

# CELLECTAR BIOSCIENCES, INC.

## FORM 10-K (Annual Report)

Filed 03/30/10 for the Period Ending 12/31/09

Address	3301 AGRICULTURE DRIVE MADISON, WI 53716
Telephone	617-244-1616
CIK	0001279704
Symbol	CLRB
SIC Code	2834 - Pharmaceutical Preparations
Industry	Biotechnology & Drugs
Sector	Healthcare
Fiscal Year	12/31

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

FORM 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the Fiscal Year Ended: December 31, 2009

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

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

Commission File Number 333-119366

**NOVELOS THERAPEUTICS, INC.**

( Exact name of Registrant as specified in its Charter )

**Delaware**

( State or other jurisdiction  
of incorporation or organization )

**04-3321804**

( I.R.S. Employer Identification No. )

**One Gateway Center, Suite 504**

**Newton, Massachusetts 02458**

( Address of principal executive offices and zip code )

Registrant's telephone number: ( 617 ) 244-1616

Securities registered pursuant to Section 12(b) of the Act:

**Title of Class**

None

**Name of each exchange on which registered**

Not Applicable

Securities Registered pursuant to Section 12(g) of the Act:

**None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes  No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Exchange Act. Yes  No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes  No

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

(Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes  No

The aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold, or the average bid and asked price of such common equity, as of June 30, 2009 was \$39,602,244.

As of March 23, 2010 there were 90,385,939 shares of the registrant's common stock outstanding.

---

---

---

NOVELOS THERAPEUTICS, INC.

FORM 10-K

TABLE OF CONTENTS

<b>PART I</b>		
Item 1.	Business	2
Item 1A.	Risk Factors	10
Item 2.	Properties	22
Item 3.	Legal Proceedings	22
<b>PART II</b>		
Item 4.	Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	22
Item 5.	Management’s Discussion and Analysis of Financial Condition and Results of Operations	25
Item 6.	Financial Statements	31
Item 7.	Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	57
Item 8A.	Controls and Procedures	57
Item 8B.	Other Information	58
<b>PART III</b>		
Item 9.	Directors, Executive Officers, and Corporate Governance	59
Item 10.	Executive Compensation	62
Item 11.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	65
Item 12.	Certain Relationships and Related Transactions, and Director Independence	68
Item 13.	Principal Accounting Fees and Services	69
<b>PART IV</b>		
Item 14.	Exhibits	70

---

*This annual report on Form 10-K contains forward-looking statements, which involve risks and uncertainties, such as our plans, objectives, expectations and intentions. You can identify these statements by our use of words such as “may,” “expect,” “believe,” “anticipate,” “intend,” “could,” “estimate,” “continue,” “plans,” or their negatives or cognates. Some of these statements include discussions regarding our future business strategy and our ability to generate revenue, income and cash flow. We wish to caution the reader that all forward-looking statements contained in this annual report on Form 10-K are only estimates and predictions. Our actual results could differ materially from those anticipated as a result of risks facing us or actual events differing from the assumptions underlying such forward-looking statements. Readers are cautioned not to place undue reliance on any forward-looking statements contained in this annual report on Form 10-K. We will not update these forward-looking statements unless the securities laws and regulations require us to do so.*

---

This annual report on Form 10-K contains trademarks and service marks of Novelos Therapeutics, Inc. Unless otherwise provided in this annual report on Form 10-K, trademarks identified by <sup>TM</sup> are trademarks of Novelos Therapeutics, Inc. All other trademarks are the properties of their respective owners.

---

## PART I

### Item 1. Business

#### Overview

We are a biopharmaceutical company focused on developing and commercializing oxidized glutathione-based compounds for the treatment of cancer and hepatitis. We are seeking to build a pipeline through licensing or acquiring clinical stage compounds or technologies for oncology indications.

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

From November 2006 through January 2010, we conducted a Phase 3 trial of NOV-002 plus first-line chemotherapy in advanced non-small cell lung cancer (“NSCLC”) following three Phase 2 trials (two conducted in Russia and one conducted by us in the U.S.) that had demonstrated clinical activity and safety. The Phase 3 trial enrolled 903 patients, 452 of whom received NOV-002. In February 2010, we announced that the primary endpoint of improvement in overall survival compared to first-line chemotherapy alone was not met in this pivotal Phase 3 trial. Following evaluation of the detailed trial data, we announced in March 2010 that the secondary endpoints also were not met in the trial and that adding NOV-002 to paclitaxel and carboplatin chemotherapy was not statistically or meaningfully different in terms of efficacy-related endpoints or recovery from chemotherapy toxicity versus chemotherapy alone. However, NOV-002 was safe and did not add to the overall toxicity of chemotherapy. Based on the results from the Phase 3 trial, we have determined to discontinue development of NOV-002 for NSCLC in combination with first-line paclitaxel and carboplatin chemotherapy.

NOV-002 is being developed to treat early-stage breast cancer. In June 2007 we commenced enrollment in a U.S. Phase 2 neoadjuvant breast cancer trial, which is ongoing at The University of Miami to evaluate the ability of NOV-002 to enhance the effectiveness of chemotherapy in HER-2 negative patients. An interim analysis of the trial was presented at the San Antonio Breast Cancer Symposium in December 2008. Six pathologic complete responses (“pCR”) occurred in the first 15 women (40%) who completed chemotherapy and underwent surgery, which is a much higher rate than the historical control of less than 20% pCR in this patient population. Patients experienced decreased hematologic toxicities. We expect to present results from this trial in the third quarter of 2010.

NOV-002 is also being developed to treat chemotherapy-resistant ovarian cancer. In a U.S. Phase 2 chemotherapy-resistant ovarian cancer trial at Massachusetts General Hospital and Dana-Farber Cancer Institute from July 2006 through May 2008, NOV-002, in combination with carboplatin, slowed progression of the disease in 60% of evaluable patients (nine out of 15 women). The median progression-free survival was 15.4 weeks, almost double the historical control of eight weeks. Furthermore, patients experienced decreased hematologic toxicities. These results were presented at the American Society of Clinical Oncology in May 2008.

NOV-205, our second glutathione-based compound, acts as a hepatoprotective agent with immunomodulating and anti-inflammatory properties. NOV-205 has been administered to approximately 200 hepatitis patients in clinical trials and is in Phase 2 development for chronic hepatitis C non-responders. An Investigational New Drug Application (“IND”) for NOV-205 as a monotherapy for chronic hepatitis C was accepted by the FDA in 2006. A U.S. Phase 1b clinical trial with NOV-205 in patients who previously failed treatment with pegylated interferon plus ribavirin was completed in December 2007. Based on favorable safety results of that trial, in March 2010 we initiated a multi-center U.S. Phase 2 trial evaluating NOV-205 as monotherapy in up to 40 chronic hepatitis C genotype 1 patients who previously failed treatment with pegylated interferon plus ribavirin. We expect to have preliminary results from this longer duration, proof-of-concept trial in the third quarter of 2010.

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

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

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

## **Corporate History**

We were incorporated in June 1996 as AVAM International, Inc. In October 1998, Novelos Therapeutics, Inc., a newly incorporated entity, merged into AVAM, and the name of AVAM was changed to Novelos Therapeutics, Inc. In 2005, we completed a two-step reverse merger with Common Horizons, Inc., and its wholly-owned subsidiary Nove Acquisition, Inc. Following the merger, the surviving corporation was Novelos Therapeutics, Inc.

## **Business Strategy**

Our overall objective is to develop and commercialize pharmaceuticals for the treatment of cancer and other life-threatening diseases, such as hepatitis. To date, we have exploited our intellectual property portfolio based on oxidized glutathione, resulting in the development of our lead compound, NOV-002, for cancers and our second product candidate, NOV-205, for hepatitis. Although we experienced negative results with NOV-002 in our Phase 3 trial in NSCLC, we are continuing NOV-002 Phase 2 development in other cancer indications. In addition, we are seeking to build a pipeline through licensing or acquiring clinical stage compounds or technologies for oncology indications.

## **Technology Overview**

NOV-002 and NOV-205 are both proprietary formulations of oxidized glutathione (GSSG). NOV-002 is a formulation of GSSG in a 1000:1 molar ratio with cisplatin, which increases the bioavailability of GSSG *in vivo*. NOV-205 is a formulation of GSSG in a 1:1 molar ratio with inosine, a known anti-inflammatory agent.

In some clinical trials conducted to date, relative to standard chemotherapy alone, administration of NOV-002 in combination with standard chemotherapy has resulted in both increased efficacy (longer survival or improved anti-tumor response) and mitigation of chemotherapy-induced toxicity (e.g., hematological toxicity). Non-clinical studies suggest that this clinical profile may be due to multiple effects exerted on both tumor cells and normal cells resulting from the modulation of the cellular oxidation/reduction redox state. These results were not demonstrated in our Phase 3 trial in advanced NSCLC in combination with paclitaxel and carboplatin.

Studies published between 2005 and 2009 (Free Radical Research, June 2005; Current Opinion on Pharmacology, 2007; Free Radical Biology and Medicine, 2007; and Trends in Biochemical Sciences, 2009) have demonstrated that the glutathione system is not only involved in cell detoxification (via reduced glutathione) but is also an important regulator of protein and cell function (via GSSG). An increasing number of cell processes and proteins have been shown to be regulated by their redox environment. Specifically, under oxidative conditions, or simply in the presence of GSSG, they undergo a structural change termed glutathionylation whereby a molecule of glutathione is covalently attached to reactive thiol groups in the protein. Glutathionylation modulates protein function, either increasing or decreasing it, and as a reversible modification serves as a regulatory mechanism analogous to protein phosphorylation/dephosphorylation.

*In vitro* and *in vivo* experiments have shown:

- When added to cells, NOV-002 results in generation of a mild and transient oxidative signal at the cell surface and intracellularly, glutathionylation of redox-sensitive proteins and a range of biochemical/molecular effects that are dependent on cell type and status, leading to alteration of cell functions.
- In tumor cells, redox modulation by NOV-002 has been shown to decrease the rate of tumor cell proliferation. For example, in a human ovarian tumor cell line (SKOV3), NOV-002 induced an intracellular oxidative signal (as evidenced by generation of reactive oxygen species), increased levels of active (i.e. phosphorylated) c-Jun N-terminal kinases (a component of cell signaling pathways regulating proliferation) and decreased the rate of tumor cell proliferation. This was also accompanied by increased tumor cell apoptosis.
- Also in tumor cells, NOV-002 decreased signaling through a redox-regulated pathway known to control cell migration, invasiveness and metastasis and inhibited invasiveness of a variety of human tumor cell types.
- In animal tumor models, NOV-002 has been shown to increase anti-tumor immune responsiveness and to inhibit tumor growth and enhance survival when combined with chemotherapy.
  - o In a mouse model of colon cancer, NOV-002 significantly increased anti-tumor response and survival when combined with chemotherapy (cyclophosphamide).
  - o In a mouse model of melanoma where animals were treated with a form of immunotherapy (adoptive T cell transfer) together with chemotherapy (cyclophosphamide) the addition of NOV-002 significantly reduced the rate of tumor growth and increased survival.
  - o In a mouse ovarian cancer model, animals treated with NOV-002 alone showed a significantly increased tumor-specific cellular immune response (interferon gamma production) compared to control mice treated with a saline vehicle.
- In contrast to these suppressive effects on tumors, similar redox modulation, protein glutathionylation and cell signaling pathway effects from NOV-002 treatment resulted in increased proliferation in myeloid lineage cells such as HL-60 cells. Furthermore, *in vivo*, NOV-002 treatment of chemosuppressed mice (using cyclophosphamide) led to increased total bone marrow cell number and proliferation of multi-lineage bone marrow progenitor cells (i.e., progenitor cells for white cells, red cells and platelets).

NOV-205 and NOV-002 have in common GSSG as an active pharmaceutical ingredient. Clinical and non-clinical results indicate that NOV-205 also possesses immunomodulatory activity, and in animal models of chemical- and viral-induced hepatic injury, NOV-205 increased survival. In addition, based on literature reports, the inosine component of NOV-205 is believed to contribute anti-inflammatory activity to its pharmacological profile.

Although these pre-clinical findings with NOV-002 and NOV-205 demonstrated favorable biological signals in cell and animal models, there can be no assurance that pre-clinical findings are predictive of clinical trial results. While some promising pre-clinical findings may have been supported in Phase 2 trials conducted to date, they were not supported in our recently concluded Phase 3 clinical trial with NOV-002.

## **Products in Development**

### ***NOV-002***

NOV-002 is an injectable small-molecule compound based on a proprietary formulation of oxidized glutathione, or “GSSG” in a 1000:1 ratio of GSSG with cisplatin, which improves the bioavailability of NOV-002 *in vivo*. NOV-002 is believed to act as a chemopotentiator and a chemoprotectant by regulating redox-sensitive cell signaling pathways. NOV-002 has been administered to approximately 1,000 cancer patients in clinical trials. NOV-002 has an extensive safety database and has been shown to be well-tolerated. Moreover, NOV-002 can be distinguished from other pharmaceuticals on the market or in development because, in several clinical trials, NOV-002 displayed a unique profile of safety, potentiation of chemotherapy (increased survival rates and/or better anti-tumor effects) and improved recovery from chemotherapy toxicity. This profile was not observed in the recently concluded Phase 3 trial in NSCLC. Based on the totality of available clinical trial results, NOV-002 does not appear to be chemotherapy or tumor specific, though it may prove to be more effective in some solid tumor indications than others and/or in combination with certain chemotherapies across these indications.

NOV-002 is currently being developed for use in combination with standard of care chemotherapies for the treatment of solid tumors.

### ***NOV-002 in NSCLC***

We announced in February 2010 that the primary endpoint of improvement in overall survival was not met in our pivotal Phase 3 trial of NOV-002 in advanced NSCLC. Following evaluation of the detailed trial data, we announced in March 2010 that the secondary endpoints also were not met in the trial. Adding NOV-002 to paclitaxel and carboplatin chemotherapy was not statistically or meaningfully different in terms of efficacy-related endpoints or recovery from chemotherapy toxicity versus chemotherapy alone. NOV-002 was safe, as it did not add to the overall toxicity of chemotherapy. We expect to present detailed results of this Phase 3 trial at the 2010 annual meeting of the American Society of Clinical Oncology (ASCO) in June 2010.

This randomized, controlled, open-label Phase 3 trial, was conducted under a Special Protocol Assessment and Fast Track designation, enrolled 903 patients with stage IIIb/IV NSCLC, and included all histological subtypes. The trial, conducted across approximately 100 clinical sites in 12 countries, evaluated NOV-002 in combination with first-line paclitaxel and carboplatin chemotherapy (in 452 patients) versus paclitaxel and carboplatin alone. The primary efficacy endpoint of the trial was improvement in overall survival. The secondary endpoints included progression-free survival, response rate and duration of response, recovery from chemotherapy-induced myelosuppression, determination of immunomodulation, quality of life and safety. Based on the results from the Phase 3 trial, we have determined to discontinue development of NOV-002 for NSCLC in combination with first-line paclitaxel and carboplatin chemotherapy.

We commenced the Phase 3 trial in November 2006 following three previously conducted Phase 2 trials (two conducted in Russia and one conducted by us in the U.S) that had demonstrated clinical activity and safety of NOV-002 in combination with first-line chemotherapy in advanced NSCLC.

Advanced NSCLC is an indication which is very difficult to treat. Platinum-based chemotherapy regimens are standard first-line treatment for advanced NSCLC patients who are subject to serious chemotherapy-induced adverse effects. According to results of 12 Phase 3 clinical trials published from 2001-2008, the one-year survival rate for patients receiving paclitaxel and carboplatin first-line therapy was approximately 40%, the weighted average for median survival was 9.7 months and the objective tumor response (defined as greater than 30% tumor shrinkage) rate was about 27%. Overall, fewer than 5% of advanced non-small cell lung cancer patients survive five years following diagnosis. Improving on the standard of care in unselected advanced NSCLC remains challenging and elusive. Approximately 20 Phase 3 first-line trials have failed in NSCLC, including some drugs that are on the market for other cancer indications. The compounds that went into these Phase 3 trials had promising Phase 2 results. Furthermore, the two compounds that did demonstrate a statistically significant improvement in survival in advanced NSCLC when added to first-line chemotherapy, did not succeed when combined with other first-line chemotherapy agents.

### ***NOV-002 in Neoadjuvant Treatment of Breast Cancer***

We are developing NOV-002 to treat early-stage breast cancer in combination with chemotherapy. Breast cancer remains a serious public health concern throughout the world. According to the American Cancer Society, approximately 192,000 women in the U.S. were expected to be diagnosed with breast cancer in 2009, and approximately 41,000 were expected to die from the disease. Neoadjuvant or preoperative systemic chemotherapy is commonly employed in patients with locally advanced stage-III breast cancer and in some patients with stage-II tumors. Administration of neoadjuvant chemotherapy reduces tumor size, thus enabling breast conservation surgery in patients who otherwise would require a mastectomy. Furthermore, several studies have shown that pathologic complete response (pCR) following neoadjuvant chemotherapy is associated with a significantly higher probability of long-term survival. However, only a small fraction of patients with HER-2 negative breast cancer achieve a pCR with standard chemotherapy.

A U.S. Phase 2 trial to evaluate the ability of NOV-002 to enhance the effectiveness of such chemotherapy while diminishing side-effects commenced in June 2007 at the Medical University of South Carolina (MUSC) Hollings Cancer Center. The trial is currently ongoing at the Braman Family Breast Cancer Institute at the Sylvester Comprehensive Care Center University of Miami Miller School of Medicine (Sylvester). Alberto Montero, MD, Assistant Professor of Medicine at Sylvester, is the Principal Investigator. The primary objective of this open-label, single-arm trial is to determine if preoperative administration of NOV-002 in combination with eight cycles of chemotherapy (four of doxorubicin and cyclophosphamide followed by four of docetaxel) results in an appreciably higher pCR rate than expected with this same chemotherapeutic regimen alone. According to the Simon two-stage trial design, if four or more pCRs were observed in the first stage of the trial (19 women), enrollment would continue into the second stage, for a total of 46 women.

As of December 2008, 19 women had been enrolled, with six pCRs already demonstrated in the first 15 women (40%) who completed chemotherapy and underwent surgery, which is much greater than the less than 20% historical expectation in HER-2 negative patients. Furthermore, NOV-002 was associated with decreased hematologic toxicities and with decreased use of growth factors, such as Ethropoiesis-Stimulating Agents, which are potentially harmful, relative to historical experience. Details of these interim results were presented at the San Antonio Breast Cancer Symposium in December 2008. Having achieved its interim efficacy target even earlier than targeted, the trial has advanced into the second stage. Overall, the trial objective is to achieve twelve pCRs out of 46 patients. We expect data from the trial to be available in the third quarter of 2010.

### ***NOV-002 in Chemotherapy (Platinum)-Resistant Ovarian Cancer***

We are also developing NOV-002 to treat platinum-resistant ovarian cancer. According to the American Cancer Society, approximately 22,000 U.S. women were expected to be diagnosed with ovarian cancer in 2009 and 15,000 women are expected to die from it. There is a lack of effective treatment, particularly in the case of patients who are chemotherapy refractory (those who do not respond to chemotherapy) or resistant (those who relapse shortly after receiving chemotherapy).

First-line chemotherapy treatment is typically the same in ovarian cancer as in NSCLC, i.e., carboplatin and paclitaxel chemotherapy in combination. Doxorubicin and topotecan alternate as second- and third-line chemotherapy treatments.

Refractory/resistant ovarian cancer patients have a very poor prognosis because they face inadequate therapeutic options. Once a woman's ovarian cancer is defined as platinum resistant, the chance of having a partial or complete response to further platinum therapy is typically less than 10%, according to an article by A. Berkenblit in the June 2005 issue of the *Journal of Reproductive Medicine*.

In a single-arm, U.S. Phase 2 chemotherapy-resistant ovarian cancer trial at the Massachusetts General Hospital and Dana-Farber Cancer Institute from July 2006 through May 2008, NOV-002 (plus carboplatin) slowed progression of the disease in 60% of evaluable patients (9 out of 15 women). The median progression-free survival was 15.4 weeks, almost double the historical control of 8 weeks. These results were presented at the American Society of Clinical Oncology in May 2008.

