against the effects of disease or other physiological response. To date, studies conducted in Russia involving the Company's NOV-002 and NOV-205 products have shown promising results and, in fact, NOV-002 has been approved for use there as an immunostimulant in combination with chemotherapy and antimicrobial therapy and indications such as tuberculosis, and NOV-205 has been approved there as a mono-therapy agent for the treatment of hepatitis B and C. Moreover, a U.S.-based Phase 1/2 clinical study involving 44 non-small cell lung cancer patients provided a favorable outcome and as a result the Company

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anticipates being able to commence a Phase 3 study of NOV-002 for non-small cell lung cancer in 2006. The Company also anticipates completing a Phase 2 trial for NOV-002 for ovarian cancer in early 2007. The Company further intends to file an Investigational New Drug Application "IND" for NOV-205 for hepatitis C by year-end 2005 and to complete a Phase 2 study in early 2007. There can be no assurance, however, that the Company can demonstrate that these products are safe or effective in advanced clinical trials. The Company is also not able to give assurances that the results of the tests already conducted can be repeated or that further testing will support the Company's applications for regulatory approval. As a result, the Company's drug and technology research program may be curtailed, redirected or eliminated at any time.

**There is no guarantee that the Company will ever generate revenue or become profitable even if one or more of the Company's drugs are approved for commercialization.**

The Company expects to incur increasing operating losses over the next several years as it incurs increasing costs for research and development and clinical trials. The Company's ability to generate revenue and achieve profitability depends upon the Company's ability, alone or with others, to complete the development of the Company's proposed products, obtain the required regulatory approvals and manufacture, market and sell the Company's proposed products. Development is costly and requires significant investment. In addition, if the Company chooses to license or obtain the assignment of rights to additional drugs, the license fees for such drugs may increase the Company's costs.

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

**The Company relies solely on research and manufacturing facilities at various universities, hospitals contract research organizations and contract manufacturers for all of its research, development, and manufacturing, which could be materially delayed should the Company lose access to those facilities.**

At the present time, the Company has no research, development or manufacturing facilities of its own. The Company is entirely dependent on contracting with third parties to use their facilities to conduct research, development and manufacturing. The Company's inability to have the facilities to conduct research, development and manufacturing may delay or impair the Company's ability to gain FDA approval and commercialization of the Company's drug delivery technology and products.

The Company currently maintains a good working relationship with such contractors. Should the situation change and the Company is required to relocate these activities on short notice, the Company does not currently have an alternate facility where the Company could relocate its research, development and/or manufacturing activities. The cost and time to establish or locate an alternative research, development and manufacturing facility to develop the Company's technology would be substantial and would delay gaining FDA approval and commercializing the Company's products.

**The Company is dependent on the Company's collaborative agreements for the development of the Company's technologies and business development, which exposes the Company to the risk of reliance on the viability of third parties.**

In conducting the Company's research, development and manufacturing activities, the Company relies and expects 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 the Company's research, development and manufacturing activities including the Company's anticipated clinical trials.

The Company may rely on third-party contract research organizations, service providers and suppliers to support development and clinical testing of the Company's 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 the Company's products, increase the Company's expenses and materially harm the Company's business, financial condition and results of operations.

**The Company is exposed to product liability, clinical and preclinical liability risks which could create a substantial financial burden should the Company be sued, because the Company does not currently have product liability insurance above and beyond the Company's general insurance coverage.**

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

Although the Company maintained product liability insurance coverage during the time of the NOV-002 Phase 1/2 clinical study, the Company does not currently have any product liability insurance or other liability insurance relating to clinical trials or any products or compounds. Currently, no clinical trials are ongoing. The Company cannot give assurances that it will be able to obtain or maintain adequate product liability insurance on acceptable terms, if at all, or that such insurance will provide adequate coverage against the Company's potential liabilities. Furthermore, the Company's current and potential partners with whom the Company has collaborative agreements or the Company's future licensees may not be willing to indemnify the Company 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 the Company could have a material adverse effect on the Company's business, financial condition and results of operations.

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

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

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

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

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

The Company may be exposed to future litigation by third parties based on claims that the Company's technologies, products or activities infringe the intellectual property rights of others or that the Company has 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 the Company, whether or not valid, could result in substantial costs, could place a significant strain on the Company's financial and managerial resources and could harm the Company's reputation. Most of the Company's license agreements would likely require that the Company pay the costs associated with defending this type of litigation. In addition, intellectual property litigation or claims could force the Company to do one or more of the following:

- cease selling, incorporating or using any of the Company's technologies and/or products that incorporate the challenged intellectual property, which would adversely affect the Company's 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 the Company's products, which would be costly and time-consuming.