### ***NOV-002 - Summary of Clinical Experience in Russia***

Glutoxim® (the tradename for NOV-002 in Russia) is approved in Russia for general medicinal usage as an immunostimulant in combination with chemotherapy and antimicrobial therapy, and specifically for indications such as tuberculosis and psoriasis. Efficacy and excellent safety have been demonstrated in trials with 390 patients in Russia across numerous types of cancer including NSCLC, breast cancer, ovarian cancer, colorectal cancer and pancreatic cancer. Since the Russian Ministry of Health approval in 1998, it is estimated that Glutoxim® has been administered to over 10,000 patients. The Russian non-clinical and clinical data set, which includes clinical safety and efficacy data, extensive animal toxicology studies and a comprehensive chemistry and manufacturing package, was accepted by the FDA as the basis of an IND in 2000.

## NOV-205

### *NOV-205 in Chronic Hepatitis C*

NOV-205 is a unique, injectable, small-molecule proprietary formulation of oxidized glutathione in a 1:1 molar ratio with inosine. NOV-205 has been administered to approximately 200 hepatitis patients in clinical trials. We are currently developing NOV-205 for the treatment of chronic hepatitis C non-responders.

The World Health Organization estimates that chronic hepatitis C affects 170 million people worldwide and in the U.S., according to the Centers for Disease Control and Prevention (“CDC”), an estimated 4.1 million persons are affected. Chronic infection can progress to cirrhosis, end-stage liver disease and hepatocellular carcinoma. While there are varying estimates about the size of the global market for hepatitis C drugs, the current global market is believed to be in excess of \$3 billion per year. Currently about 8,000-10,000 hepatitis C-related deaths occur annually in the U.S. and this could double over the next 10 to 20 years. The current standard-of-care drugs for chronic hepatitis C – the combination of pegylated interferon and ribavirin – are expensive, have significant toxicities, are difficult to tolerate for many patients and have limited long-term efficacy in genotype 1 patients (the most common HCV genotype seen in the U.S. and much of the world). Approximately 50% of the genotype 1 patients do not benefit from treatment with pegylated interferon plus ribavirin, and currently there is no approved standard of care to treat these non-responding chronic hepatitis C patients.

NOV-205 acts as a hepatoprotective agent with immunomodulating and anti-inflammatory properties. The therapeutic profile of NOV-205 contrasts with those of currently approved therapies in the U.S., which have limited effectiveness, are expensive and have severe side effects, particularly in the case of chronic hepatitis C. For example, pegylated interferon and ribavirin combinations have limitations of safety and tolerability (40-65% of treated patients experience fatigue, depression, fever, headaches, muscle pain or anemia). Furthermore, these pharmaceuticals are effective in only a fraction of the patient population and are very expensive.

NOV-205 was approved in Russia by the Ministry of Health in 2001 as a monotherapy for the treatment of hepatitis B and C. Previously, NOV-205 demonstrated clinical activity (reduced viral load and improved liver function) and safety as monotherapy for treatment of hepatitis B and C in a total of 178 patients from Russia.

On the basis of the clinical and pre-clinical data package underlying Russian approval of NOV-205, in combination with U.S. chemistry and manufacturing information, we filed an IND with the FDA for NOV-205 as a monotherapy in chronic hepatitis C in March 2006. The FDA accepted our IND in April 2006, and a U.S. Phase 1b trial in patients who previously failed treatment with pegylated interferon plus ribavirin commenced in September 2006 and was completed in December 2007. Based on favorable safety results of that trial, in March 2010 we initiated a multi-center U.S. Phase 2 trial evaluating NOV-205 as monotherapy in up to 40 chronic hepatitis C genotype 1 patients who previously failed treatment with pegylated interferon plus ribavirin. The ongoing U.S. Phase 2 trial aims to expand the safety database for NOV-205 and assess its effects on the same efficacy related endpoints using a comparable dosing regimen as in prior Russian studies, although this trial is being conducted in patients that have not responded to interferon/ribavirin, which is a more difficult-to-treat patient population. We expect to have preliminary results from this longer duration, proof-of-concept trial in the third quarter of 2010.

### **Non-Clinical Research Programs**

Our non-clinical research programs are aimed at gaining a better understanding of the mechanism(s) of action of our oxidized glutathione-based pharmaceutical compounds to inform and guide ongoing and future clinical studies. This research is being performed via a network of academic and commercial (i.e., contract research organizations) laboratories.

We are engaged in a funded research collaboration with the laboratory of Kenneth Tew, Ph.D., D.Sc., Chairman of the Department of Cell and Molecular Pharmacology and Experimental Therapeutics at the Medical University of South Carolina. Dr. Tew is also chairman of our Scientific Advisory Board and a stockholder. The general objectives of this research program are to add to the understanding of NOV-002 and NOV-205 as pharmaceutical products, particularly with respect to their molecular and cellular mechanisms of action. Funded research collaborations have been conducted or are underway at other academic/scientific institutions including Harvard/Massachusetts General Hospital, the Wistar Institute, the University of Massachusetts Medical Center and the University of Miami to further elaborate *in vitro* and *in vivo* mechanisms of action that may underlie the clinical therapeutic profiles of NOV-002 and NOV-205 and to suggest future clinical directions.

## **Manufacturing**

Our proprietary manufacturing process is well-established, simple and scalable. We have used U.S. and Canadian contract manufacturing facilities that are registered with the FDA to support our U.S. development efforts. We do not plan to build manufacturing capability over the next several years. Rather, we plan to continue to employ contract manufacturers.

The active pharmaceutical ingredient of NOV-002 was manufactured in the U.S. in compliance with current Good Manufacturing Practices in a single, synthetic step and then filled, finished and packaged most recently at Hyaluron (Burlington, MA) as a sterile, filtered, aseptically-processed solution for intravenous and subcutaneous use. NOV-002 clinical trial material (vials and syringes containing the active pharmaceutical ingredient and solution) has successfully completed 36-month stability studies.

We have most recently manufactured NOV-205 clinical trial material at Lyophilization Services of New England (Manchester, NH) in compliance with current Good Manufacturing Practices in a single, synthetic step and then filled, finished and packaged into glass vials as a sterile, filtered, aseptically-processed solution for subcutaneous use.

## **Sales and Marketing**

Outside of the U.S., we sought to commercialize NOV-002 through partnerships with pharmaceutical companies that have development capabilities along with commercial expertise and infrastructure. In February 2009, we entered into a collaboration with Mundipharma under which we granted Mundipharma exclusive rights to develop, manufacture and commercialize NOV-002 in Europe (other than the Russian Territory), Asia (other than the Chinese Territory) and Australia. In December 2007 we entered into a collaboration agreement with Lee's Pharm under which we granted Lee's Pharm exclusive rights to develop, manufacture and commercialize NOV-002 for cancer and NOV-205 for hepatitis in the Chinese Territory.

Should we obtain regulatory approval for NOV-002 in the U.S., we plan to pursue and evaluate all available options to launch and commercialize NOV-002. These options presently include, but are not limited to, building our own salesforce, utilizing a contract sales organization or entering into a partnering arrangement with a pharmaceutical company with strong commercial expertise and infrastructure in the U.S.

## **Intellectual Property**

We own all intellectual property rights worldwide (excluding the Russian Territory) related to both of our clinical-stage compounds, i.e., NOV-002 and NOV-205, and other pre-clinical compounds based on oxidized glutathione. We have six issued patents in the U.S. We also have two issued patents in Europe and one in Japan. Overall, we have filed more than 30 patent applications worldwide.

Issued composition of matter patents cover proprietary formulations of oxidized glutathione that do not expire until 2019, and these patents include methods of manufacture for oxidized glutathione formulated with various metals. Claims further include treatment of cancer, hematologic, immunologic and infectious diseases and other medical conditions. Furthermore, issued patents that are valid until 2016 cover methods of use for oxidized glutathione (+/- formulation enhancers) for simulation of cytokine and hematopoietic factors, and for treatment of cancer, hematologic, immunologic and infectious diseases.

We intend to pursue extensions of the patent term and/or of the data exclusivity term in the countries where such extensions are available. We also plan to file patent applications that reflect new uses, applications and compositions of our oxidized glutathione platform technology.

We believe that our breadth of intellectual property may allow us to expand our pipeline by claiming and commercializing additional compounds that are based on oxidized glutathione.

## Licenses / Collaborations

Novelos has entered into a collaboration agreement granting Mundipharma exclusive rights to develop, manufacture and commercialize NOV-002 in Europe (other than the Russian Territory), Asia (other than the Chinese Territory) and Australia. Both of our clinical-stage compounds, NOV-002 and NOV-205, have been licensed to Lee's Pharm for exclusive development, manufacture and commercialization in the Chinese Territory.

Under a securities purchase agreement dated August 25, 2009 (the "August 2009 Purchase Agreement"), we granted Purdue Pharma, L.P. ("Purdue") a right of first refusal with respect to bona fide offers received from third parties to obtain NOV-002 Rights (as defined in the August 2009 Purchase Agreement) in the United States. The right of first refusal terminates upon business combinations, as defined in the August 2009 Purchase Agreement.

We expect that the negative results of our Phase 3 trial in advanced NSCLC will adversely affect development and commercialization of NOV-002 under the collaboration agreements.

## Employees

As of March 23, 2010 we had eight full-time employees. We believe our relationships with our employees are good.

## Regulation

The manufacturing and marketing of NOV-002 and NOV-205 and our related research and development activities are subject to regulation for safety, efficacy and quality by numerous governmental authorities in the U.S. and other countries. We anticipate that these regulations will apply separately to each of our compounds.

In the U.S., pharmaceuticals are subject to rigorous federal regulation and, to a lesser extent, state regulation. The Federal Food, Drug and Cosmetic Act and other federal and state statutes and regulations govern, among other things, the testing, manufacture, safety, efficacy, labeling, storage, recordkeeping, approval, advertising and promotion of our pharmaceuticals.

The steps required before a pharmaceutical agent may be marketed in the U.S. include:

- Pre-clinical laboratory tests, *in vivo* pre-clinical studies, and formulation studies;
- The submission to the FDA of an IND for human clinical testing, which must become effective before human clinical trials can commence;
- Adequate and well-controlled human clinical trials to establish the safety and efficacy of the product;
- The submission of a New Drug Application ("NDA") or Biologic Drug License Application to the FDA; and
- FDA approval of the NDA or Biologic Drug License.

In addition to obtaining FDA approval for each product, each product manufacturing facility must be registered with and approved by the FDA. Manufacturing facilities are subject to biennial inspections by the FDA and must comply with the FDA's Good Manufacturing Practices for products, drugs and devices.

Whether or not FDA approval has been obtained, approval of a product by regulatory authorities in foreign countries must be obtained prior to the commencement of commercial sales of the pharmaceutical in such countries. The requirements governing the conduct of clinical trials and drug approvals vary widely from country to country, and the time required for approval may be longer or shorter than that required for FDA approval.

## **Item 1A. Risk Factors**

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

The report from our independent registered public accounting firm dated March 23, 2010 and included with this annual report on Form 10-K indicated that factors exist that raised substantial doubt about our ability to continue as a going concern.

We are currently continuing development of our oxidized glutathione-based compounds for the treatment of cancer and hepatitis and seeking to build a product pipeline through acquiring or licensing clinical stage compounds or technologies for oncology indications. We believe that we have adequate cash to fund these activities, including related overhead costs, into the fourth quarter of 2010. Our ability to execute our operating plan beyond early in the fourth quarter of 2010 is dependent on our ability to obtain additional capital, principally through the sale of equity and debt securities, to fund our development activities. We plan to actively pursue financing alternatives during 2010, but there can be no assurance that we will obtain the additional capital necessary to fund our business beyond early in the fourth quarter of 2010. On February 24, 2010, we announced that our Phase 3 clinical trial for NOV-002 in non-small cell lung cancer (the "Phase 3 Trial") did not meet its primary endpoint of a statistically significant increase in median overall survival. On March 18, 2010, we announced that the secondary endpoints had not been met in the Phase 3 Trial and that we had discontinued development of NOV-002 for NSCLC in combination with first-line paclitaxel and carboplatin chemotherapy. The negative outcome of the Phase 3 Trial, as well as continuing difficult conditions in the capital markets globally, may adversely affect our ability to obtain funding in a timely manner. We are continuously evaluating measures to reduce our costs to preserve existing capital. If we are unable to obtain sufficient additional funding, we will be required, beginning in mid 2010, to scale back our administrative and clinical development activities and may be required to cease our operations entirely.

### **Our Phase 3 Trial for NOV-002 in advanced non-small cell lung cancer did not meet its primary and secondary endpoints. This could negatively impact our ability to successfully develop NOV-002 for other cancer indications.**

On February 24, 2010, we announced that our Phase 3 Trial did not meet its primary endpoint of a statistically significant increase in median overall survival. Following evaluation of the detailed trial data, we announced on March 18, 2010 that the secondary endpoints also were not met in the trial and that adding NOV-002 to paclitaxel and carboplatin chemotherapy was not statistically or meaningfully different in terms of efficacy-related endpoints or recovery from chemotherapy toxicity versus chemotherapy alone. The secondary endpoints included progression-free survival, response rate and duration of response, recovery from chemotherapy-induced myelosuppression, determination of immunomodulation, quality of life and safety. While these results are not necessarily predictive of the results that we may experience in clinical trials for NOV-002 in other cancer indications, the results could negatively impact our ability to obtain funding or regulatory approval to pursue further clinical development in NOV-002. If we are unable to pursue further clinical development in NOV-002, our development efforts will be limited to our other drug compound, NOV-205 and other compounds that we are able to acquire or license. There can be no assurance that we will be successful in our efforts to develop NOV-205 or in our efforts to acquire or license new compounds. If we are unsuccessful in developing our drug compounds or acquiring or licensing new compounds, we may be required to cease our operations.

### **A class action lawsuit has been filed against the Company which could divert management's attention and harm our business.**

A purported class action complaint was filed on March 5, 2010 in the United States District Court for the District of Massachusetts by an alleged shareholder on behalf of himself and all others who purchased or otherwise acquired our common stock in the period between December 14, 2009 and February 24, 2010, against Novelos and our President and Chief Executive Officer, Harry S. Palmin. The complaint claims that we violated Section 10(b) of the Securities Exchange Act of 1934, as amended, and Rule 10b-5 promulgated thereunder in connection with alleged disclosures related to the Phase 3 Trial. We believe the allegations are without merit and intend to defend vigorously against the allegations. However, this type of litigation often is expensive and diverts management's attention and resources, whether or not the claims are ultimately successful, and this could adversely affect our business.

**We may have difficulty raising additional capital for our future operations in the longer term.**

We currently generate insignificant revenue from our proposed products or otherwise. We do not know when this will change. We have expended and will continue to expend substantial funds on the research, development and clinical and pre-clinical testing of our drug compounds. We will require additional funds to conduct research and development, establish and conduct clinical and pre-clinical trials, establish commercial-scale manufacturing arrangements and provide for the marketing and distribution of our products. Additional funds may not be available on acceptable terms, if at all. If adequate funding is not available to us, we may have to delay, reduce the scope of or eliminate one or more of our research or development programs or product launches or marketing efforts, which may materially harm our business, financial condition and results of operations.

Our capital requirements and our ability to meet them depend on many factors, including:

- the number of potential products and technologies in development;
- continued progress and cost of our research and development programs;
- progress with pre-clinical studies and clinical trials;
- the time and costs involved in obtaining regulatory clearance;
- costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims;
- costs of developing sales, marketing and distribution channels and our ability to sell our drugs;
- costs involved in establishing manufacturing capabilities for clinical trial and commercial quantities of our drugs;
- competing technological and market developments;
- market acceptance of our products;
- costs for recruiting and retaining management, employees and consultants;
- costs for educating physicians;
- our status as a Bulletin-Board-listed company and the prospects for our stock being listed on a national exchange;
- uncertainty and economic instability resulting from terrorist acts and other acts of violence or war; and
- the condition of capital markets and the economy generally, both in the U.S. and globally.

We may consume available resources more rapidly than currently anticipated, resulting in the need for additional funding sooner than expected. We may seek to raise any necessary additional funds through the issuance of warrants, equity or debt financings or executing collaborative arrangements with corporate partners or other sources, which may be dilutive to existing stockholders or otherwise have a material effect on our current or future business prospects. In addition, in the event that additional funds are obtained through arrangements with collaborative partners or other sources, we may have to relinquish economic and/or proprietary rights to some of our technologies or products under development that we would otherwise seek to develop or commercialize by ourselves. If adequate funds are not available, we may be required to significantly reduce or refocus our development efforts with regard to our drug compounds.

**The failure to complete development of our therapeutic technology, to 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 our ongoing business.**

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

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

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

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

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

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

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

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

Data already obtained, or obtained in the future, from pre-clinical studies and clinical trials do 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, which would result in delays to commercialization and could materially harm our business. Our clinical trials may not demonstrate sufficient levels of safety and efficacy necessary to obtain the requisite regulatory approvals for our drugs, and our proposed drugs may not be approved for marketing.

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

Even if we do ultimately receive FDA approval for any of our products, these products will be subject to extensive ongoing regulation, including 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 to comply with any applicable regulations could further delay or preclude development and commercialization of our drugs and subject us to enforcement action.

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

In order to obtain regulatory approvals, we must demonstrate that each drug is safe and effective for use in humans and functions as a therapeutic against the effects of a disease or other physiological response. While we have experienced positive preliminary results in the earlier stage trials for certain indications in the U.S., in February 2010, we announced that our Phase 3 Trial did not meet its primary endpoint of a statistically significant increase in median overall survival and in March 2010 we announced that the secondary endpoints were not met. There can be no assurance that we can demonstrate that these products are safe or effective in additional advanced clinical trials for other indications. We are also not able to give assurances that the positive results of certain of the tests already conducted can be repeated or that further testing will support our applications for regulatory approval. As a result, our drug and technology research program may be curtailed, redirected or eliminated at any time. If this occurs, we may have to cease our operations entirely.

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

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

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

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

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

We believe that we have a good working relationship with our contractors. However, should the situation change, we may be required to relocate these activities on short notice, and we do not currently have access to alternate facilities to which we could relocate our research, development and/or manufacturing activities. The cost and time to establish or locate an alternate research, development and/or manufacturing facility to develop our technology would be substantial and would delay obtaining FDA approval and commercializing our products.

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

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

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

As a result of our collaboration agreements with Mundipharma and Lee's Pharm for the development, manufacture and commercialization of NOV-002 in Europe, Asia and Australia (and NOV-205 in the Chinese Territory), the commercial value of our products in those territories will largely be dependent on the ability of these collaborators to perform.

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

Purdue has been granted a right of first refusal on bona fide offers to obtain NOV-002 Rights in the United States received from third parties and approved by our board of directors. Under Purdue's right of first refusal, Purdue would have 30 days to enter into a definitive agreement with Novelos on terms representing the same economic benefit for Novelos as in the third-party offer. The right of first refusal terminates only upon specified business combinations. Novelos has separately entered into letter agreements with Mundipharma and an independent associated company providing for a conditional exclusive right to negotiate for, and a conditional right of first refusal with respect to third party offers to obtain NOV-002 Rights (i) for Mexico, Central America, South America and the Caribbean and (ii) for Canada, respectively. The existence of these rights may discourage other possible strategic partners from entering into discussions with us to obtain NOV-002 Rights in North and South America.

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

Our business exposes us to potential product liability and other liability risks that are inherent in the testing, manufacturing and marketing of pharmaceutical products. In addition, the use in our clinical trials of pharmaceutical products that we or our current or potential collaborators may develop and then subsequently sell may cause us to bear a portion of or all product liability risks. While we carry an insurance policy covering up to \$5,000,000 per occurrence and \$5,000,000 in the aggregate of liability incurred in connection with such claims should they arise, there can be no assurance that our insurance will be adequate to cover all situations. Moreover, there can be no assurance that such insurance, or additional insurance, if required, will be available in the future or, if available, will be available on commercially reasonable terms. Furthermore, our current and potential partners with whom we have collaborative agreements or our future licensees may not be willing to indemnify us against these types of liabilities and may not themselves be sufficiently insured or have a net worth sufficient to satisfy any product liability claims. A successful product liability claim or series of claims brought against us could have a material adverse effect on our business, financial condition and results of operations.

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

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

- the receipt of regulatory clearance of marketing claims for the uses that we are developing;

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

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

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

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

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

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

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

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

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

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

**We have limited manufacturing experience. Even if our products are approved for manufacture and sale by applicable regulatory authorities, we may not be able to manufacture sufficient quantities at an acceptable cost, and our contract manufacturers could experience shut-downs or delays.**

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

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

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

We have not yet had to establish marketing, sales or distribution capabilities for our proposed products. Until such time as our products are further along in the regulatory process, we will not devote any meaningful time and resources to this effort. At the appropriate time, we intend to develop our own sales and marketing capabilities or enter into agreements with third parties to sell our products.

We have limited experience in developing, training or managing a sales force. If we choose to establish a direct sales force, we may incur substantial additional expenses in developing, training and managing such an organization. We may be unable to build a sales force on a cost-effective basis or at all. Any such direct marketing and sales efforts may prove to be unsuccessful. In addition, we will compete with many other companies that currently have extensive marketing and sales operations. Our marketing and sales efforts may be unable to compete against these other companies. We may be unable to establish a sufficient sales and marketing organization on a timely basis, if at all.

If we choose to enter into agreements with third parties to sell our products, we may be unable to establish or maintain third-party relationships on a commercially reasonable basis, if at all. In addition, these third parties may have similar or more established relationships with our competitors.

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

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

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

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

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

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

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

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

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

**If users of our products are unable to obtain adequate reimbursement from third-party payers, or if new healthcare reform measures are adopted, it could hinder or prevent our product candidates' commercial success.**

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 adversely affect our ability to generate future revenues and achieve profitability, including by limiting the future revenues and profitability of our potential customers, suppliers and collaborative partners. For example, in certain foreign markets, pricing or profitability of prescription pharmaceuticals is subject to government control. The U.S. government and other governments have shown significant interest in pursuing healthcare reform. Any government-adopted reform measures could adversely affect the pricing of healthcare products and services in the U.S. or internationally and the amount of reimbursement available from governmental agencies or other third party payers. The continuing efforts of the U.S. and foreign governments, insurance companies, managed care organizations and other payers of health care services to contain or reduce health care costs may adversely affect our ability to set prices for our products, should we be successful in commercializing them, and this would negatively affect our ability to generate revenues and achieve and maintain profitability.

New laws, regulations and judicial decisions, or new interpretations of existing laws, regulations and decisions, that relate to healthcare availability, methods of delivery or payment for healthcare products and services, or sales, marketing or pricing of healthcare products and services, also may limit our potential revenue and may require us to revise our research and development programs. The pricing and reimbursement environment may change in the future and become more challenging for several reasons, including policies advanced by the current or future executive administrations in the U.S., new healthcare legislation or fiscal challenges faced by government health administration authorities. Specifically, in both the U.S. and some foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the health care system in ways that could affect our ability to sell our products profitably. In the U.S., changes in federal health care policy are being considered by Congress this year. Some of these proposed reforms could result in reduced reimbursement rates for our product candidates, which would adversely affect our business strategy, operations and financial results.

Our ability to commercialize our products will depend in part on the extent to which appropriate reimbursement levels for the cost of our products and related treatment are obtained by governmental authorities, private health insurers and other organizations, such as health maintenance organizations (HMOs). 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 HMOs that could control or significantly influence the purchase of healthcare services and drugs, as well as legislative proposals to reform health care or change government insurance programs, may all result in lower prices for or rejection of our drugs. The cost containment measures that healthcare payers and providers are instituting and the effect of any healthcare reform could materially harm our ability to operate profitably.

**We depend on key personnel who may terminate their employment with us at any time, and our success will depend on our ability to hire additional qualified personnel.**

Our success will depend to a significant degree on the continued services of our key management and advisors. There can be no assurance that these individuals will continue to provide service to us. Furthermore, as a result of the decline in stock price following the announcement of the negative results of our Phase 3 Trial, many of the stock options held by key employees and advisors have exercise prices in excess of current market prices, thus significantly diminishing their incentive effect. We may be required to restructure stock compensation arrangements in order to retain key management and advisors. In addition, our success may depend on our ability to attract and retain other highly skilled personnel. We may be unable to recruit such personnel on a timely basis, if at all. Our management and other employees may voluntarily terminate their employment with us at any time. The loss of services of key personnel, or the inability to attract and retain additional qualified personnel, could result in delays in development or approval of our products, loss of sales and diversion of management resources.

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

Keeping abreast of, and in compliance with, changing laws, regulations and standards relating to corporate governance, public disclosure and internal controls, including the Sarbanes-Oxley Act of 2002, new SEC regulations and, in the event we seek and are approved for listing on a registered national securities exchange, the stock exchange rules, will require an increased amount of management attention and external resources. We intend to continue to invest all resources reasonably necessary to comply with evolving standards, which may result in increased general and administrative expense and a diversion of management time and attention from revenue-generating activities to compliance activities. In our annual report for the fiscal year ending December 31, 2010 we may be required to include an attestation report of our independent registered public accounting firm on internal control over financial reporting which may result in additional costs.

**In the time that our common stock has traded, our stock price has experienced price fluctuations.**

There can be no assurance that the market price for our common stock will remain at its current level and a decrease in the market price could result in substantial losses for investors. The market price of our common stock may be significantly affected by one or more of the following factors:

- announcements or press releases relating to the biopharmaceutical sector or to our own business or prospects;
- regulatory, legislative, or other developments affecting us or the healthcare industry generally;
- the dilutive effect of conversion of our Series E or Series C preferred stock into common stock or the exercise of options and warrants;
- sales by those financing our company through convertible securities and warrants of the underlying common stock, when it is registered with the SEC and may be sold into the public market, immediately upon conversion or exercise; and
- market conditions specific to biopharmaceutical companies, the healthcare industry and the stock market generally.

**There may be a limited public market for our securities; we may fail to qualify for listing on certain national securities exchanges.**

Our common stock currently does not meet the requirements for initial listing on a registered stock exchange. Trading in our common stock continues to be conducted on the electronic bulletin board in the over-the-counter market and in what are commonly referred to as “pink sheets.” As a result, an investor may find it difficult to dispose of or to obtain accurate quotations as to the market value of our common stock, and our common stock may be less attractive for margin loans, for investment by financial institutions, as consideration in future capital raising transactions or other purposes.

**Our common stock constitutes a “penny stock” under SEC rules, which may make it more difficult to resell shares of our common stock.**

Our common stock constitutes a “penny stock” under applicable SEC rules. These rules impose additional sales practice requirements on broker-dealers that recommend the purchase or sale of penny stocks to persons other than those who qualify as “established customers” or “accredited investors.” For example, broker-dealers must determine the appropriateness for non-qualifying persons of investments in penny stocks and make special disclosures concerning the risks of investments in penny stocks.

Many brokerage firms will discourage or refrain from recommending investments in penny stocks. Most institutional investors will not invest in penny stocks. In addition, many individual investors will not invest in penny stocks due, among other reasons, to the increased financial risk generally associated with these investments. For these reasons, the fact that our common stock is a penny stock may limit the market for our common stock and, consequently, the liquidity of an investment in our common stock. Although our common stock had recently been trading at above its historic levels, our common stock remained a “penny stock” during that time because our tangible net assets are insufficient to exclude our common stock from that designation. We can give no assurance at what time, if ever, our common stock will cease to be a “penny stock.”

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

Holders of our Series E preferred stock beneficially own, in the aggregate, approximately 45% of our outstanding voting shares on an as-converted basis (subject to certain blocking provisions that may be waived with 61 days' notice). In addition, our executive officers, directors and other principal stockholders own in excess of 2% of our outstanding voting shares calculated on the same basis. The interests of our current officers, directors and Series E investors may differ from the interests of other stockholders. Further, our current officers, directors and Series E investors may have the ability to significantly affect the outcome of all corporate actions requiring stockholder approval, including the following actions:

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

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

In the past, we have issued common stock, convertible securities, such as convertible preferred stock, and warrants in order to raise money. We have also issued options and warrants as compensation for services and incentive compensation for our employees and directors. We have shares of common stock reserved for issuance upon the conversion and exercise of these securities and may increase the shares reserved for these purposes in the future. Our issuance of additional common stock, convertible securities, options and warrants could affect the rights of our stockholders, could reduce the market price of our common stock or could result in adjustments to conversion or exercise prices of outstanding preferred stock and warrants (resulting in these securities becoming convertible into or exercisable for, as the case may be, a greater number of shares of our common stock), or could obligate us to issue additional shares of common stock to certain of our stockholders.

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

For as long as any shares of Series E preferred stock remain outstanding we are prohibited from taking certain actions or entering into certain transactions without the prior consent of specific holders of outstanding shares of Series E preferred stock (currently consisting of Xmark Opportunity Fund, L.P., Xmark Opportunity Fund, Ltd., and Xmark JV Investment Partners, LLC (collectively, the "Xmark Funds"), and Purdue). We are prohibited from paying dividends to common stockholders, amending our certificate of incorporation or by-laws, issuing any equity security or any security convertible into or exercisable for any equity security at a price of \$0.65 or less or with rights senior to the Series E preferred stock (except for certain exempted issuances), increasing the number of shares of Series E preferred stock or issuing any additional shares of Series E preferred stock other than the 735 shares designated in the Series E Certificate of Designations, or changing the number of our directors. We are also prohibited from entering into certain transactions such as:

- selling or otherwise granting any rights with respect to all or substantially all of our assets (and in the case of licensing, any material intellectual property) or the Company's business and we shall not enter into a merger or consolidation with another company unless we are the surviving corporation, the Series E preferred stock remains outstanding, there are no changes to the rights and preferences of the Series E preferred stock and there is not created any new class of capital stock senior to the Series E preferred stock;
- redeeming or repurchasing any capital stock other than Series E preferred stock or the related warrants; or

- incurring any new debt for borrowed money in excess of \$500,000.

Even though our board of directors may determine that any of these actions are in the best interest of the Company or our shareholders, we may be unable to complete them if we do not get the approval of specific holders of the outstanding shares of Series E preferred stock. The interests of the holders of Series E preferred stock may differ from those of stockholders generally. Moreover, the right of first refusal granted to Purdue and its independent associated companies under the August 2009 Purchase Agreement and the collaboration agreement with Mundipharma (our collaborator on most non-U.S. development, manufacturing and commercialization of NOV-002) have the potential of creating situations where the interests of the Company and those of Purdue may conflict. If we are unable to obtain consent from each of the holders identified above, we may be unable to complete actions or transactions that our board of directors has determined are in the best interest of the Company and its shareholders.

**We have not paid dividends to preferred stockholders totaling \$2,903,000 as of December 31, 2009 and we may be unable to pay dividends to preferred stockholders when due in future periods.**

Our ability to pay cash dividends on stated future dividend payment dates will be dependent on a number of factors including the timing of future financings and the amount of net losses in future periods. We anticipate that future dividends on Series E preferred stock will be paid by issuing shares of common stock or additional shares of Series E preferred stock, which will result in additional dilution to existing shareholders. We anticipate that the accrued unpaid dividend on our Series C preferred stock (\$710,000 at December 31, 2009) will continue to accumulate. During 2009, an aggregate of approximately \$486,000 in accumulated dividends were converted into shares of common stock in connection with the conversion of the associated shares of preferred stock.

**Item 2. Properties**

We lease our executive office in Newton, Massachusetts. Our office consists of approximately 2,000 square feet and is rented for approximately \$5,300 per month. This lease expires in August 2010 and we anticipate that an extension on the lease will be available on terms that are acceptable to us. We believe that our present facilities are adequate to meet our current needs. If new or additional space is required, we believe that adequate facilities are available at competitive prices.

**Item 3. Legal Proceedings**

A purported class action complaint was filed on March 5, 2010 in the United States District Court for the District of Massachusetts by an alleged shareholder on behalf of himself and all others who purchased or otherwise acquired our common stock in the period between December 14, 2009 and February 24, 2010, against Novelos and our President and Chief Executive Officer, Harry S. Palmin. The complaint claims that we violated Section 10(b) of the Securities Exchange Act of 1934, as amended, and Rule 10b-5 promulgated thereunder in connection with alleged disclosures related to the Phase 3 Trial. We believe the allegations are without merit and intend to defend vigorously against the allegations.

**PART II****Item 4. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities****MARKET FOR COMMON EQUITY****Market Information**

Our common stock has been quoted on the OTC Bulletin Board under the symbol "NVLT" since June 14, 2005. The following table provides, for the periods indicated, the high and low bid prices for our common stock. These over-the-counter market quotations reflect inter-dealer prices, without retail mark-up, mark-down or commission, and may not represent actual transactions.

<b>Fiscal Year 2008</b>	<b>High</b>	<b>Low</b>
First Quarter	\$ 0.82	\$ 0.43
Second Quarter	0.64	0.44
Third Quarter	0.54	0.35
Fourth Quarter	0.49	0.19
<b>Fiscal Year 2009</b>	<b>High</b>	<b>Low</b>
First Quarter	\$ 0.60	\$ 0.30
Second Quarter	0.90	0.34
Third Quarter	0.98	0.57
Fourth Quarter	2.90	0.65

On March 23, 2010, there were 92 holders of record of our common stock. This number does not include stockholders for whom shares were held in a "nominee" or "street" name.

We have not declared or paid any cash dividends on our common stock and do not anticipate declaring or paying any cash dividends in the foreseeable future. We are prohibited from paying any dividends on common stock as long as any shares of our Series E preferred stock are outstanding or as long as there are accumulated but unpaid dividends on our Series C preferred stock. We currently expect to retain future earnings, if any, for the development of our business. As of December 31, 2009, accumulated undeclared dividends totaled approximately \$2,903,000. From January 1, 2010 through March 23, 2010, a total of approximately \$560,000 in dividends was converted into shares of common stock in connection with the conversion of the associated shares of preferred stock.

Our transfer agent and registrar is American Stock Transfer and Trust Company, 59 Maiden Lane, New York, NY 10038.

### **Recent Sales of Unregistered Securities**

In the last three years we have sold the following securities in reliance on, unless otherwise indicated, the exemption under Section 4(2) of the Securities Act of 1933, as amended, as transactions not involving any public offering.

#### **2010**

From January 1, 2010 through March 30, 2010:

- We issued 11,745,779 shares of our common stock upon conversion of approximately 140 shares of our Series E preferred stock, having an aggregate stated value of approximately \$7,000,000, and accumulated undeclared dividends thereon.
- We issued 7,191,132 shares of our common stock upon the cashless exercise of warrants to purchase 11,865,381 shares of common stock. The warrants had an expiration date of December 31, 2015 and an exercise price of \$0.65 per share.
- We issued 226,544 shares of our common stock upon the cashless exercise of warrants to purchase 317,350 shares of common stock. The warrants had an expiration date of August 9, 2010 and an exercise price of \$0.65 per share.
- We issued 35,106 shares of our common stock upon the cashless exercise of warrants to purchase 75,000 shares of common stock. The warrants had an expiration date of May 2, 2012 and an exercise price of \$1.25 per share.
- We issued 366,492 shares of our common stock upon the cashless exercise of warrants to purchase 991,516 shares of common stock. The warrants had an expiration date of March 7, 2011 and an exercise price of \$1.72 per share.
- We issued 47,902 shares of our common stock upon the cashless exercise of warrants to purchase 83,333 shares of common stock. The warrants had an expiration date of May 2, 2012 and an exercise price of \$1.25 per share.
- We issued 314,982 shares of our common stock upon the cashless exercise of warrants to purchase 400,000 shares of common stock. The warrants had an expiration date of April 1, 2010 and an exercise price of \$0.625 per share.

#### **2009**

From October 1, 2009 through December 31, 2009:

- We issued 4,801,889 shares of our common stock upon conversion of approximately 58 shares of our Series E preferred stock, having an aggregate stated value of approximately \$2,907,000, and accumulated undeclared dividends thereon.
- We issued 662,584 shares of our common stock upon conversion of 28 shares of our Series C preferred stock having an aggregate stated value of \$336,000, and accumulated undeclared dividends thereon.

- We issued 26,454 shares of our common stock upon the cashless exercise of warrants to purchase an aggregate of 201,462 shares of common stock. The warrants had an expiration date of March 7, 2011 and an exercise price of \$1.72 per share.
- We issued 121,476 shares of our common stock upon the cashless exercise of warrants to purchase an aggregate of 201,984 shares of common stock. The warrants had an expiration date of August 9, 2010 and an exercise price of \$0.65 per share.
- We issued 218,648 shares of our common stock upon the cashless exercise of warrants to purchase an aggregate of 320,000 shares of common stock. The warrants had an expiration date of April 1, 2010 and an exercise price of \$0.625 per share.
- We issued 38,223 shares of our common stock upon the cashless exercise of warrants to purchase an aggregate of 60,606 shares of common stock. The warrants had an expiration date of October 3, 2010 and an exercise price of \$0.65 per share.
- We sold 8,333,334 shares of our common stock and warrants to purchase 2,916,668 shares of common stock at an exercise price of \$0.66 per share for gross proceeds of approximately \$5,500,000.

From July 1, 2009 through September 30, 2009:

- We sold 5,303,030 shares of our common stock and warrants to purchase 1,856,062 shares of common stock at an exercise price of \$0.66 per share for gross proceeds of approximately \$3,500,000.
- We issued 2,084,308 shares of our common stock in exchange for outstanding warrants to purchase 6,947,728 shares of common stock at an exercise price of \$1.82 per share. These warrants had been issued in a March 2006 financing. The issuance was made pursuant to an exchange agreement with each warrant holder and was exempt from registration under Section 3(a)(9) of the Securities Act.
- We issued 3,137,119 shares of our common stock upon conversion of approximately 39 shares of our Series E preferred stock, having an aggregate stated value of approximately \$1,952,000, and accumulated undeclared dividends thereon.
- We issued 114,410 shares of our common stock upon conversion of 5 shares of our Series C preferred stock, having an aggregate stated value of \$60,000, and accumulated dividends thereon.
- We issued 72,916 shares of our common stock upon the cashless exercise of warrants to purchase an aggregate of 262,503 shares of common stock. The warrants had an expiration date of August 9, 2010 and an exercise price of \$0.65 per share.

From April 1, 2009 through June 30, 2009:

- We issued 6,112 shares of our common stock upon the cashless exercise of warrants to purchase an aggregate of 20,830 shares of common stock. The warrants had an expiration date of August 9, 2010 and an exercise price of \$0.65 per share.
- We issued 761,843 shares of our common stock upon conversion of 35 shares of our Series C preferred stock, having an aggregate stated value of \$420,000, and accumulated dividends thereon.

From January 1, 2009 through March 31, 2009:

- We sold 200 shares of our Series E preferred stock and warrants to purchase 9,230,769 shares of our common stock at an exercise price of \$0.65 per share for gross proceeds of approximately \$10,000,000 and paying approximately \$800,000 in fees and expenses. In addition, 413.5 shares of our Series D preferred stock and accumulated undeclared dividends thereon were exchanged for 445.442875 shares of our Series E preferred stock.

## **2008**

In August 2008, we sold 4,615,384 shares of our common stock to two related accredited investors at \$0.65 per share, for gross proceeds of approximately \$3,000,000.

In April 2008, we sold 113.5 shares of our Series D preferred stock and warrants to purchase 4,365,381 shares of our common stock at an exercise price of \$0.65 per share to institutional investors. We received gross proceeds of \$5,675,000 and paid approximately \$200,000 in fees and expenses. In connection with this transaction, 300 shares of our Series B preferred stock were exchanged for 300 shares of our Series D preferred stock.

In January 2008, we issued 100,000 shares of our common stock to Howard Schneider, one of our directors, upon the exercise of his stock option at a price of \$0.01 per share for total consideration of \$1,000, pursuant to an option granted in February 2005.