**If the Company is unable to adequately protect or enforce the Company's rights to intellectual property or secure rights to third-party patents, the Company may lose valuable rights, experience reduced market share, assuming any, or incur costly litigation to protect such rights.**

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

The patent positions of biotechnology and pharmaceutical companies, including the Company, 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, the Company's patent applications and any issued and licensed patents may not provide protection against competitive technologies or may be held invalid if challenged or circumvented. The Company's competitors may also independently develop products similar to the Company's or design around or otherwise circumvent patents issued or licensed to the Company. In addition, the laws of some foreign countries may not protect the Company's proprietary rights to the same extent as U.S. law.

The Company also relies upon trade secrets, technical know-how and continuing technological innovation to develop and maintain the Company's competitive position. The Company generally requires the Company's employees, consultants, advisors and collaborators to execute appropriate confidentiality and assignment-of-inventions agreements. The Company's competitors may independently develop substantially equivalent proprietary information and techniques, reverse engineer the Company's information and techniques, or otherwise gain access to the Company's proprietary technology. The Company may be unable to meaningfully protect the Company's rights in trade secrets, technical know-how and other non-patented technology.

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

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

**The Company has limited manufacturing experience and if the Company's products are approved the Company 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.**

The Company remains in the research and development and clinical and pre-clinical trial phase of product commercialization. Accordingly, if the Company's products are approved for commercial sale, the Company will need to establish the capability to commercially manufacture the Company's product(s) in accordance with FDA and other regulatory requirements. The Company has limited experience in establishing, supervising and conducting commercial manufacturing. If the Company fails to adequately establish, supervise and conduct all aspects of the manufacturing processes, the Company may not be able to commercialize its products.

The Company presently plans to rely on third-party contractors to manufacture its products. This may expose the Company 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 the Company's limited marketing, sales and distribution experience, the Company may be unsuccessful in its efforts to sell its products, enter into relationships with third parties or develop a direct sales organization.**

The Company has not yet had to establish marketing, sales or distribution capabilities for its proposed products. Until such time as the Company's products are further along in the regulatory process, the Company will not devote any meaningful time and resources to this effort. At the appropriate time, the Company intends to enter into agreements with third parties to sell its products or the Company may develop its own sales and marketing force. The Company 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 the Company's competitors.

If the Company does not enter into relationships with third parties for the sale and marketing of the Company's products, the Company will need to develop the Company's own sales and marketing capabilities. The Company has limited experience in developing, training or managing a sales force. If the Company chooses to establish a direct sales force, the Company may incur substantial additional expenses in developing, training and managing such an organization. The Company 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, the Company will compete with many other companies that currently have extensive marketing and sales operations. The Company's marketing and sales efforts may be unable to compete against these other companies. The Company may be unable to establish a sufficient sales and marketing organization on a timely basis, if at all.

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

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

If the Company fails to develop sales, marketing and distribution channels, the Company would experience delays in product sales and incur increased costs, which would harm the Company's financial results.

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**If the Company is unable to convince physicians as to the benefits of the Company's intended products, the Company may incur delays or additional expense in the Company's attempt to establish market acceptance.**

Broad use of the Company's 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 the Company's products. The Company may be unable to timely educate physicians regarding the Company's intended products in sufficient numbers to achieve the Company's marketing plans or to achieve product acceptance. Any delay in physician education may materially delay or reduce demand for the Company's products. In addition, the Company may expend significant funds towards physician education before any acceptance or demand for the Company's products is created, if at all.

**The Company may have difficulty raising needed capital in the future because of the Company's limited operating history and business risks associated with the Company.**

The Company currently generates no revenue from its proposed products or otherwise. The Company does not know when this will change. The Company has expended and will continue to expend substantial funds in the research, development and clinical and pre-clinical testing of its drug compounds. The Company 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 its products. Additional funds may not be available on acceptable terms, if at all. If adequate funds are unavailable from any available source, the Company may have to delay, reduce the scope of or eliminate one or more of the Company's research or development programs or product launches or marketing efforts, which may materially harm the Company's business, financial condition and results of operations.

The Company's 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 the Company's 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 the Company's ability to sell the Company's drugs;
- costs involved in establishing manufacturing capabilities for clinical trial and commercial quantities of the Company's drugs;
- competing technological and market developments;
- market acceptance of the Company's products;
- costs for recruiting and retaining management, employees and consultants; and
- costs for training physicians.

The Company may consume available resources more rapidly than currently anticipated, resulting in the need for additional funding. The Company may seek to raise any necessary additional funds through the exercising of warrants, equity or debt financings, collaborative arrangements with corporate partners or other sources, which may be dilutive to existing stockholders or otherwise have a material effect on the Company's current or future business prospects. In addition, in the event that additional funds are obtained through arrangements with collaborative partners or other sources, the Company may have to relinquish economic and/or proprietary rights to some of the Company's

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technologies or products under development that the Company would otherwise seek to develop or commercialize by itself. If adequate funds are not available, the Company may be required to significantly reduce or refocus its development efforts with regard to its drug compounds.