## **2007**

In May 2007, we sold 300 shares of our Series B preferred stock and warrants to purchase 7,500,000 shares of our common stock at an exercise price of \$1.25 per share to institutional investors. We received gross proceeds of \$15,000,000 and paid approximately \$1,300,000 in fees and expenses. We also issued warrants to purchase 900,000 shares of our common stock at an exercise price of \$1.25 per share to Rodman & Renshaw LLC and VFT Special Ventures, Ltd. (an affiliate of Emerging Growth Equities) as partial consideration for their placement agent services in connection with the financing.

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

## **Item 5. Management's Discussion and Analysis of Financial Condition and Results of Operations**

### **Overview**

We are a biopharmaceutical company focused on developing and commercializing oxidized glutathione-based compounds for the treatment of cancer and hepatitis. We are seeking to build an oncology pipeline through licensing or acquiring clinical stage compounds or technologies for oncology indications.

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

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

NOV-002 is being developed to treat early-stage breast cancer. In June 2007 we commenced enrollment in a U.S. Phase 2 neoadjuvant breast cancer trial, which is ongoing at The University of Miami to evaluate the ability of NOV-002 to enhance the effectiveness of chemotherapy in HER-2 negative patients. An interim analysis of the trial was presented at the San Antonio Breast Cancer Symposium in December 2008. Six pathologic complete responses (“pCR”) occurred in the first 15 women (40%) who completed chemotherapy and underwent surgery, which is a much higher rate than the historical control of less than 20% pCR in this patient population. Furthermore, patients experienced decreased hematologic toxicities. We expect to present results from this trial in the third quarter of 2010.

NOV-002 is also being developed to treat chemotherapy-resistant ovarian cancer. In a U.S. Phase 2 chemotherapy-resistant ovarian cancer trial at Massachusetts General Hospital and Dana-Farber Cancer Institute from July 2006 through May 2008, NOV-002, in combination with carboplatin, slowed progression of the disease in 60% of evaluable patients (nine out of 15 women). The median progression-free survival was 15.4 weeks, almost double the historical control of eight weeks. Furthermore, patients experienced decreased hematologic toxicities. These results were presented at the American Society of Clinical Oncology in May 2008.

NOV-205, our second glutathione-based compound, acts as a hepatoprotective agent with immunomodulating and anti-inflammatory properties. NOV-205 has been administered to approximately 200 hepatitis patients in clinical trials and is in Phase 2 development for chronic hepatitis C non-responders. An Investigational New Drug Application (“IND”) for NOV-205 as a monotherapy for chronic hepatitis C was accepted by the FDA in 2006. A U.S. Phase 1b clinical trial with NOV-205 in patients who previously failed treatment with pegylated interferon plus ribavirin was completed in December 2007. Based on favorable safety results of that trial, in March 2010 we initiated a multi-center U.S. Phase 2 trial evaluating NOV-205 as monotherapy in up to 40 chronic hepatitis C genotype 1 patients who previously failed treatment with pegylated interferon plus ribavirin. We expect to have preliminary results from this longer duration, proof-of-concept trial in the third quarter of 2010.

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

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

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

## **Results of Operations**

**Revenue.** Revenue consists of amortization of license fees received in connection with partner agreements and income received from a grant from the U.S. Department of Health and Human Services.

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

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

#### **Years Ended December 31, 2009 and 2008**

**Revenue.** During the years ended December 31, 2009 and 2008, we recognized \$33,000 in license fees in connection with our collaboration agreement with Lee's Pharm. During the year ended December 31, 2009 and 2008, we also recognized \$63,000 and \$93,000, respectively, in grant revenue related to a grant received from the U.S. Department of Health and Human Services. The related costs are included as a component of research and development expense.

**Research and Development.** Research and development expense for the year ended December 31, 2009 was \$8,080,000, compared to \$14,527,000 for the same period in 2008. The \$6,447,000, or 44%, decrease in research and development expense was due to a combination of factors. In March 2008, we reached the enrollment target for our Phase 3 clinical trial of NOV-002, and an increasing number of patients completed their treatment regimen throughout 2008. In February 2010 the trial concluded. As a result, certain clinical costs have leveled off or declined. Contract research services such as those related to clinical research organizations, consultants and central laboratory services decreased by \$3,370,000. Clinical investigator expenses, which are affected by the number of patients that remain on treatment, decreased by \$2,134,000. The cost of chemotherapy drug to be provided to patients in Europe decreased by \$1,717,000. Salaries and overhead costs decreased by \$199,000 resulting from actions taken to reduce discretionary spending in order to conserve cash. These decreases were offset by a \$680,000 increase in drug manufacturing and related costs as we undertook manufacturing activities in preparation for the possible filing of a new drug application in 2010. Stock compensation expense also increased by \$293,000.

**General and Administrative.** General and administrative expense for the year ended December 31, 2009 was \$2,182,000. We recorded general and administrative expense of \$2,190,000 for the same period in 2008. However, during the year ended December 31, 2008 we recorded a \$404,000 credit to account for a waiver of potential liquidated damages associated with registration rights agreements. We had previously accrued an estimate for such damages in 2007. Without this \$404,000 credit, general and administrative expense during the year ended December 31, 2008 would have been \$2,594,000, representing a decrease of \$412,000, or 16%, during the year ended December 31, 2009 compared to the same period in the prior year. This decrease is due principally to a \$256,000 decrease in professional fees and a \$274,000 decrease in salaries and overhead costs, resulting from actions taken to reduce discretionary spending in order to conserve cash. The decrease was partially offset by an increase in stock-based compensation of \$118,000.

**Interest Income.** Interest income for the year ended December 31, 2009 was \$1,000 compared to \$131,000 for the same period in 2008. Beginning in March 2009, our cash was on deposit in a non-interest bearing account that is fully insured by the FDIC.

**Loss on Derivative Warrants.** Effective January 1, 2009, we adopted the guidance of Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC), Topic 815-40, *Derivatives and Hedging* and, as a result, we recorded a loss on derivative warrants of \$12,114,000 during the year ended December 31, 2009. This amount represents the increase in fair value, during the year ended December 31, 2009, of outstanding warrants which contain "down-round" anti-dilution provisions whereby the number of shares for which the options are exercisable and/or the exercise price of the warrants is subject to change in the event of certain issuances of stock at prices below the then-effective exercise prices of the warrants. During the year ended December 31, 2009, an aggregate of 2,084,308 shares of our common stock with a fair value of \$1,626,000 was issued in exchange for the tender of certain of these warrants. The difference of \$517,000 between the fair value of the warrants at the date of exchange and the fair value of the common stock issued to settle the derivative liability has been included as a component of the loss on derivatives in the year ended December 31, 2009.

*Preferred Stock Dividends.* During the year ended December 31, 2009, we accrued \$3,296,000 in dividends with respect to our Series C, D and E preferred stock. On February 11, 2009, all shares of Series D preferred stock and accrued dividends thereon totaling \$1,597,000 (including \$202,000 that accrued during 2009 prior to the exchange) were exchanged for approximately 445.5 shares of Series E preferred stock. The remaining accrued dividends have not been paid. During the year ended December 31, 2009, we also recorded deemed dividends on preferred stock totaling \$714,000. This amount was recorded in connection with the financing that occurred in February 2009 and represents the value attributed to the modification of certain warrants less the net adjustment required to record the newly issued shares of Series E preferred stock at fair value, as described in Note 6 to the financial statements.

During the year ended December 31, 2008 we paid cash dividends to Series B and C preferred stockholders of \$740,000 and accrued \$1,689,000 of dividends due to our Series C and D preferred stockholders. The accrued dividends were not paid because we did not have legally available funds for the payment of dividends under Delaware corporate law. In February 2009, all outstanding shares of Series D preferred stock and associated rights, including accrued dividends totaling \$1,597,000 (\$1,396,000 of which had accrued at December 31, 2008) were exchanged for 445.5 shares of Series E preferred stock. During the year ended December 31, 2008 we also recorded deemed dividends to preferred stockholders totaling \$4,417,000. This amount represents the value attributed to the reduction in exercise and conversion prices of the warrants and preferred stock issued in May 2007 in connection with the financing that occurred in April 2008, as described in Note 6 to the financial statements.

The deemed dividends, cash dividends and accrued dividends have been included in the calculation of net loss attributable to common stockholders of \$26,284,000, or \$0.53 per share, for the year ended December 31, 2009 and \$22,961,000, or \$0.56 per share, for the year ended December 31, 2008. The deemed dividends and cash dividends are excluded from our net loss (from operating activities) of \$22,273,000, or \$0.45 per share, for the year ended December 31, 2009 and \$16,451,000, or \$0.40 per share, for the year ended December 31, 2008.

### **Liquidity and Capital Resources**

We have financed our operations since inception through the sale of securities and the issuance of debt (which was subsequently paid off or converted into equity). As of December 31, 2009, we had \$8,770,000 in cash and equivalents.

During the year ended December 31, 2009, approximately \$10,618,000 in cash was used in operations, primarily due to a net loss of \$22,273,000 and a net decrease of \$1,349,000 in accounts payable and accrued liabilities. Other changes in working capital used cash of \$6,000. The cash impact of the net loss was reduced by a \$12,114,000 non-cash loss on derivatives, non-cash stock-based compensation expense of \$864,000 and depreciation and amortization of fixed assets totaling \$32,000.

During the year ended December 31, 2009, we purchased \$18,000 in fixed assets. We received net proceeds of \$9,205,000 from the sale of our Series E preferred stock and received net proceeds of \$8,939,000 from the sale of common stock.

We are currently continuing development of our oxidized glutathione-based compounds for the treatment of cancer and hepatitis and seeking to build a product pipeline through acquiring or licensing clinical stage compounds or technologies for oncology indications. We believe that we have adequate cash to fund these activities, including related overhead costs, into the fourth quarter of 2010. Our ability to execute our operating plan beyond early in the fourth quarter of 2010 is dependent on our ability to obtain additional capital, principally through the sale of equity and debt securities, to fund our development activities. We plan to actively pursue financing alternatives during 2010, but there can be no assurance that we will obtain the additional capital necessary to fund our business beyond early in the fourth quarter of 2010. On February 24, 2010, we announced that our Phase 3 clinical trial for NOV-002 in non-small cell lung cancer (the "Phase 3 Trial") did not meet its primary endpoint of a statistically significant increase in median overall survival. On March 18, 2010, we announced that the secondary endpoints had also not been met in the Phase 3 Trial and that we had discontinued development of NOV-002 for NSCLC in combination with first-line paclitaxel and carboplatin chemotherapy. The negative outcome of the Phase 3 Trial, as well as continuing difficult conditions in the capital markets globally, may adversely affect our ability to obtain funding in a timely manner. We are continuously evaluating measures to reduce our costs to preserve existing capital. If we are unable to obtain sufficient additional funding, we will be required, beginning in mid-2010, to scale back our administrative and clinical development activities and may be required to cease our operations entirely.

## Critical Accounting Policies

The preparation of financial statements and related disclosures in conformity with accounting principles generally accepted in the United States, or GAAP, requires management to make certain estimates, judgments and assumptions that 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. Actual results could differ from those estimates. We review these estimates and assumptions periodically and reflect the effects of revisions in the period that they are determined to be necessary.

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

*Accrued Liabilities.* As part of the process of preparing financial statements, we are required to estimate accrued liabilities. 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 research organizations and investigators in conjunction with clinical trials; fees paid to contract manufacturers in conjunction with the production of clinical materials; and professional service fees, such as for 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 high or too low. 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 on the facts and circumstances known to us in accordance with GAAP.

*Stock-based Compensation .* We account for stock-based compensation in accordance with FASB ASC Topic 740, *Compensation, Stock Compensation* which requires measurement of the cost of employee services received in exchange for an award of equity instruments based on the grant-date fair value of the award. That cost is recognized over the period during which an employee is required to provide service in exchange for the award, the requisite service period (usually the vesting period). 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 the guidance of FASB ASC Topic 740 and FASB ASC Topic 505, *Equity* .

Accounting for equity instruments granted or sold by us under accounting guidance 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. 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 on consideration of factors that we deem to be relevant at that time.

*Derivative Warrants.* Starting January 1, 2009, certain warrants to purchase common stock that do not meet the requirements for classification as equity, in accordance with the Derivatives and Hedging Topic of the FASB ASC, are now classified as liabilities on our balance sheet. In such instances, net-cash settlement is assumed for financial reporting purposes, even when the terms of the underlying contracts do not provide for a net-cash settlement. These warrants are considered derivative instruments as the agreements contain “down-round” provisions whereby the number of shares for which the warrants are exercisable and/or the exercise price of the warrants is subject to change in the event of certain issuances of stock at prices below the then-effective exercise price of the warrants. The primary underlying risk exposure pertaining to the warrants is the change in fair value of the underlying common stock. Such financial instruments are initially recorded at fair value, or relative fair value when issued with other instruments, with subsequent changes in fair value recorded as a component of gain or loss on derivatives in each reporting period.

The fair value of the outstanding derivative warrants is estimated as of a reporting date using a Black-Scholes pricing model. The significant assumptions used to estimate the fair value include the market price of our common stock at the reporting date, an estimated volatility rate, the remaining term of the warrant and a risk-free interest rate that corresponds to the remaining term. We estimate volatility based on an average of our historical volatility and volatility estimates of publicly held drug development companies with similar market capitalizations. If our estimates of the fair value of these derivative warrants are too high or too low, our expenses may be over- or understated.

**FINANCIAL STATEMENTS  
INDEX TO FINANCIAL STATEMENTS FOR NOVELOS THERAPEUTICS, INC.**

	<u>Page</u>
Report of Independent Registered Public Accounting Firm	32
Balance Sheets at December 31, 2009 and 2008	33
Statements of Operations for the Years Ended December 31, 2009 and 2008	34
Statements of Redeemable Preferred Stock and Stockholders' Deficiency for the Years Ended December 31, 2009 and 2008	35
Statements of Cash Flows for the Years Ended December 31, 2009 and 2008	36
Notes to Financial Statements	37

## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and Board of Directors  
Novelos Therapeutics, Inc.  
Newton, Massachusetts

We have audited the accompanying balance sheets of Novelos Therapeutics, Inc. as of December 31, 2009 and 2008 and the related statements of operations, redeemable preferred stock and stockholders' deficiency, and cash flows for the years then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Novelos Therapeutics, Inc. as of December 31, 2009 and 2008 and the results of its operations, changes in redeemable preferred stock and stockholders' deficiency, and cash flows for the years then ended in conformity with accounting principles generally accepted in the United States.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has incurred continuing losses in the development of its products and has a stockholders' deficiency at December 31, 2009. These factors raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in this regard are described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

As described in Note 2 to the financial statements, the Company adopted Emerging Issues Task Force Issue No. 07-5, *Determining Whether an Instrument (or Embedded Feature) Is Indexed to an Entity's Own Stock* (Accounting Standards Codification Topic 815, *Derivatives and Hedging*) effective as of January 1, 2009.

/s/ Stowe & Degon LLC

Westborough, Massachusetts  
March 23, 2010

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

	<u>December 31,</u> <u>2009</u>	<u>December 31,</u> <u>2008</u>
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and equivalents	\$ 8,769,529	\$ 1,262,452
Prepaid expenses and other current assets	102,923	129,785
Total current assets	<u>8,872,452</u>	<u>1,392,237</u>
<b>FIXED ASSETS, NET</b>	44,097	58,451
<b>DEPOSITS</b>	15,350	15,350
<b>TOTAL ASSETS</b>	<u>\$ 8,931,899</u>	<u>\$ 1,466,038</u>
<b>LIABILITIES, REDEEMABLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIENCY</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable and accrued liabilities	\$ 3,299,217	\$ 4,653,912
Accrued compensation	245,711	240,639
Accrued dividends	2,902,963	1,689,322
Derivative liability (see Note 2)	10,486,594	—
Deferred revenue – current	33,333	33,333
Total current liabilities	<u>16,967,818</u>	<u>6,617,206</u>
<b>DEFERRED REVENUE – NONCURRENT</b>	400,000	433,333
<b>COMMITMENTS AND CONTINGENCIES</b>		
<b>REDEEMABLE PREFERRED STOCK:</b>		
Series D convertible preferred stock, \$0.00001 par value; no shares designated or outstanding at December 31, 2009; 420 shares designated and 413.5 shares issued and outstanding at December 31, 2008	—	13,904,100
Series E convertible preferred stock, \$0.00001 par value; 735 shares designated and 548.26078125 shares issued and outstanding at December 31, 2009; no shares designated or outstanding at December 31, 2008 (liquidation preference \$29,606,082 at December 31, 2009) (see Note 6)	18,459,619	—
Total redeemable preferred stock	<u>18,459,619</u>	<u>13,904,100</u>
<b>STOCKHOLDERS' DEFICIENCY:</b>		
Preferred Stock, \$0.00001 par value; 7,000 shares authorized: Series C 8% cumulative convertible preferred stock; 272 shares designated; 204 and 272 shares issued and outstanding at December 31, 2009 and 2008, respectively (liquidation preference \$3,157,920 at December 31, 2009)	—	—
Common stock, \$0.00001 par value; 225,000,000 shares authorized; 69,658,002 and 43,975,656 shares issued and outstanding at December 31, 2009 and 2008, respectively	697	440
Additional paid-in capital	49,175,853	40,204,112
Accumulated deficit	<u>(76,072,088)</u>	<u>(59,693,153)</u>
Total stockholders' deficiency	<u>(26,895,538)</u>	<u>(19,488,601)</u>
<b>TOTAL LIABILITIES, REDEEMABLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIENCY</b>	<u>\$ 8,931,899</u>	<u>\$ 1,466,038</u>

*See report of independent registered public accounting firm and notes to financial statements.*

**NOVELOS THERAPEUTICS, INC.**  
**STATEMENTS OF OPERATIONS**

	<b>Year Ended December 31,</b>	
	<b>2009</b>	<b>2008</b>
<b>REVENUES</b>	<b>\$ 96,314</b>	<b>\$ 125,968</b>
<b>COSTS AND EXPENSES:</b>		
Research and development	8,080,242	14,526,619
General and administrative	2,182,253	2,190,366
Total costs and expenses	<u>10,262,495</u>	<u>16,716,985</u>
<b>LOSS FROM OPERATIONS</b>	<b>(10,166,181)</b>	<b>(16,591,017)</b>
<b>OTHER INCOME (EXPENSE):</b>		
Interest income	1,013	130,611
Loss on derivative warrants (see Note 2)	(12,114,371)	—
Miscellaneous	6,233	9,000
Total other income (expense)	<u>(12,107,125)</u>	<u>139,611</u>
<b>NET LOSS</b>	<b>(22,273,306)</b>	<b>(16,451,406)</b>
<b>PREFERRED STOCK DIVIDENDS</b>	<b>(3,296,289)</b>	<b>(2,092,102)</b>
<b>PREFERRED STOCK DEEMED DIVIDENDS</b>	<b>(714,031)</b>	<b>(4,417,315)</b>
<b>NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS</b>	<b>\$ (26,283,626)</b>	<b>\$ (22,960,823)</b>
<b>BASIC AND DILUTED NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS PER COMMON SHARE</b>	<b>\$ (0.53)</b>	<b>\$ (0.56)</b>
<b>SHARES USED IN COMPUTING BASIC AND DILUTED NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS PER COMMON SHARE</b>	<b><u>49,910,010</u></b>	<b><u>41,100,883</u></b>

*See report of independent registered public accounting firm and notes to financial statements.*

**NOVELOS THERAPEUTICS, INC.**  
**STATEMENTS OF REDEEMABLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIENCY**

	REDEEMABLE PREFERRED STOCK Series B, D and E Convertible Preferred Stock		Common Stock		Series C Cumulative Convertible Preferred Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficiency
	Shares	Amount	Shares	Par Amount	Shares	Par Amount			
BALANCE AT JANUARY 1, 2008	300	\$ 9,918,666	39,260,272	\$ 392	272	\$ —	\$ 37,370,959	\$ (43,241,747)	\$ (5,870,396)
Exercise of stock options	—	—	100,000	1	—	—	999	—	1,000
Compensation expense associated with options issued to employees	—	—	—	—	—	—	395,194	—	395,194
Compensation expense associated with options issued to non-employees	—	—	—	—	—	—	58,133	—	58,133
Issuance of common stock in a private placement	—	—	4,615,384	47	—	—	2,986,691	—	2,986,738
Issuance of Series D redeemable convertible preferred stock and warrants, net of issuance costs of \$205,328	113.5	4,167,080	—	—	—	—	1,302,592	—	1,302,592
Adjustment to record the carrying value of Series D redeemable convertible preferred stock at market value on the date of sale	—	(181,646)	—	—	—	—	181,646	—	181,646
Fair value of reduction in conversion and exercise price of Series B redeemable convertible preferred stock and warrants	—	3,876,912	—	—	—	—	722,049	—	722,049
Accretion of deemed dividend associated with the reduction of conversion and exercise prices on Series B redeemable convertible preferred stock and warrants	—	(3,876,912)	—	—	—	—	(722,049)	—	(722,049)
Dividends paid on preferred stock	—	—	—	—	—	—	(402,780)	—	(402,780)
Dividends accrued on preferred stock	—	—	—	—	—	—	(1,689,322)	—	(1,689,322)
Net loss	—	—	—	—	—	—	—	(16,451,406)	(16,451,406)
BALANCE AT DECEMBER 31, 2008	413.5	13,904,100	43,975,656	440	272	—	40,204,112	(59,693,153)	(19,488,601)
Reclassification of warrants to derivative liability (see Note 2)	—	—	—	—	—	—	(6,893,316)	5,894,371	(998,945)
Conversion of Series C convertible preferred stock and accumulated dividends into common stock	—	—	1,538,837	15	(68)	—	184,231	—	184,246
Conversion of Series E convertible preferred stock and accumulated dividends into common stock	(97.18209375)	(3,213,056)	7,939,008	79	—	—	3,514,235	—	3,514,314
Cashless exercise of warrants	—	—	483,829	5	—	—	1,000,957	—	1,000,962
Issuance of common stock in exchange for warrants	—	—	2,084,308	21	—	—	1,625,739	—	1,625,760
Issuance of common stock and warrants in a private placement, net of issuance costs of \$61,116	—	—	13,636,364	137	—	—	8,938,747	—	8,938,884
Compensation expense associated with options issued to employees	—	—	—	—	—	—	437,066	—	437,066
Compensation expense associated with options issued to non-employees	—	—	—	—	—	—	427,271	—	427,271
Issuance of Series E redeemable convertible preferred stock and warrants, net of issuance costs of \$795,469	200	6,297,323	—	—	—	—	2,907,208	—	2,907,208
Issuance of Series E redeemable convertible preferred stock in payment of accumulated dividends	31.942875	1,597,144	—	—	—	—	—	—	—
Adjustment to record the carrying value of Series E redeemable convertible preferred stock at fair value on the date of sale	—	(125,892)	—	—	—	—	125,892	—	125,892
Fair value of the extension of expiration date of warrants	—	—	—	—	—	—	839,923	—	839,923
Accretion of deemed dividend associated with the extension of expiration date of warrants	—	—	—	—	—	—	(839,923)	—	(839,923)
Dividends accrued on preferred stock	—	—	—	—	—	—	(3,296,289)	—	(3,296,289)
Net loss	—	—	—	—	—	—	—	(22,273,306)	(22,273,306)
BALANCE AT DECEMBER 31, 2009	548.26078125	\$ 18,459,619	69,658,002	\$ 697	204	\$ —	\$ 49,175,853	\$ (76,072,088)	\$ (26,895,538)

*See report of independent registered public accounting firm and notes to financial statements.*

**NOVELOS THERAPEUTICS, INC.**  
**STATEMENTS OF CASH FLOWS**

	<b>Year Ended December 31,</b>	
	<b>2009</b>	<b>2008</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$ (22,273,306)	\$ (16,451,406)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	32,354	16,889
Loss on disposal of fixed assets	—	6,472
Stock-based compensation	864,337	453,327
Loss on derivative warrants	12,114,371	—
Changes in:		
Prepaid expenses and other current assets	26,862	3,496
Accounts payable and accrued liabilities	(1,354,695)	(1,718,566)
Accrued compensation	5,072	(108,773)
Deferred revenue	(33,333)	466,666
Cash used in operating activities	<u>(10,618,338)</u>	<u>(17,331,895)</u>
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Purchases of fixed assets	(18,000)	(49,003)
Change in restricted cash	—	1,184,702
Cash provided by (used in) investing activities	<u>(18,000)</u>	<u>1,135,699</u>
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from issuance of common stock, net	8,938,884	2,986,738
Proceeds from issuance of Series D convertible preferred stock and warrants, net	—	5,469,672
Proceeds from issuance of Series E convertible preferred stock and warrants, net	9,204,531	—
Dividends paid to preferred stockholders	—	(740,280)
Proceeds from exercise of stock options	—	1,000
Cash provided by financing activities	<u>18,143,415</u>	<u>7,717,130</u>
<b>INCREASE (DECREASE) IN CASH AND EQUIVALENTS</b>	<b>7,507,077</b>	<b>(8,479,066)</b>
<b>CASH AND EQUIVALENTS AT BEGINNING OF YEAR</b>	<b>1,262,452</b>	<b>9,741,518</b>
<b>CASH AND EQUIVALENTS AT END OF YEAR</b>	<b><u>\$ 8,769,529</u></b>	<b><u>\$ 1,262,452</u></b>
<b>SUPPLEMENTAL DISCLOSURES OF NON-CASH FINANCING ACTIVITIES</b>		
Dividends accumulated on shares of Series E preferred stock exchanged or converted into shares of common stock	<u>\$ 1,898,402</u>	<u>\$ —</u>
Dividends accumulated on shares of Series C preferred stock converted into shares of common stock	<u>\$ 184,246</u>	<u>\$ —</u>
Fair value of derivative warrants upon adoption of new accounting principle	<u>\$ 998,945</u>	<u>\$ —</u>
Fair value of common stock issued in exchange for tender of derivative warrants	<u>\$ 1,625,760</u>	<u>\$ —</u>
Fair value of derivative warrants upon cashless exercise	<u>\$ 1,000,962</u>	<u>\$ —</u>
Exchange of Series B for Series D preferred stock	<u>\$ —</u>	<u>\$ 9,918,666</u>
Exchange of Series D for Series E preferred stock	<u>\$ 13,904,100</u>	<u>\$ —</u>
Relative fair value of warrants issued to stockholders	<u>\$ 4,835,727</u>	<u>\$ 1,302,592</u>

*See report of independent registered public accounting firm and notes to financial statements.*

**NOVELOS THERAPEUTICS, INC.**  
**NOTES TO FINANCIAL STATEMENTS**

**1. NATURE OF BUSINESS, ORGANIZATION AND GOING CONCERN**

Novelos Therapeutics, Inc. (“Novelos” or the “Company”) is a biopharmaceutical company focused on developing and commercializing oxidized glutathione-based compounds for the treatment of cancer and hepatitis and building a pipeline through licensing or acquiring clinical stage compounds or technologies for oncology indications. Novelos owns exclusive worldwide intellectual property rights (excluding Russia and other states of the former Soviet Union (the “Russian Territory”), but including Estonia, Latvia and Lithuania) related to certain clinical compounds and other pre-clinical compounds based on oxidized glutathione.

The Company is subject to a number of risks similar to those of other small biopharmaceutical companies. Principal among these risks are dependence on key individuals, competition from substitute products and larger companies, the successful development and marketing of its products in a highly regulated environment and the need to obtain additional financing necessary to fund future operations.

These financial statements have been prepared on the basis that the Company will continue as a going concern. The Company has incurred operating losses since inception and is devoting substantially all of its efforts toward the research and development of its oxidized glutathione-based compounds for the treatment of cancer and hepatitis and is seeking to build a pipeline through acquiring or licensing clinical stage compounds or technologies for oncology indications. The process of developing products will continue to require significant research and development, non-clinical testing, clinical trials and regulatory approval. The Company expects that these activities, together with general and administrative costs, will result in continuing operating losses for the foreseeable future. The Company believes that it has adequate cash to fund these activities into the fourth quarter of 2010. The Company’s ability to execute its operating plan beyond early in the fourth quarter of 2010 is dependent on its ability to obtain additional capital, principally through the sale of equity and debt securities, to fund its development activities. The Company plans to actively pursue financing alternatives during 2010, but there can be no assurance that it will obtain the additional capital necessary to fund its business beyond early in the fourth quarter of 2010. On February 24, 2010, the Company announced that its Phase 3 clinical trial for NOV-002 in non-small cell lung cancer (the “Phase 3 Trial”) did not meet its primary endpoint of a statistically significant increase in median overall survival. Following evaluation of the detailed trial data, on March 18, 2010, the Company announced that the secondary endpoints had also not been met in the Phase 3 Trial and that it had discontinued development of NOV-002 for NSCLC in combination with first-line paclitaxel and carboplatin chemotherapy, although development for other indications is continuing. The negative outcome of the Phase 3 Trial, as well as continuing difficult conditions in the capital markets globally, may adversely affect the ability of the Company to obtain funding in a timely manner. The Company is continuously evaluating measures to reduce costs to preserve existing capital. If the Company is unable to obtain sufficient additional funding, it will be required, beginning in mid-2010, to scale back its administrative and clinical development activities and may be required to cease its operations entirely.

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

The accompanying financial statements reflect the application of certain accounting policies, as described in this note and elsewhere in the accompanying notes to the financial statements.

*Use of Estimates* — The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires the Company’s management to make estimates and judgments that may affect the reported amounts of assets, liabilities, revenue and expenses and disclosure of contingent assets and liabilities. On an on-going basis, the Company’s management evaluates its estimates including those related to unbilled research and development costs, valuation of derivatives and share-based compensation. The Company bases its estimates on historical experience and on various other assumptions that are believed to be reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results may differ from those estimates under different assumptions or conditions. Changes in estimates are reflected in reported results in the period in which they become known.

**Cash Equivalents** — The Company considers all short-term investments purchased with original maturities of three months or less to be cash equivalents.

**Fixed Assets** — Property and equipment are stated at cost. Depreciation on property and equipment is provided using the straight-line method over the estimated useful lives of the assets, which range from three to five years. Leasehold improvements are depreciated over the lesser of the estimated useful lives of the assets or the remaining lease term.

**Impairment of Long - Lived Assets** — Whenever events or circumstances change, the Company assesses whether there has been an impairment in the value of long-lived assets by determining whether projected undiscounted cash flows generated by the applicable asset exceed its net book value as of the assessment date. There were no impairments of the Company's assets at the end of each period presented.

**Stock-Based Compensation** — The Company accounts for employee stock-based compensation in accordance with the guidance of FASB ASC Topic 718, *Compensation – Stock Compensation* which requires all share-based payments to employees, including grants of employee stock options, to be recognized in the financial statements based on their fair values. The Company accounts for non-employee stock-based compensation in accordance with the guidance of FASB ASC Topic 505, *Equity* which requires that companies recognize compensation expense based on the estimated fair value of options granted to non-employees over their vesting period, which is generally the period during which services are rendered by such non-employees.

**Revenue Recognition** — Revenue is recognized when persuasive evidence of an arrangement exists, the price is fixed and determinable, delivery has occurred, and there is reasonable assurance of collection. Upfront payments received in connection with technology license or collaboration agreements are recognized over the estimated term of the related agreement. The Company has not yet received milestone or royalty payments in connection with license or collaboration agreements.

**Research and Development** — Research and development costs are expensed as incurred.

**Income Taxes** — The Company uses the liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on temporary differences between the financial statement and tax basis of assets and liabilities and net operating loss and credit carryforwards using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. Valuation allowances are established when it is more likely than not that some portion of the deferred tax assets will not be realized. Tax positions taken or expected to be taken in the course of preparing the Company's tax returns are required to be evaluated to determine whether the tax positions are "more-likely-than-not" of being sustained by the applicable tax authority. Tax positions deemed not to meet a more-likely-than-not threshold would be recorded as tax expense in the current year. There were no uncertain tax positions that require accrual or disclosure to the financial statements as of December 31, 2009.

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

**Fair Value of Financial Instruments** — The guidance under FASB ASC Topic 825, *Financial Instruments*, requires disclosure of the fair value of certain financial instruments. The Company's financial instruments consist of cash equivalents, accounts payable, accrued expenses and redeemable preferred stock. The estimated fair value of the redeemable preferred stock, determined on an as-converted basis including conversion of accumulated unpaid dividends, was \$114,780,000 and \$15,959,000 at December 31, 2009 and 2008, respectively. The estimated fair value of the remaining financial instruments approximates their carrying value due to their short-term nature.

**Concentration of Credit Risk** — Financial instruments that subject the Company to credit risk consist of cash and equivalents on deposit with financial institutions. The Company's excess cash is on deposit in a non-interest-bearing transaction account that is fully covered by FDIC deposit insurance until June 30, 2010.

**Derivative Instruments** — The Company generally does not use derivative instruments to hedge exposures to cash flow or market risks; however, starting January 1, 2009, certain warrants to purchase common stock that do not meet the requirements for classification as equity, in accordance with the Derivatives and Hedging Topic of the FASB ASC, are classified as liabilities. In such instances, net-cash settlement is assumed for financial reporting purposes, even when the terms of the underlying contracts do not provide for a net-cash settlement. These warrants are considered derivative instruments as the agreements contain “down-round” provisions whereby the number of shares for which the warrants are exercisable and/or the exercise price of the warrants is subject to change in the event of certain issuances of stock at prices below the then-effective exercise price of the warrants. The number of such warrants was 14,003,319 at January 1, 2009 and 7,418,893 at December 31, 2009. The primary underlying risk exposure pertaining to the warrants is the change in fair value of the underlying common stock. Such financial instruments are initially recorded at fair value, or relative fair value when issued with other instruments, with subsequent changes in fair value recorded as a component of gain or loss on derivatives in each reporting period. If these instruments subsequently meet the requirements for equity classification, the Company reclassifies the fair value to equity. At December 31, 2009, these warrants represent the only outstanding derivative instruments issued or held by the Company.

**New Accounting Pronouncements** — In June 2009, the FASB issued FASB ASC 105, *Generally Accepted Accounting Principles*, which establishes the FASB Accounting Standards Codification (“ASC”) as the sole source of authoritative generally accepted accounting principles (“GAAP”). Pursuant to the provisions of FASB ASC 105, the Company has updated references to GAAP in the accompanying financial statements. The adoption of FASB ASC 105 did not impact the Company’s financial position or results of operations.

In May 2009, the FASB issued authoritative guidance now codified as FASB ASC Topic 855 related to subsequent events, which establishes general standards of accounting for and disclosures of subsequent events that occur after the balance sheet date but prior to the issuance of financial statements.

In December 2007, the FASB issued new authoritative guidance now codified as FASB ASC Topic 808, *Collaborative Arrangements*. The new guidance defines collaborative arrangements and establishes reporting requirements for transactions between participants in a collaborative arrangement and between participants in the arrangement and third parties. The new guidance became effective for fiscal years beginning after December 15, 2008 and had no effect on the Company’s reported financial position or results of operations in the year ended December 31, 2009.

**Adoption of New Accounting Principle** — Effective January 1, 2009, the Company adopted the guidance of FASB ASC 815-40-15, *Derivatives and Hedging*, which establishes a framework for determining whether certain freestanding and embedded instruments are indexed to a company’s own stock for purposes of evaluation of the accounting for such instruments under existing accounting literature. As a result of this adoption, certain warrants that were previously determined to be indexed to the Company’s common stock upon issuance were determined not to be indexed to the Company’s common stock because they include “down-round” anti-dilution provisions whereby the number of shares for which the warrants are exercisable and/or the exercise price of the warrants is subject to change in the event of certain issuances of stock at prices below the then-effective exercise price of the warrants. The fair value of the warrants at the dates of issuance totaling \$6,893,000 was initially recorded as a component of additional paid-in capital. Upon adoption of this guidance on January 1, 2009, the Company recorded a derivative liability of \$999,000, a decrease to the opening balance of additional paid-in capital of approximately \$6,893,000 and recorded a decrease to accumulated deficit totaling approximately \$5,894,000, representing the decrease in the fair value of the warrants from the date of issuance to December 31, 2008. The increase in fair value of the warrants of approximately \$12,114,000 during the year ended December 31, 2009 has been included as a component of other income in the accompanying statement of operations. Certain of the warrants that had been recorded as a derivative liability were exchanged or exercised for shares of the Company’s common stock during the year ended December 31, 2009. See Note 6 for a description of those transactions. The fair value of the warrants at December 31, 2009 of \$10,487,000 is included as a current liability in the accompanying balance sheet as of that date.

### 3. FIXED ASSETS

Fixed assets consisted of the following at December 31:

	<u>2009</u>	<u>2008</u>
Office and computer equipment	\$ 73,261	\$ 73,261
Computer software	43,896	25,896
Leasehold improvements	4,095	4,095
Total fixed assets	121,252	103,252
Less accumulated depreciation and amortization	(77,155)	(44,801)
Fixed assets, net	<u>\$ 44,097</u>	<u>\$ 58,451</u>

### 4. FAIR VALUES OF ASSETS AND LIABILITIES

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

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

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

	<u>December 31, 2009</u>			
	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>	<u>Fair Value</u>
<b>Liabilities:</b>				
Warrants	<u>\$ -</u>	<u>\$ 10,487,000</u>	<u>\$ -</u>	<u>\$ 10,487,000</u>

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

### 5. COLLABORATION AGREEMENTS

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

In December 2007 the Company entered into a Collaboration Agreement with Lee's Pharmaceutical (HK) Ltd. ("Lee's Pharm"). Pursuant to this agreement, Lee's Pharm obtained an exclusive license to develop, manufacture and commercialize NOV-002 and NOV-205 in China, Hong Kong, Taiwan and Macau (the "Chinese Territory"). Under the terms of the agreement the Company received a license fee of \$500,000 in March 2008 and is entitled to receive up to \$1,700,000 in future milestone payments upon the completion of development and marketing milestones by Lee's Pharm. This initial \$500,000 payment received is being amortized over the estimated term of this agreement, 15 years. Accordingly, \$33,334 of license revenue was recognized in each of the years ended December 31, 2009 and 2008.

The Lee's Pharm agreement provides that the Company receive royalty payments of 20-25% of net sales of NOV-002 in the Chinese Territory and receive royalty payments of 12-15% of net sales of NOV-205 in the Chinese Territory. Lee's Pharm is obligated to reimburse the Company for the manufacturing cost of pharmaceutical products provided to Lee's Pharm in connection with the agreement. Lee's Pharm has committed to spend a minimum amount on development in the first four years of the agreement. The agreement expires upon the expiration of the last patent covering any of the licensed products, or twelve years from the date of the first commercial sale in China, whichever occurs later.

### ***2009 Collaboration Agreement with Mundipharma***

On February 11, 2009, Novelos entered into a collaboration agreement (the "Collaboration Agreement") with Mundipharma International Corporation Limited ("Mundipharma") to develop, manufacture and commercialize, on an exclusive basis, Licensed Products (as defined in the Collaboration Agreement), which includes the Company's lead compound, NOV-002, in Europe (other than the Russian Territory), Asia (other than the Chinese Territory) and Australia (collectively referred to as the "Mundipharma Territory"). Mundipharma is an independent associated company of Purdue Pharma, L.P. ("Purdue"). Following is a summary of the terms of the Collaboration Agreement, however, the Company anticipates that the negative results of its Phase 3 Trial (see Note 11) will substantially reduce the likelihood that any payments will be received by the Company under the Collaboration Agreement.

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

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

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

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

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

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

## **6. STOCKHOLDERS' EQUITY (DEFICIENCY)**

### *Issuance of Series B Preferred Stock –*

On May 2, 2007, pursuant to a securities purchase agreement with accredited investors dated April 12, 2007 (the "Purchase Agreement"), as amended May 2, 2007, the Company sold 300 shares of a newly created series of preferred stock, designated "Series B Convertible Preferred Stock," with a stated value of \$50,000 per share (the "Series B Preferred Stock"), and issued warrants (the "Series B Warrants") to purchase 7,500,000 shares of common stock for an aggregate purchase price of \$15,000,000. The Series B Preferred Stock was initially convertible into 15,000,000 shares of common stock at \$1.00 per share. During 2008, the Company declared and paid \$675,000 in dividends to Series B stockholders (\$2,250 per share). See "Issuance of Series D Preferred Stock" below for a description of the exchange of Series B Preferred Stock that occurred on April 11, 2008.