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

The pharmaceutical and biotechnology industries are subject to rapid and substantial technological change. Developments by others may render the Company's technologies and intended products noncompetitive or obsolete, or the Company 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. Many of these entities have significantly greater research and development capabilities and budgets than the Company does, as well as substantially more marketing, manufacturing, financial and managerial resources. These entities represent significant competition for the Company. Acquisitions of, or investments in, competing pharmaceutical or biotechnology companies by large corporations could increase such competitors' financial, marketing, manufacturing and other resources.

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

The potential widespread acceptance of therapies that are alternatives to the Company's may limit market acceptance of the Company's products even if commercialized. Many of the Company's 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 the Company's technologies and products to receive widespread acceptance if commercialized.

**If users of the Company's products are unable to obtain adequate reimbursement from third-party payers, or if new restrictive legislation is adopted, market acceptance of the Company's products may be limited and the Company 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 the Company's future revenues and profitability, and the future revenues and profitability of the Company's 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 health care reform, the cost of prescription pharmaceuticals and on the reform of the Medicare and Medicaid systems. While the Company cannot predict whether any such legislative or regulatory proposals will be adopted, the announcement or adoption of such proposals could materially harm the Company's business, financial condition and results of operations.

The Company's ability to commercialize its products will depend in part on the extent to which appropriate reimbursement levels for the cost of its 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, which could control or significantly influence the purchase of health care 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 the Company's drugs. The cost containment measures that health care payers and providers are instituting and the effect of any health care reform could materially harm the Company's ability to operate profitably.

**The Company depends upon key personnel who may terminate their employment with the Company at any time, and the Company would need to hire additional qualified personnel.**

The Company's success will depend to a significant degree upon the continued services of key management and advisors of the Company. There can be no assurance that these individuals will continue to provide service to the Company. In addition, the Company's success will depend on its ability to attract and retain other highly skilled personnel. The Company may be unable to recruit such personnel on a timely basis, if at all. The Company's management and other employees may voluntarily terminate their employment with the Company 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 the Company's products, loss of sales and diversion of management resources.

**Item 3. Controls and Procedures**

In October 2006, our current 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, 2005. 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 our current evaluation of our disclosure controls and procedures as of September 30, 2005, our Chief Executive Officer and our Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were not effective because of the material weakness discussed below.

**Identification of a Material Weakness**

A material weakness is a significant deficiency, or combination of significant deficiencies, that results in more than a remote likelihood that a material misstatement of the annual or interim financial statements will not be prevented or detected.

In August 2006, our recently hired Director of Finance and Controller began an internal review of the terms associated with our historical private placements of securities, during which the Director of Finance and Controller, in consultation with management, determined that the intrinsic value associated with the beneficial conversion feature ("BCF") of the Company's Series A 8% Cumulative Convertible Preferred Stock issued on September 30, 2005 and October 3, 2005 had not been properly presented as a deemed (non-cash) dividend nor deducted from net loss in determining net loss attributable to common stockholders for the three- and nine-month periods ended September 30, 2005 and the fiscal year ended December 31, 2005 (the "Relevant Periods") in our Statements of Operations in accordance with generally accepted accounting principles. Based on the results of this internal review, on October 18, 2006, our management concluded that our audited financial statements and our unaudited financial statements and financial information for the Relevant Periods should be

restated in order to reflect a deemed (non-cash) dividend associated with the BCF of the Series A 8% Cumulative Convertible Preferred Stock. As a result of the restatement described above, our management has determined that a material weakness existed in the Company's internal controls over financial reporting with respect to the identification of and accounting for the beneficial conversion feature of the preferred stock financing transaction. Due to this material weakness in internal control over financial reporting, our Chief Executive Officer and our Chief Financial Officer concluded that, as of September 30, 2005, our disclosure controls and procedures were not effective.