The common stock purchase warrants issued to these purchasers were initially exercisable for an aggregate of 7,500,000 shares of the Company's common stock at an exercise price of \$1.25 per share and had an initial expiration date of May 2, 2012. The terms of the warrant provide for adjustment to the exercise price and/or number of warrants only for stock dividends, stock splits or similar capital reorganizations so that the rights of the warrant holders after such event would be equivalent to the rights of warrant holders prior to such event. The Series B Warrants were amended on April 11, 2008 to reduce the exercise price to \$0.65 per share and were further amended on February 11, 2009 to extend their expiration date to December 31, 2015.

Upon the closing of the Series B Preferred Stock financing, the Company issued to placement agents warrants to purchase a total of 900,000 shares of common stock with the same terms as the warrants issued to the investors.

### *Issuance of Series C Preferred Stock –*

As a condition to closing of the sale of Series B Preferred Stock described above, the Company entered into an agreement to exchange and consent with the holders of the Company's Series A preferred stock providing for the exchange of all 3,264 shares of Series A preferred stock for 272 shares of a new Series C convertible preferred stock (the "Series C Preferred Stock"), junior to the Series B Preferred Stock as set forth in the Series C Preferred Stock Certificate of Designations. The Series C Preferred Stock was initially convertible at \$1.00 per share into 3,264,000 shares of common stock. As part of the exchange, the Company issued to the holders of the Series A preferred stock warrants to purchase 1,333,333 shares of common stock expiring on May 2, 2012 at a price of \$1.25 per share; paid them a cash allowance to defray expenses totaling \$40,000; and paid them an amount of cash equal to unpaid dividends accumulated through the date of the exchange. In connection with the sale of Series D Preferred Stock described below, the conversion price of the Series C Preferred Stock was reduced to \$0.65 per share.

### *Terms of the Series C Preferred Stock*

The Series C Preferred Stock had an annual dividend rate of 8% until October 1, 2008 and thereafter has an annual dividend rate of 20%. The dividends are payable quarterly. Such dividends shall be paid only after all outstanding dividends on the Series D Preferred Stock (with respect to the current fiscal year and all prior fiscal years) have been paid to the holders of the Series D Preferred Stock. During 2008, the Company paid \$65,280 in dividends on Series C Preferred Stock (\$240 per share). No dividends were paid on Series C Preferred Stock during 2009. During 2009, a total of \$184,246 in dividends accumulated on Series C Preferred Stock were converted into shares of the Company's common stock in connection with the conversion of shares of Series C Preferred Stock. As of December 31, 2009, there were accumulated unpaid dividends of \$709,920 (\$3,480 per share) on Series C Preferred Stock. The conversion price is subject to adjustment for stock dividends, stock splits or similar capital reorganizations. The Series C Preferred Stock does not have voting rights and is redeemable only at the option of the Company upon 30 days' notice at a 20% premium plus any accrued but unpaid dividends. In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company's affairs, the Series C Preferred Stock will be treated as senior to Novelos common stock. After all required payments are made to holders of Series D Preferred Stock, the holders of Series C Preferred Stock will be entitled to receive first, \$12,000 per share and all accrued and unpaid dividends. If, upon any winding up of the Company's affairs, the Company's remaining assets available to pay the holders of Series C Preferred Stock are not sufficient to permit the payment in full, then all of the Company's assets will be distributed to the holders of Series C Preferred Stock (and any remaining holders of Series D Preferred Stock as may be required) on a pro rata basis.

### *Conversions of Series C Preferred Stock*

During the year ended December 31, 2009, 68 shares of the Company's Series C Preferred Stock, having an aggregate stated value of \$816,000, and accumulated dividends thereon of \$184,000 were converted into shares of the Company's common stock, leaving 204 shares of Series C Preferred Stock outstanding which are convertible into 3,766,153 shares of common stock. See Note 11 for a description of conversions of Series C Preferred Stock which occurred subsequent to December 31, 2009.

### *Issuance of Series D Preferred Stock –*

On April 11, 2008, pursuant to a securities purchase agreement with accredited investors dated March 26, 2008, as amended on April 9, 2008, the Company sold 113.5 shares of Series D Convertible Preferred Stock, par value \$0.00001 per share (the "Series D Preferred Stock") and issued warrants (the "Series D Warrants") to purchase 4,365,381 shares of its common stock for an aggregate purchase price of \$5,675,000 (the "Series D Financing").

### *Exchange of Series B Preferred Stock for Series D Preferred Stock*

In connection with the closing of the Series D Financing, the holders of the Company's Series B Preferred Stock exchanged all 300 of their shares of Series B Preferred Stock for 300 shares of Series D Preferred Stock. Following the exchange, no shares of Series B Preferred Stock were outstanding. The rights and preferences of the Series D Preferred Stock were substantially the same as the Series B Preferred Stock. However, the conversion price of the Series D Preferred Stock was \$0.65. In addition, the holders of Series B Preferred Stock waived liquidated damages that had accrued from December 7, 2007 through the closing date of the Series D Financing as a result of the Company's failure to register for resale 100% of the shares of common stock underlying the Series B Preferred Stock and Series B Warrants. As a result, during 2008, the Company recorded a reduction of general and administrative expenses of \$395,000 relating to the reversal of estimated liquidated damages that had been accrued through the date of the closing. The purchase agreement covering the issuance and sale of the Series D Preferred Stock provided that the dividends that accrued on the shares of Series B Preferred Stock from April 1, 2008 through the date of exchange were to be paid, out of legally available funds, on June 30, 2008. As of June 30, 2008 and through December 31, 2008 the Company did not have legally available funds for the payment of dividends under Delaware corporate law and therefore was not able to pay any dividends accrued in respect of the preferred stock totaling \$1,396,000 (\$3,375 per share) as of December 31, 2008. These dividends were subsequently exchanged for shares of Series E preferred stock. See "Exchange of Series D Preferred Stock for Series E Preferred Stock" below.

### *Board and Observer Rights*

Pursuant to the Series D Preferred Stock purchase agreement, from and after the closing, Xmark Opportunity Fund, L.P., Xmark Opportunity Fund, Ltd. and Xmark JV Investment Partners, LLC (collectively, the “Xmark Funds”), retained the right to designate one member to the Company’s Board of Directors. This right lasts until such time as the Xmark Funds no longer hold at least one-third of the Series D Preferred Stock issued to them at the closing of the Series D Financing. In addition, the Xmark Funds, Caduceus Master Fund Limited, Caduceus Capital II, L.P., Summer Street Life Sciences Hedge Fund Investors, LLC, UBS Eucalyptus Fund, LLC and PW Eucalyptus Fund, Ltd. (collectively, the “Series D Lead Investors”) have the right to designate one observer to attend all meetings of the Company’s Board of Directors (the “Board”), committees thereof and access to all information made available to members of the Board. This right lasts until such time as the Series D Lead Investors no longer hold at least one-third of the Series D Preferred Stock issued to them at closing. The rights to designate a Board member and Board observer have not been exercised.

### *Common Stock Purchase Warrants*

The Series D Warrants, as amended, are exercisable for an aggregate of 4,365,381 shares of the Company’s common stock at an exercise price of \$0.65 per share and expire on December 31, 2015. See “Series E Preferred Stock Private Placement” below for a description of the amendment to the Series D Warrants. If there is no effective registration statement registering, or no current prospectus available for, the resale of the shares issuable upon the exercise of the warrants, the holder may conduct a cashless exercise whereby the holder may elect to pay the exercise price by having the Company withhold, upon exercise, shares having a fair market value equal to the applicable aggregate exercise price. In the event of such a cashless exercise, the Company would receive no proceeds from the sale of common stock in connection with such exercise.

The warrant exercise price and/or number of warrants is subject to adjustment only for stock dividends, stock splits or similar capital reorganizations so that the rights of the warrant holders after such event will be equivalent to the rights of warrant holders prior to such event.

### *Placement Agent Fee and Other Costs*

Following the closing of the Series D Financing, the Company paid Rodman & Renshaw LLC a cash fee of \$100,000 and paid other closing costs of approximately \$105,000.

### *Amendments to Prior Warrants and Registration Rights Agreement*

At the closing on April 11, 2008, the Company entered into an amendment to the registration rights agreement dated May 2, 2007 with the holders of its Series B Preferred Stock to revise the definition of registrable securities under the agreement to include only the 12,000,000 shares of common stock that were included on a prior registration statement and to extend the registration obligations under the agreement by one year.

In addition, in connection with the closing on April 11, 2008, the warrants to purchase common stock issued in connection with the sale of Series B Preferred Stock were amended to conform the terms of those warrants to the terms of the warrants issued in the Series D Financing.

### *Exchange of Series D Preferred Stock for Series E Preferred Stock*

On February 11, 2009, all outstanding shares of Series D Preferred Stock and accumulated dividends thereon were exchanged for shares of Series E Preferred Stock. See “Series E Preferred Stock Private Placement” below.

### *2008 Issuance of Common Stock –*

On August 15, 2008, the Company sold 4,615,384 shares of its common stock to two related accredited investors for gross proceeds of approximately \$3,000,000, pursuant to a securities purchase agreement dated August 14, 2008.

## *Series E Preferred Stock Private Placement –*

### *Sale of Series E Preferred Stock to Purdue*

Concurrently with the execution of the Collaboration Agreement on February 11, 2009, Novelos sold to Purdue 200 shares of a newly created series of the Company's preferred stock, designated "Series E Convertible Preferred Stock," par value \$0.00001 per share (the "Series E Preferred Stock"), and a warrant (the "Series E Warrant") to purchase 9,230,769 shares of Novelos common stock for an aggregate purchase price of \$10,000,000 (the "Series E Financing"). Pursuant to the August 25, 2009 securities purchase agreement with Purdue (the "August 2009 Purchase Agreement"), Purdue has the right either to designate one member to the Board or to designate one observer to attend all meetings of the Board and committees thereof and to have access to all information made available to members of the Board. This right lasts until such time as Purdue or its independent associated companies no longer hold at least one half of the common stock purchased pursuant to the August 2009 Purchase Agreement and no longer hold at least one-half of the Series E Preferred Stock issued to them on February 11, 2009. See "August 2009 Common Stock Private Placement" below. Purdue has the right to participate in future equity financings in proportion to their pro rata ownership of common and preferred stock.

The Series E Warrant is exercisable for an aggregate of 9,230,769 shares of Novelos common stock at an exercise price of \$0.65 per share. The warrant expires on December 31, 2015. The warrant exercise price and/or the common stock issuable pursuant to such warrant are subject to adjustment for stock dividends, stock splits or similar capital reorganizations so that the rights of the warrant holder after such event will be equivalent to the rights of the warrant holder prior to such event.

### *Exchange of Series D Preferred Stock for Series E Preferred Stock*

The Company also entered into an exchange agreement with the holders (the "Series D Investors") of the Company's Series D Preferred Stock under which all 413.5 outstanding shares of Series D Preferred Stock and accumulated but unpaid dividends thereon totaling \$1,597,144 were exchanged for 445.442875 shares of Series E Preferred Stock. The rights and preferences of the Series E Preferred Stock are substantially the same as the Series D Preferred Stock. In addition, the holders of Series D Preferred Stock waived liquidated damages through the date of the exchange as a result of the Company's failure to file a registration statement covering the shares of common stock underlying the Series D Preferred Stock and warrants not otherwise registered. In connection with the execution of this exchange agreement, warrants held by the Series D Investors to purchase a total of 11,865,381 shares of the Company's common stock were amended to extend the expiration of the warrants to December 31, 2015 (from April 11, 2013) and to remove a forced exercise provision.

### *Terms of Series E Preferred Stock*

The shares of Series E Preferred Stock have a stated value of \$50,000 per share and are convertible into shares of common stock at any time after issuance at the option of the holder at \$0.65 per share of common. If there is an effective registration statement covering the shares of common stock underlying the Series E Preferred Stock and the VWAP, as defined in the Series E Certificate of Designations, of Novelos common stock exceeds \$2.00 for 20 consecutive trading days, then the outstanding shares of Series E Preferred Stock will automatically convert into common stock at the conversion price then in effect. The conversion price will be subject to adjustment for stock dividends, stock splits or similar capital reorganizations.

The Series E Preferred Stock has an annual dividend rate of 9%, payable semi-annually on June 30 and December 31. Such dividends may be paid in cash, in shares of Series E Preferred Stock or in registered shares of Novelos common stock at the Company's option, subject to certain conditions. The Company has not paid any dividends on Series E Preferred Stock. During 2009, a total of \$301,258 in dividends accumulated on Series E Preferred Stock was converted into shares of the Company's common stock in connection with the conversion of shares of Series E Preferred Stock. As of December 31, 2009, there were accumulated unpaid dividends of \$2,193,043 (\$4,000 per share) on shares of Series E Preferred Stock.

For as long as any shares of Series E Preferred Stock remain outstanding, Novelos is prohibited without the prior consent of holders of a majority of the outstanding shares of Series E preferred stock (which majority must include the Xmark Funds and Purdue) from (i) paying dividends to its common stockholders, (ii) amending its certificate of incorporation or by-laws, (iii) issuing any equity security or any security convertible into or exercisable for any equity security at a price of \$0.65 or less or with rights senior to the Series E Preferred Stock (except for certain exempted issuances), (iv) increasing the number of shares of Series E Preferred Stock or issuing any additional shares of Series E Preferred Stock, (v) selling or otherwise granting rights with respect to all or substantially all of its assets (or in the case of licensing, any material intellectual property) or the Company's business and shall not enter into a merger or consolidation with another company unless Novelos is the surviving corporation, the Series E Preferred Stock remains outstanding, there are no changes to the rights and preferences of the Series E Preferred Stock and there is not created any new class of capital stock senior to the Series E Preferred Stock, (vi) redeeming or repurchasing any capital stock other than the Series E Preferred Stock, (vii) incurring any new debt for borrowed money in excess of \$500,000 and (viii) changing the number of the Company's directors.

#### *Advisor Fees*

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

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

The terms of the Series E Preferred Stock contain provisions that may require redemption in circumstances that are beyond the Company's control, such as the acquisition of more than 50% of our outstanding stock by any person or entity. Therefore, the shares have been recorded as redeemable preferred stock outside of permanent equity in the balance sheet as of December 31, 2009. The gross proceeds of \$10,000,000 received in conjunction with the Series E Financing were allocated on a relative fair value basis between the Series E Preferred Stock and the warrants. The relative fair value of the warrants issued to investors of \$2,907,000 (determined using the Black-Scholes option pricing model, estimated volatility of 80%, a risk-free interest rate of 2.17% and a term equal to the term of the warrant) was recorded as additional paid-in capital while the relative fair value of the Series E Preferred Stock of \$7,093,000 was recorded as temporary equity. The carrying value of the Series E Preferred Stock was immediately adjusted to its fair value of \$7,385,000 based on the fair value of the as-converted common stock. The difference of \$292,000 represents a beneficial conversion feature and was recorded as a deemed dividend to preferred stockholders. Issuance costs related to the Series E Financing of \$795,000 were netted against temporary equity. The Series E Preferred Stock that was issued in payment of dividends was initially recorded in temporary equity at the value of the dividends that had accrued totaling \$1,597,000. This amount was then adjusted to the fair value of \$1,179,000 based on the fair value of the as-converted common stock. The difference of \$418,000 was recorded as an offset to the deemed dividends recorded. The Series E Preferred Stock that was issued in exchange for outstanding shares of Series D Preferred Stock was recorded at \$13,904,000, the carrying value of the shares of Series D Preferred Stock as of the date of the exchange.

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

Since the Company has concluded it is not probable that an event will occur which would allow the holders of Series E Preferred Stock to elect to receive a liquidation payment, the carrying value will not be adjusted until the time that such event becomes probable. The liquidation preference (redemption value) is \$29,606,000 at December 31, 2009.

### *Conversions of Series E Preferred Stock*

During the year ended December 31, 2009, 97,182,093.75 shares of the Company's Series E Preferred Stock, having an aggregate stated value of \$4,859,000 and accumulated dividends thereon of \$301,000, were converted into 7,939,008 shares of common stock. The associated carrying value of the converted shares totaling approximately \$3,213,000 was reclassified to permanent equity from temporary equity. See Note 11 for a description of conversions of Series E Preferred Stock which occurred subsequent to December 31, 2009.

### *August 2009 Common Stock Private Placement*

#### *Securities Purchase Agreement*

On August 25, 2009, the Company entered into the August 2009 Purchase Agreement with Purdue to sell 13,636,364 shares of its common stock, \$0.00001 par value and warrants to purchase 4,772,728 shares of its common stock at an exercise price of \$0.66 per share, expiring December 31, 2015, for an aggregate purchase price of \$9,000,000 (the "August 2009 Private Placement"). Concurrent with the execution and delivery of the August 2009 Purchase Agreement, the Company sold Purdue 5,303,030 shares of its common stock and a warrant to purchase 1,856,062 shares of its common stock at \$0.66 per share for approximately \$3,500,000 (the "Initial Closing"). On November 10, 2009, the Company completed the final closing under the August 2009 Purchase Agreement and sold Purdue 8,333,334 shares of Novelos common stock and warrants to purchase 2,916,668 shares of Novelos common stock for gross proceeds of \$5,500,000. Issuance costs associated with the transactions totaled \$61,000 and such amount was recorded as a reduction of additional paid-in capital.

Pursuant to the August 2009 Purchase Agreement, Purdue is entitled to a right of first refusal (the "Right of First Refusal") with respect to bona fide offers for the license or other acquisition of NOV-002 Rights (as defined in the August 2009 Purchase Agreement) in the United States (the "U.S. License") received from third parties and approved by the Company's board of directors. Under the Right of First Refusal, Novelos will be required to communicate to Purdue the terms of any such third-party offers received and Purdue will have 30 days to enter into a definitive agreement with Novelos on substantially similar terms that provide no lesser economic benefit to Novelos as provided in the third-party offer. The Right of First Refusal terminates upon business combinations, as defined in the August 2009 Purchase Agreement. Novelos has separately entered into letter agreements with Mundipharma and its independent associated company providing for a conditional exclusive right to negotiate for, and a conditional right of first refusal with respect to, NOV-002 Rights for Latin America, Mexico and Canada.

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

#### *Common Stock Purchase Warrant*

The common stock purchase warrants have an exercise price of \$0.66 per share and expire on December 31, 2015. The warrant exercise price and/or the number of shares of common stock issuable pursuant to such warrant will be subject to adjustment for stock dividends, stock splits or similar capital reorganizations so that the rights of the warrant holders after such event will be equivalent to the rights of warrant holders prior to such event. The relative fair value of the warrants issued to Purdue totaled \$1,929,000 and was recorded as a component of additional paid-in capital. The fair value of the warrants was determined based on the market value of the Company's common stock on the dates of issuance using the Black-Scholes method of valuation, estimated volatility of 90%, risk-free interest rates ranging from 2.02% to 2.7% and a term equal to the term of the warrant.

### ***Registration Rights Agreements***

The Company and the purchasers of Series B Preferred Stock entered into a registration rights agreement (the “Series B Registration Agreement”) in connection with the closing of the sale of the Series B Preferred Stock. The Series B Registration Agreement was subsequently amended on April 11, 2008 and on February 11, 2009. The agreement, as amended, requires the Company to use its best efforts to keep a registration statement covering 12,000,000 shares of common stock issuable upon conversion of Series E Preferred Stock continuously effective under the Securities Act until the earlier of the date when all securities covered by the registration statement have been sold or the second anniversary of the closing. In the event the Company does not fulfill the requirements of the registration rights agreement, the Company is required to pay to the investors liquidated damages equal to 1.5% per month of the aggregate purchase price of the preferred stock and warrants until the requirements have been met. The 12,000,000 shares of common stock were included on a registration statement that became effective on April 28, 2008. The second post-effective amendment was declared effective on April 27, 2009. As of December 31, 2009, and through the date of this filing, the Company has not concluded that it is probable that damages will become due; therefore, no accrual for damages has been recorded.