#### **Remediation of Material Weakness in Internal Control over Financial Reporting**

In the fourth quarter of 2005 we identified the need to establish the full-time position of Director of Finance. At that time, we began discussions regarding permanent employment with a consultant who had provided part-time finance and accounting services to us for several years. Over the course of the next two months, this individual worked to complete outstanding consulting engagements with a view to becoming a full-time Novelos employee during the first quarter of 2006. In February 2006 it became apparent to us that this individual would be unable to accept this full-time role. We then renewed our search and upgraded the required qualifications for a suitable candidate. In April 2006 we identified a candidate who is a CPA with extensive experience at a "big four" public accounting firm as well as substantial public company experience at the management level in the areas of finance and accounting, including the accounting for and reporting of complex financial transactions. In May 2006, the candidate began performing consulting services for us on a part-time basis and in June 2006 the candidate accepted the position of Director of Finance and Controller. Shortly after beginning employment, this individual began an internal review of our historical financing transactions. It was during the course of this review that the error requiring the restatement was discovered. The Director of Finance and Controller is performing a major role in ensuring the accuracy and completeness of our financial reporting and the effectiveness of our disclosure controls and procedures. We believe that the addition of this individual in this key position has remediated the material weakness in internal control over financial reporting described above.

#### **Changes in Internal Control**

There were no changes in our internal control over financial reporting during the third quarter ended September 30, 2005 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. The change described above occurred subsequent to the fourth quarter of fiscal 2005.

#### **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 upon 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.

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## **PART II. OTHER INFORMATION**

### ***Item 1. Legal Proceedings***

None.

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

None.

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

None.

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

None.

### ***Item 5. Other Information***

None.

### ***Item 6. Exhibits***



Exhibit No.	Description	Form		Exhibit No.
		10-QSB/A	Form Filing Date	
2.1	Agreement and plan of merger among Common Horizons, Inc., Nove Acquisition, Inc. and Novelos Therapeutics, Inc. dated May 26, 2005	8-K	June 2, 2005	99.2
2.2	Agreement and plan of merger between Common Horizons and Novelos Therapeutics, Inc. dated June 7, 2005	10-QSB	August 15, 2005	2.2
3.1	Certificate of Incorporation	8-K	June 17, 2005	1
3.2	Certificate of Designations of Series A cumulative convertible preferred stock	8-K	October 3, 2005	99.2
3.3	By-Laws	8-K	June 17, 2005	2
10.1	Employment agreement with Christopher J. Pazoles dated July 15, 2005	10-QSB	August 15, 2005	10.4
10.2	Form of subscription agreement dated September 30, 2005	8-K	October 3, 2005	99.1
10.3	Form of Class A common stock purchase warrant dated September 30, 2005	8-K	October 3, 2005	99.3
10.4	Form of Share Escrow Agreement	8-K	November 3, 2005	10.3
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 1, 2006

By: /s/ Harry S. Palmin

Harry S. Palmin  
President, Chief Executive Officer

Exhibit No.	Description	Filed with this Form 10-QSB/A	Incorporated by Reference		Exhibit No.
			Form	Filing Date	
2.1	Agreement and plan of merger among Common Horizons, Inc., Nove Acquisition, Inc. and Novelos Therapeutics, Inc. dated May 26, 2005		8-K	June 2, 2005	99.2
2.2	Agreement and plan of merger between Common Horizons and Novelos Therapeutics, Inc. dated June 7, 2005		10-QSB	August 15, 2005	2.2
3.1	Certificate of Incorporation		8-K	June 17, 2005	1
3.2	Certificate of Designations of Series A cumulative convertible preferred stock		8-K	October 3, 2005	99.2
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10.1	Employment agreement with Christopher J. Pazoles dated July 15, 2005		10-QSB	August 15, 2005	10.4
10.2	Form of subscription agreement dated September 30, 2005		8-K	October 3, 2005	99.1
10.3	Form of Class A common stock purchase warrant dated September 30, 2005		8-K	October 3, 2005	99.3
10.4	Form of Share Escrow Agreement		8-K	November 3, 2005	10.3
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			

**CERTIFICATION**

I, HARRY S. PALMIN, certify that:

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

Date: November 1, 2006

By: /s/ Harry S. Palmin  
Harry S. Palmin

President, Chief Executive Officer

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**CERTIFICATION**

I, GEORGE R. VAUGHN, certify that:

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

Date: November 1, 2006

By: /s/ George R. Vaughn

George R. Vaughn

Chief Financial Officer

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

In connection with the Quarterly Report on Form 10-QSB/A of Novelos Therapeutics, Inc., (the “Company”) for the quarter ended September 30, 2005, as filed with the Securities and Exchange Commission on the date hereof (the “Report”), the undersigned chief executive officer of the Company certifies, to his best knowledge and belief, pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Harry S. Palmin

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Harry S. Palmin  
President, Chief Executive Officer

Date: November 1, 2006

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

In connection with the Quarterly Report on Form 10-QSB/A of Novelos Therapeutics, Inc., (the “Company”) for the quarter ended September 30, 2005, as filed with the Securities and Exchange Commission on the date hereof (the “Report”), the undersigned chief financial officer of the Company certifies, to his best knowledge and belief, pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ George R. Vaughn

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George R. Vaughn  
Chief Financial Officer

Date: November 1, 2006

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