Simultaneous with the execution of the Series E purchase agreement, the Company entered into a registration rights agreement (the “Series E Registration Agreement”) with Purdue and the Series D Investors. The Series E Registration Agreement replaces a prior agreement dated April 11, 2008 between Novelos and the Series D Investors. The Series E Registration Agreement required Novelos to file with the Securities and Exchange Commission no later than 5 business days following the six-month anniversary of the execution of the Series E purchase agreement (the “Filing Deadline”), a registration statement covering the resale of (i) a number of shares of common stock equal to 100% of the shares issuable upon conversion of the Series E Preferred Stock (excluding 12,000,000 shares of common stock issuable upon conversion of the Series E Preferred Stock issued in exchange for shares of outstanding Series D Preferred Stock as described above that are included on a prior registration statement) and (ii) an aggregate of 21,096,150 shares of common stock issuable upon exercise of the Series B Warrants, the Series D Warrants and the Series E Warrant. Novelos was required to use its best efforts to have the registration statement declared effective and to keep the registration statement continuously effective under the Securities Act until the earlier of the date when all the registrable securities covered by the registration statement have been sold or the second anniversary of the closing of the Series E purchase agreement. Purdue and the Series D Investors consented to extend the Filing Deadline to September 15, 2009. The registration statement was filed on that date. The Series E Registration Agreement was amended on January 21, 2010 (see Note 11) principally to consent to a reduction in the number of shares offered. The registration statement covering the resale of a total of 19,000,000 shares of the Company’s common stock was declared effective on February 12, 2010. The use of the registration statement may be suspended for not more than 15 consecutive days or for a total of not more than 30 days in any 12-month period. The Company will use its reasonable best efforts to register the shares excluded from the registration statement as may be permitted by the SEC until such time as all of these shares either have been registered or may be sold without restriction in reliance on Rule 144 under the Securities Act.

As part of the August 2009 Private Placement, the Company entered into a registration rights agreement with Purdue (the “Purdue Registration Agreement”). The Purdue Registration Agreement requires the Company to file with the Securities and Exchange Commission no later than May 17, 2010, a registration statement covering the resale of all the shares of common stock issued pursuant to the August 2009 Purchase Agreement and all shares of common stock issuable upon exercise of the warrants issued pursuant to the August 2009 Purchase Agreement. The Company is required to use its best efforts to have the registration statement declared effective and to keep the registration statement continuously effective under the Securities Act until the earlier of the date when all the registrable securities covered by the registration statement have been sold or the second anniversary of the final closing. In the event the Company fails to file the registration statement timely, it will be required to pay Purdue liquidated damages equal to 1.5% per month (pro-rated on a daily basis for any period of less than a full month) of the aggregate purchase price of the common stock until the delinquent registration statement is filed. The Company will be allowed to suspend the use of the registration for not more than 15 consecutive days or for a total of not more than 30 days in any 12-month period. As of December 31, 2009, and through the date of this filing, the Company has not concluded that it is probable that damages will become due; therefore, no accrual for damages has been recorded.

**Common Stock Warrants** — the following table summarizes information with regard to outstanding warrants as of December 31, 2009, issued in connection with equity and debt financings since 2005.

<u>Offering</u>	<u>Outstanding (as adjusted)</u>	<u>Exercise Price (as adjusted)</u>	<u>Expiration Date</u>
2005 Bridge Financing	400,000	\$ 0.625	April 1, 2010
2005 Issuance of Common Stock	560,826	\$ 0.65	August 9, 2010
Series A Preferred Stock (1)	909,090	\$ 0.65	September 30, 2010
2006 Issuance of Common Stock	5,548,977	\$ 1.72	March 7, 2011
Series B Preferred Stock (2):			
Purchasers	7,500,000	\$ 0.65	December 31, 2015
Placement agents	900,000	\$ 1.25	May 2, 2012
Series C Exchange	1,333,333	\$ 1.25	May 2, 2012
Series D Preferred Stock (3)	4,365,381	\$ 0.65	December 31, 2015
Series E Preferred Stock	9,230,769	\$ 0.65	December 31, 2015
August 2009 Private Placement	<u>4,772,730</u>	\$ 0.66	December 31, 2015
<b>Total</b>	<u><u>35,521,106</u></u>		

- (1) Concurrent with the closing of the sale of Series B Preferred Stock in 2007, all shares of Series A Preferred Stock were exchanged for shares of Series C Preferred Stock.
- (2) Concurrent with the closing of the sale of Series D Preferred Stock in 2008, all shares of Series B Preferred Stock were exchanged for shares of Series D Preferred Stock.
- (3) Concurrent with the closing of the sale of Series E Preferred Stock in 2009, all shares of Series D Preferred Stock and accumulated unpaid dividends thereon were exchanged for shares of Series E Preferred Stock.

On August 11, 2008, warrants to purchase 6,923,028 shares of common stock expired unexercised.

On August 21, 2009, the Company entered into exchange agreements with certain accredited investors who held warrants, issued in the 2006 private placement, to purchase 6,947,728 shares of its common stock. Pursuant to the exchange agreements, an aggregate of 2,084,308 shares of the Company's common stock with a fair value of \$1,626,000 were issued in exchange for these warrants. The holders agreed not to transfer or dispose of the shares of common stock before February 18, 2010. The warrants had been recorded as a derivative liability on the Company's balance sheet at their estimated fair value of \$1,109,000 at the date of exchange. The difference of \$517,000 between the estimated fair value of the warrants at the date of exchange and the common stock issued to settle the derivative liability has been included as a component of the loss on derivative warrants for the year ended December 31, 2009. Following the exchange, warrants expiring on March 7, 2011 to purchase a total of 5,432,120 shares of common stock at \$1.82 per share remained outstanding. Following the final closing of the August 2009 Private Placement, described above, the number of these outstanding warrants was increased to 5,750,439 and the exercise price was reduced to \$1.72, as a result of anti-dilution provisions in the warrants.

During the year ended December 31, 2009, a total of 483,829 shares of the Company's common stock were issued upon the cashless exercise of warrants to purchase 1,067,385 shares of common stock. The Company reclassified a total of \$1,001,000 from derivative liability to additional paid-in capital upon the exercise of warrants. The following is a summary of the exercises:

<b>Original private placement</b>	<b>Shares of Common Stock Issued</b>	<b>Warrants Exercised</b>	<b>Exercise Price</b>	<b>Expiration Date</b>
2005 Bridge Financing	218,648	320,000	\$ 0.625	April 1, 2010
2005 Common Stock	200,504	485,317	\$ 0.65	August 9, 2010
Series A Preferred Stock	38,223	60,606	\$ 0.65	October 3, 2010
2006 Issuance of Common Stock	26,454	201,462	\$ 1.72	March 7, 2011
<b>Total</b>	<b>483,829</b>	<b>1,067,385</b>		

Other than those described above, there have been no warrant exercises through December 31, 2009. See Note 11 for a description of warrant exercises which occurred subsequent to December 31, 2009.

**Authorized and Reserved Shares** — On November 3, 2009, the Company's stockholders approved an amendment to the certificate of incorporation to increase the total number of authorized shares of the Company's common stock from 150,000,000 to 225,000,000.

The following shares were reserved for future issuance upon exercise of stock options or warrants or conversion of preferred stock as of the dates indicated:

	<b>December 31,</b>	
	<b>2009</b>	<b>2008</b>
2000 Stock Option Plan	56,047	56,047
2006 Stock Incentive Plan	6,710,000	4,770,000
Options issued outside of formalized plans	2,453,778	2,453,778
Warrants	35,521,106	28,102,033
Preferred stock	50,406,149	36,829,192
<b>Total shares reserved for future issuance</b>	<b>95,147,080</b>	<b>72,211,050</b>

## 7. STOCK-BASED COMPENSATION

The Company's stock-based compensation plans are summarized below:

*2000 Stock Option Plan.* As of December 31, 2009, there are options to purchase 56,047 shares of the Company's common stock outstanding under a stock option plan established in August 2000 (the "2000 Plan"). There will be no further grants made under the 2000 Plan. Options generally vested annually over three years and expire on the tenth anniversary of the grant date. No options were granted or exercised under the 2000 Plan during 2009 or 2008. During 2008, options to purchase 17,826 shares of common stock were canceled.

*2006 Stock Incentive Plan.* On May 1, 2006, the Company's board of directors adopted, and on July 21, 2006 the Company's stockholders approved, the 2006 Stock Incentive Plan (the "2006 Plan"). A total of 10,000,000 shares of common stock are reserved for issuance under the 2006 Plan for grants of incentive or nonqualified stock options, rights to purchase restricted and unrestricted shares of common stock, stock appreciation rights and performance share grants. A committee of the board of directors determines exercise prices, vesting periods and any performance requirements on the date of grant, subject to the provisions of the 2006 Plan. Options are granted at or above the fair market value of the common stock at the grant date and expire on the tenth anniversary of the grant date. Vesting periods are generally two to three years. In the years ended December 31, 2009 and 2008, stock options for the purchase of 1,940,000 and 2,560,000 shares of common stock, respectively, were granted under the 2006 Plan. During 2008, options to purchase 10,000 shares of common stock were canceled. Through December 31, 2009, there have been no exercises under the 2006 Plan. As of December 31, 2009, 3,290,000 shares remain available for grant under the 2006 Plan. Options granted pursuant to the 2006 Plan generally will become fully vested upon a termination event occurring within one year following a change in control, as defined. A termination event is defined as either termination of employment or services other than for cause or constructive termination of employees or consultants resulting from a significant reduction in either the nature or scope of duties and responsibilities, a reduction in compensation or a required relocation.

*Other Stock Option Activity.* During 2005 and 2004, the Company issued a total of 2,653,778 stock options to employees, directors and consultants outside of any formalized plan. These options are exercisable within a ten-year period from the date of grant, and vest at various intervals with all options being fully vested within two to three years of the grant date. The options are not transferable except by will or domestic relations order. The option price per share is not less than the fair market value of the shares on the date of the grant. During the year ended December 31, 2008 options to purchase 100,000 shares of common stock were exercised. No options were exercised during the year ended December 31, 2009.

### Accounting for Stock-Based Compensation

The Company accounts for employee stock-based compensation in accordance with the guidance of FASB ASC Topic 718, *Compensation – Stock Compensation* which requires all share-based payments to employees, including grants of employee stock options, to be recognized in the financial statements based on their fair values. The Company accounts for non-employee stock-based compensation in accordance with the guidance of FASB ASC Topic 505, *Equity* which requires that companies recognize compensation expense based on the estimated fair value of options granted to non-employees over their vesting period, which is generally the period during which services are rendered by such non-employees.

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

	<b>Year Ended December 31,</b>	
	<b>2009</b>	<b>2008</b>
<b>Employee and director stock option grants:</b>		
Research and development	\$ 148,030	\$ 159,519
General and administrative	289,036	235,675
	<u>437,066</u>	<u>395,194</u>
<b>Non-employee consultants stock option grants and restricted stock awards:</b>		
Research and development	328,614	24,131
General and administrative	98,657	34,002
	<u>427,271</u>	<u>58,133</u>
<b>Total stock-based compensation</b>	<u>\$ 864,337</u>	<u>\$ 453,327</u>

During 2008, the Company entered into a separation agreement with a former officer of the Company that provided, among other terms, for the immediate vesting of 166,667 unvested options to purchase the Company's common stock and provided for an extension, until December 31, 2009, of the expiration of the total of 350,000 options held by the former officer. The 2008 stock-based compensation for research and development employees included in the table above includes incremental stock-based compensation expense of \$23,700 that was recorded in connection with the modification of the option terms. On December 31, 2009, the expiration of the options was extended until January 31, 2010 and incremental stock-based compensation expense for non-employees of \$15,000 was recorded in connection with the one-month extension.

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

## Determining Fair Value

*Valuation and amortization method* . The fair value of each stock award is estimated on the grant date using the Black-Scholes option-pricing model. The estimated fair value of employee stock options is amortized to expense using the straight-line method over the vesting period.

*Volatility*. The Company estimates volatility based on an average of (1) the Company's historical volatility since its common stock has been publicly traded and (2) review of volatility estimates of publicly held drug development companies with similar market capitalizations.

*Risk-free interest rate* . The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the time of grant commensurate with the expected term assumption.

*Expected term* . The expected term of stock options granted is based on the Company's estimate of when options will be exercised in the future as there have been limited stock option exercises to date. The expected term is generally applied to one group as a whole as the Company does not expect substantially different exercise or post-vesting termination behavior within its population of option holders.

*Forfeitures*. The Company records stock-based compensation expense only for those awards that are expected to vest. FASB ASC Topic 718 requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. The term "forfeitures" is distinct from "cancellations" or "expirations" and represents only the unvested portion of the surrendered option. The Company has applied an annual forfeiture rate of 0% to all unvested options as of December 31, 2009 as the Company has experienced very few forfeitures to date and believes that there is insufficient history to develop an accurate estimate of future forfeitures. This analysis will be re-evaluated semi-annually and the forfeiture rate will be adjusted as necessary. Ultimately, the actual expense recognized over the vesting period will be for only those shares that vest.

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

	Year Ended	
	December 31,	
	2009	2008
Volatility	90%	80%
Weighted-average volatility	90%	80%
Risk-free interest rate	2.12%	1.50%-3.28%
Expected life (years)	5	5
Dividend	0%	0%
Weighted-average exercise price	\$ 0.75	\$ 0.46
Weighted-average grant-date fair value	\$ 0.53	\$ 0.30

## Stock Option Activity

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

	Options Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Contracted Term in Years	Aggregate Intrinsic Value
Outstanding at January 1, 2008	4,847,651	\$ 0.67	8.1	\$ 1,308,961
Options granted	2,560,000	\$ 0.46		
Options exercised	(100,000)	\$ 0.01		
Options canceled	(27,826)	\$ 2.23		
Outstanding at December 31, 2008	7,279,825	\$ 0.60	7.9	\$ 989,718
Options granted	1,940,000	\$ 0.75		
Options exercised	—			
Outstanding at December 31, 2009	9,219,825	\$ 0.63	7.5	\$ 17,650,255
Exercisable at December 31, 2009	5,753,149	\$ 0.64	6.3	\$ 11,031,302

The aggregate intrinsic value of options outstanding is calculated based on the positive difference between the closing market price of the Company's common stock at the end of the respective period and the exercise price of the underlying options. During the year ended December 31, 2008, the total intrinsic value of options exercised was \$74,000 and the total amount of cash received from exercise of these options was \$1,000. Shares of common stock issued upon the exercise of options are from authorized but unissued shares.

As of December 31, 2009, there was approximately \$1,972,000 of total unrecognized compensation cost related to unvested stock-based compensation arrangements. Of this total amount, 45%, 36% and 19% are expected to be recognized during 2010, 2011 and 2012, respectively. The Company expects 3,466,676 in unvested options to vest in the future. The weighted-average grant-date fair value of vested and unvested options outstanding at December 31, 2009 was \$0.39 and \$0.42, respectively.

## 8. INCOME TAXES

The Company's deferred tax assets consisted of the following at December 31:

	2009	2008
Net operating loss carryforwards	\$ 9,543,000	\$ 7,128,000
Research and development expenses	14,906,000	13,681,000
Tax credits	1,563,000	1,311,000
Capital loss carryforward	340,000	340,000
Stock-based compensation	650,000	449,000
Gross deferred tax asset	27,002,000	22,909,000
Valuation allowance	(27,002,000)	(22,909,000)
Net deferred tax asset	\$ —	\$ —

As of December 31, 2009, the Company had federal and state net operating loss carryforwards of approximately \$25,140,000 and \$18,073,000 respectively, which expire through 2029. In addition, the Company has federal and state research and development and investment tax credits of approximately \$1,276,000 and \$434,000, respectively which expire through 2029. The amount of net operating loss carryforwards which may be utilized annually in future periods may be limited pursuant to Section 382 of the Internal Revenue Code as a result of substantial changes in the Company's ownership that have occurred or that may occur in the future.

The capital loss carryforward relates to the loss recorded in prior years for Novelos' investment in an unrelated company.

Because of the Company's limited operating history, continuing losses and uncertainty associated with the utilization of the net operating loss carryforwards in the future, management has provided a 100% allowance against the Company's gross deferred tax asset. In 2009, the difference between the Company's total statutory tax rate of approximately 38% and its effective tax rate of 0% is due equally to the increase in valuation allowance and the reduction in tax loss resulting from the nondeductible loss on derivative warrants. In 2008, the increase in the valuation allowance represents the principal difference between the Company's total statutory tax rate of approximately 38% and its effective tax rate of 0%.

The Company did not have any unrecognized tax benefits or accrued interest and penalties at any time during the years ended December 31, 2009 and 2008, and does not anticipate having any unrecognized tax benefits over the next twelve months. The Company is subject to audit by the IRS for tax periods commencing January 1, 2006.

## 9. NET LOSS PER SHARE

Basic net loss per share is computed by dividing net loss attributable to common stockholders by the weighted average number of shares of common stock outstanding during the period. Diluted net loss per share is computed by dividing net loss attributable to common stockholders by the weighted average number of shares of common stock and the dilutive potential common stock equivalents then outstanding. Potential common stock equivalents consist of stock options, warrants and convertible preferred stock and accumulated dividends. Since the Company has a net loss for all periods presented, the inclusion of common stock equivalents in the computation would be antidilutive. Accordingly, basic and diluted net loss per share are the same.

The following potentially dilutive securities have been excluded from the computation of diluted net loss per share since their inclusion would be antidilutive:

	<b>Year Ended</b>	
	<b>December 31,</b>	
	<b>2009</b>	<b>2008</b>
Stock options	9,219,825	7,279,825
Warrants	35,521,106	28,102,033
Conversion of preferred stock	50,406,149 (1)	36,829,192

(1) Includes shares of common stock that may become issuable upon conversion of dividends accumulated at December 31, 2009.

## 10. COMMITMENTS

### *Property Lease*

On May 11, 2009, the Company entered into a twelve-month lease for office space, commencing September 1, 2009 at a rate of \$5,275 per month. Rent expense was \$87,000 and \$92,000 for the years ended December 31, 2009 and 2008, respectively. Future minimum lease payments under this non-cancelable lease are \$42,200 during 2010.

### *Royalty Arrangements*

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

If a royalty is not being paid to ZAO BAM on net sales of oxidized glutathione products, then the Company is required to pay ZAO BAM 3% of all license revenues. If license revenues exceed the Company's cumulative expenditures including, but not limited to, preclinical and clinical studies, testing, FDA and other regulatory agency submission and approval costs, general and administrative costs, and patent expenses, then the Company would be required to pay ZAO BAM an additional 9% of the amount by which license revenues exceed the Company's cumulative expenditures. During 2008, the Company paid ZAO BAM \$15,000, which was 3% of license payments received under the collaboration agreement described in Note 5. This amount is included in research and development expense on the statement of operations.

As a result of the assignment to Novelos of the exclusive worldwide intellectual property and marketing rights of oxidized glutathione (excluding the Russian Territory), Novelos is obligated to the Oxford Group, Ltd., or its assignees, for future royalties. Simyon Palmin, a founder of Novelos, a director until August 12, 2008 and the father of the Company's president and chief executive officer, is president of Oxford Group, Ltd. Mr. Palmin was also an employee of the Company and is now a consultant to the Company. Pursuant to the agreement, as revised May 26, 2005, Novelos is required to pay Oxford Group, Ltd. a royalty in the amount of 0.8% of the Company's net sales of oxidized glutathione-based products.

### ***Employment Agreements***

On July 15, 2005, the Company entered into an employment agreement with Christopher J. Pazoles, whereby he agreed to serve as the Company's vice president of research and development for an initial term of two years. The agreement is automatically renewed for successive one-year terms unless notice of termination is provided by either party at least 60 days prior to the end of any such term. The agreement was renewed for an additional one-year term on July 15, 2009 in accordance with its terms. The agreement provides for a minimum salary of \$195,000 during the current and any future terms as well as participation in standard benefit programs. The agreement further provides that upon resignation for good reason or termination without cause, both as defined in the agreement, Dr. Pazoles will receive his base salary for the remainder of the contract term. In addition, his benefits will be paid for the twelve months following termination.

The Company entered into an employment agreement with Harry Palmin effective January 1, 2006, whereby he agreed to serve as the Company's president and chief executive officer for an initial term of two years. The agreement is automatically renewed for successive one-year terms unless notice of termination is provided by either party at least 90 days prior to the end of such term. The agreement was renewed for an additional one-year term on January 1, 2010 in accordance with its terms. The agreement provides for an initial salary of \$225,000, participation in standard benefit programs and an annual cash bonus at the discretion of the compensation committee. The agreement further provides that upon resignation for good reason or termination without cause, both as defined in the agreement, Mr. Palmin will receive his pro rata share of the average of his annual bonus paid during the two fiscal years preceding his termination; his base salary and benefits for 11 months after the date of termination and fifty percent of his unvested stock options will vest. The agreement also contains a non-compete provision, which prohibits Mr. Palmin from competing with the Company for one year after termination of his employment with the Company.

### ***Phase 3 Clinical Trial Bonus Plan***

On December 8, 2009, the board of directors of the Company approved a special bonus plan for all employees of the Company. The bonus plan provides for the payment of contingent cash bonuses in three equal installments in aggregate amounts ranging from 80% to 150% of annual 2009 salaries for each employee. All payments under the bonus plan are conditioned upon the achievement of favorable results for our Phase 3 clinical trial of NOV-002 in non-small cell lung cancer (the "Phase 3 Trial"). As a result of the unfavorable results of the Phase 3 Trial (see Note 11), no amounts will be paid under the special bonus plan.

## 11. SUBSEQUENT EVENTS

### *Phase 3 Clinical Trial Results*

On February 24, 2010, the Company announced that the primary endpoint of improvement in overall survival was not met in its pivotal Phase 3 Trial. Following evaluation of the detailed trial data, the Company further announced on March 18, 2010 that the secondary endpoints also were not met in the trial. The secondary endpoints included progression-free survival, response rate and duration of response, recovery from chemotherapy-induced myelosuppression, determination of immunomodulation, quality of life and safety. Adding NOV-002 to paclitaxel and carboplatin chemotherapy was not statistically or meaningfully different in terms of efficacy-related endpoints or recovery from chemotherapy toxicity versus chemotherapy alone. Based on the results from the Phase 3 Trial, the Company has determined to discontinue development of NOV-002 for NSCLC in combination with first-line paclitaxel and carboplatin chemotherapy.

### *Conversions of Preferred Stock*

From January 1, 2010 through March 30, 2010, a total of 11,745,779 shares of the Company's common stock were issued upon conversion of approximately 140 shares of its Series E Preferred Stock, having an aggregate stated value of approximately \$7,000,000, and accumulated undeclared dividends thereon.

### *Warrant Exercises*

From January 1, 2010 through March 30, 2010, a total of 8,182,158 shares of the Company's common stock were issued upon the cashless exercise of warrants to purchase 13,732,580 shares of the Company's common stock as follows:

<b>Original private placement</b>	<b>Shares of Common Stock Issued</b>	<b>Warrants Exercised</b>	<b>Exercise Price</b>	<b>Expiration Date</b>
2005 Bridge Financing	314,982	400,000	\$ 0.625	April 1, 2010
2005 Common Stock	226,544	317,350	\$ 0.65	August 9, 2010
2006 Issuance of Common Stock	366,492	991,516	\$ 1.72	March 7, 2011
Series B Preferred Stock – Purchasers	4,545,447	7,500,000	\$ 0.65	December 31, 2015
Series B Preferred Stock – Placement agents	35,106	75,000	\$ 1.25	May 2, 2012
Series D Preferred Stock	2,645,685	4,365,381	\$ 0.65	December 31, 2015
Series C Exchange	47,902	83,333	\$ 1.25	May 2, 2012
<b>Total</b>	<b>8,182,158</b>	<b>13,732,580</b>		

### *Stock Option Exercises*

From January 1, 2010 through March 30, 2010, options to purchase 800,000 shares of the Company's common stock were exercised for an aggregate exercise price of \$157,400 and options to purchase 150,000 shares of common stock expired unexercised.

### *Consent and Amendment Agreement*

The Company entered into a consent and amendment agreement with the holders of its Series E Preferred Stock that provided for the filing of an amendment to a registration statement previously filed on December 7, 2009, reducing the number of shares offered from 58,745,592 to 19,000,000. In addition, the Company agreed to use its reasonable best efforts to register the shares excluded from the registration statement as may be permitted by the SEC until such time as all of these shares either have been registered or may be sold without restriction in reliance on Rule 144 under the Securities Act.

### ***Class Action Complaint***

A purported class action complaint was filed on March 5, 2010 in the United States District Court for the District of Massachusetts by an alleged shareholder of the Company, on behalf of himself and all others who purchased or otherwise acquired the Company's common stock in the period between December 14, 2009 and February 24, 2010, against the Company and its President and Chief Executive Officer. The complaint claims that the Company violated Section 10(b) of the Securities Exchange Act of 1934, as amended, and Rule 10b-5 promulgated thereunder in connection with alleged disclosures related to the Phase 3 clinical trial of NOV-002 for non-small cell lung cancer. The Company believes the allegations are without merit and intends to defend vigorously against the allegations. Legal costs related to the complaint will be expensed as incurred.

#### **ITEM 7. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE**

None.

#### **ITEM 8A. CONTROLS AND PROCEDURES**

*Management's report on internal control over financial reporting.* Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rule 13a-15(f) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on criteria established in the *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Management's evaluation included such elements as the design and operating effectiveness of key financial reporting controls, process documentation, accounting policies, and our overall control environment. Based on this evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, 2009. This annual report does not include an attestation report of the Company's independent registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by the Company's independent registered public accounting firm pursuant to temporary rules of the Securities and Exchange Commission that permit the Company to provide only management's report in this annual report.

*Evaluation of disclosure controls and procedures.* Based on our management's evaluation (with the participation of our principal executive officer and principal financial officer), as of the end of the period covered by this report, our principal executive officer and principal financial officer have concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) are effective to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms.

It should be noted that any system of controls, however well designed and operated, can provide only reasonable, and not absolute, assurance that the objectives of the system are met. In addition, the design of any control system is based in part on certain assumptions about the likelihood of future events. Because of these and other inherent limitations of control systems, there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions, regardless of how remote.

*Changes in internal control over financial reporting* . Our management, in connection with its evaluation of internal controls (with the participation of our principal executive officer and principal financial officer), did not identify any change in internal control over the financial reporting process that occurred during our fourth fiscal quarter of 2009 that would have materially affected, or would have been reasonably likely to materially affect, our internal control over financial reporting.

**ITEM 8B. OTHER INFORMATION**

**Submission of Matters to Security Holders**

We held a Special Meeting in Lieu of Annual Meeting of Stockholders at the offices of Foley Hoag LLP, 155 Seaport Boulevard, Boston, Massachusetts on November 3, 2009.

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

	<b>Shares of Series E Preferred Stock Voting on an As-Converted Basis</b>			
	<b>Shares of Common Stock Votes</b>		<b>Votes</b>	
	<b><u>Voted For</u></b>	<b><u>Withheld</u></b>	<b><u>Voted For</u></b>	<b><u>Withheld</u></b>
Stephen A. Hill	40,580,322	843,732	8,609,712	0
Harry S. Palmin	40,571,904	852,150	8,609,712	0
Michael J. Doyle	40,580,322	843,732	8,609,712	0
Sim Fass	40,580,322	843,732	8,609,712	0
James S. Manuso	40,580,322	843,732	8,609,712	0
David B. McWilliams	40,580,322	843,732	8,609,712	0
Howard M. Schneider	40,580,322	843,732	8,609,712	0

(ii) The stockholders approved an amendment to our Certificate of Incorporation to increase the number of shares of our common stock authorized thereunder from 150,000,000 to 225,000,000. Holders of shares of our common stock cast 39,335,673 votes for the proposal; 1,955,403 votes against the proposal; 133,078 votes abstained; and there were no broker non-votes. Holders of shares of our Series E preferred stock cast 615.692875 votes for the proposal; no votes against the proposal; no votes abstained; and there were no broker non-votes. Holders of shares of our common stock and holders of our Series E preferred stock voting together on an as-converted basis cast 47,945,285 votes for the proposal; 1,955,403 votes against the proposal; 133,078 votes abstained; and there were no broker non-votes.

(iii) The stockholders approved an amendment to our 2006 Stock Incentive Plan to increase the number of shares of our common stock authorized for issuance thereunder from 5,000,000, to 10,000,000. Holders of shares of our common stock cast 22,970,092 votes for the proposal; 2,547,321 votes against the proposal; 131,391 votes abstained; and there were no broker non-votes. Holders of shares of our Series E preferred stock voting on an as-converted basis cast 8,609,712 votes for the proposal; no votes against the proposal; no votes abstained; and there were no broker non-votes.

### PART III

#### ITEM 9. DIRECTORS, EXECUTIVE OFFICERS, AND CORPORATE GOVERNANCE

As of March 22, 2010, our current directors and executive officers are:

<u>Name</u>	<u>Age</u>	<u>Position</u>
Stephen A. Hill, B.M. B.Ch., M.A., F.R.C.S.	51	Chairman of the Board
Harry S. Palmin	40	President, Chief Executive Officer and Director
Elias B. Nyberg, DVM, BVSc, MACVS, MRCVS, MBA	55	Vice President of Regulatory, Quality and Compliance
Christopher J. Pazoles, Ph.D.	60	Vice President of Research and Development
Joanne M. Protano	41	Vice President, Chief Financial Officer and Treasurer
Kristin C. Schuhwerk	39	Vice President of Clinical Development and Operations
Michael J. Doyle (1) (2) (3)	51	Director
Sim Fass, Ph.D. (1) (2) (3)	68	Director
James S. Manuso, Ph.D.	61	Director
David B. McWilliams (2) (3)	66	Director
Howard M. Schneider (1) (3)	66	Director

- (1) Member of the audit committee.  
(2) Member of the compensation committee.  
(3) Member of the nominating and corporate governance committee.

Our executive officers are appointed by, and serve at the discretion of, our board of directors.

**Stephen A. Hill** . Dr. Hill was elected our chairman of the board of directors in September 2007. Dr. Hill has served as the President and Chief Executive Officer of Solvay Pharmaceuticals, Inc. since April 2008. Prior to joining Solvay, Dr. Hill had served as ArQule's President and Chief Executive Officer since April 1999. Prior to his tenure at ArQule, Dr. Hill was the Head of Global Drug Development at F. Hoffmann-La Roche Ltd. from 1997 to 1999. Dr. Hill joined Roche in 1989 as Medical Adviser to Roche Products in the United Kingdom. He held several senior positions at Roche, including Medical Director where he was responsible for clinical trials of compounds across a broad range of therapeutic areas, including CNS, HIV, cardiovascular, metabolic and oncology products. Subsequently, he served as Head of International Drug Regulatory Affairs at Roche headquarters in Basel, Switzerland, where he led the regulatory submissions for seven major new chemical entities. Dr. Hill also was a member of Roche's Portfolio Management, Research, Development and Pharmaceutical Division Executive Boards. Prior to Roche, Dr. Hill served seven years with the National Health Service in the United Kingdom in General and Orthopedic Surgery. Dr. Hill is a Fellow of the Royal College of Surgeons of England and holds his scientific and medical degrees from St. Catherine's College at Oxford University. Dr. Hill's extensive experience in a broad range of senior management positions with companies in the life sciences sector make him a highly qualified member of our board of directors.

**Harry S. Palmin** . Mr. Palmin has served as our president and a director since 1998 and our chief executive officer since January 2005. From 1998 to September 2005, he served as our acting chief financial officer. From 1996 to 1998, he was a vice president at Lehman Brothers and from 1993 to 1996, he was an associate at Morgan Stanley & Co. Mr. Palmin earned a B.A. in economics and business and a M.A. in international economics and finance from the International Business School at Brandeis University. He has also studied at the London School of Economics and the Copenhagen Business School. Mr. Palmin's experience managing the funding and development of our product candidates for 12 years and his knowledge of capital markets are strong qualifications to serve on our board of directors.

**Elias B. Nyberg** . Dr. Nyberg has served as our vice president of regulatory, quality and compliance since May 2008. From September 2006 to April 2008, Dr. Nyberg was a regulatory advisor to several companies including Labopharm and Novartis Pharmaceuticals, Inc. From February 2004 to September 2006 he was the Vice President Regulatory Affairs for CombinatoRx. From April 2001 to January 2004 he served as the Senior Director International Regulatory Affairs for Biogen. Dr. Nyberg has also held senior regulatory positions with INC Research/PRA International Inc., Astra Arcus AB, Pfizer Pharmaceuticals and Ciba-Geigy. Prior to his tenure in the biotechnology industry, Dr. Nyberg practiced as a veterinarian for 12 years, specializing in exotic animals. He undertook his primary veterinary training in the Philippines followed by post-doctorate work in South Africa and Australia. Dr. Nyberg earned an MBA in England and his specialty (diplomate) boards in Exotic Animal (Avian) Medicine (MACVS) in Australia. He is also a member of the Royal College of Veterinary Surgeons (MRCVS) in London.

**Christopher J. Pazoles** . Dr. Pazoles has served as our vice president of research and development since July 2005. From May 2004 to June 2005, he held a senior research and development position at the Abbott Bioresearch Center, a division of Abbott Laboratories. From October 2002 to January 2004, he served as chief operating officer and head of research and development at ALS Therapy Development Foundation. From 1994 to October 2002, Dr. Pazoles served as vice president of research for Phytera, Inc. From 1981 to 1994, he served as a researcher and senior manager with Pfizer. Dr. Pazoles holds a Ph.D. in microbiology from the University of Notre Dame.

**Joanne M. Protano** . Ms. Protano was appointed our vice president, chief financial and accounting officer, and treasurer in December 2007. She previously held the position of Senior Director of Finance and Controller of the Company from June 2006 to December 2007. From 1996 to 2006, she held various management and senior management positions with Ascential Software, Inc. and predecessor companies including Assistant Controller, Reporting for Ascential Software, Vice President and Chief Financial Officer for the Ascential Software Division of Informix Software, Inc. and Corporate Controller of Ardent Software, Inc. Prior to her tenure in the technology industry, from 1990 to 1996 she was employed by Deloitte and Touche LLP as an audit manager, serving technology and healthcare clients. Ms. Protano received a B.S. in business administration from Bryant College.

**Kristin C. Schuhwerk** . Ms. Schuhwerk was appointed our vice president of clinical development and operations in December 2007. She previously served as our Director/Senior Director of Operations from July 2005 to December 2007. Prior to her employment at Novelos, she worked in the biopharmaceutical industry managing and overseeing business operations for multiple global Phase 2 and 3 clinical studies. From 2002 to 2005 she held the positions of Senior Project Manager and Director of Planning and Business Operations in Clinical Development at Antigenics, Inc., a cancer biotechnology company. From 1993 to 2002, she held research, project management and management positions at Boston University Medical Center, Parexel International, AstraZeneca and Brigham & Women's Hospital. Ms. Schuhwerk earned a B.S. degree in Chemistry from the University of New Hampshire.

**Michael J. Doyle** . Mr. Doyle has served as one of our directors since October 2005. Since October 2007 he has served as the chief executive officer of Medsphere Systems Corporation. From April 2006 to June 2007, he served as chief executive officer of Advantedge Healthcare Solutions. From January 2005 to March 2006, he served as chief executive officer of Windward Advisors. From March 2000 to December 2004, Mr. Doyle served as chairman and chief executive officer of Salesnet. From 1989 to 1997, he served as chairman and chief executive officer of Standish Care/Carematrix, a company he founded. He received a B.S. in biology from Tufts University and a M.B.A. with a concentration in finance and health care from the University of Chicago. Mr. Doyle's extensive experience leading emerging companies make him a highly qualified member of our board of directors.

**Sim Fass** . Dr. Fass has served as one of our directors since February 2005. Dr. Fass, now retired, served as chief executive officer and chairman of Savient Pharmaceuticals from 1997 to 2004, its president and chief executive officer from 1984 to 1997, and its chief operating officer from 1983 to 1984. From 1980 to 1983, Dr. Fass served as vice president and general manager of Wampole Laboratories. From 1969 to 1980, he held a number of marketing, sales and senior management positions at Pfizer, Inc in both pharmaceuticals and diagnostics. Dr. Fass has served as a director of Nanovibronix since 2005. He received a B.S. in biology and chemistry from Yeshiva College and a doctoral degree in developmental biology/biochemistry from the Massachusetts Institute of Technology. Dr. Fass' qualifications to serve on our board of directors include his extensive senior management experience with pharmaceutical companies.

**James S. Manuso** . Dr. Manuso was elected as one of our directors in August 2007. Since January 2005, Dr. Manuso has served as Chairman, President and Chief Executive Officer of SuperGen, Inc. and has served as a director of SuperGen since February 2001. Dr. Manuso is co-founder and former president and chief executive officer of Galenica Pharmaceuticals, Inc. Dr. Manuso co-founded and was general partner of PrimeTech Partners, a biotechnology venture management partnership, from 1998 to 2002, and Managing General Partner of The Channel Group LLC, an international life sciences corporate advisory firm. He was also president of Manuso, Alexander & Associates, Inc., management consultants and financial advisors to pharmaceutical and biotechnology companies. Dr. Manuso was a vice president and Director of Health Care Planning and Development for The Equitable Companies (now Group Axa), where he also served as Acting Medical Director. He currently serves on the board of privately-held KineMed, Inc. and Merrion Pharmaceuticals Ltd. (Dublin, Ireland). Dr. Manuso earned a B.A. in economics and chemistry from New York University, a Ph.D. in experimental psychophysiology from the Graduate Faculty of The New School University, a certificate in health systems management from Harvard Business School, and an executive M.B.A. from Columbia Business School. Dr. Manuso's experience founding, leading and serving as a director for pharmaceutical companies makes him a highly qualified member of our board of directors.

**David B. McWilliams** . Mr. McWilliams has served as one of our directors since March 2004. From February 2004 to December 2004, Mr. McWilliams performed chief executive officer services for us. Mr. McWilliams is currently retired. From August 2004 to July 2008, Mr. McWilliams served as chief executive officer of Opexa Therapeutics, Inc. (formerly PharmaFrontiers Corp.). From 1992 to March 2002, he served as president, chief executive officer and a director of Encysive Pharmaceuticals (formerly Texas Biotech). From 1989 to 1992, Mr. McWilliams served as president, chief executive officer and director of Zonagen. From 1984 to 1988, he served as president and chief executive officer of Kallestad Diagnostics. From 1980 to 1984, he served as president of Harleco Diagnostics Division. From 1972 to 1980, he was an executive at Abbott Laboratories, rising to general manager for South Africa. From 1969 to 1972, he was a management consultant at McKinsey & Co. Mr. McWilliams is also a director of ApoCell Biosciences, Houston Technology Center and Opexa Therapeutics. Mr. McWilliams received a M.B.A. in finance from the University of Chicago and a B.A. in chemistry from Washington and Jefferson College. Mr. McWilliams' qualifications to serve on our board of directors include his extensive experience in a broad range of senior management positions with companies in the life sciences sector.

**Howard M. Schneider** . Mr. Schneider has served as one of our directors since February 2005. Mr. Schneider is currently retired. From January to December 2003, he served as chief executive officer of Metrosoft, Inc., and had been an advisor to such company from July to December 2002. From May 2000 to May 2001, he served as president of Wofex Brokerage, Inc. and from 1965 to 1999, he served as an executive at Bankers Trust Company holding a variety of positions in the commercial banking and investment banking businesses. Mr. Schneider received a B.A. in economics from Harvard College and a M.B.A. from New York University. Mr. Schneider's extensive senior management experience in the financial sector make him a highly qualified member of our board of directors.

### **Code of Ethics**

The board of directors has adopted a Code of Ethics applicable to all of our directors, officers and employees, including our principal executive officer, principal financial officer and principal accounting officer. A copy of the Code of Ethics is available at our website [www.novelos.com](http://www.novelos.com).

## ITEM 10. EXECUTIVE COMPENSATION

### Executive Officer Compensation

*Summary Compensation:* The following table sets forth certain information about the compensation we paid or accrued with respect to our principal executive officer and our two most highly compensated executive officers (other than our chief executive officer) who served as executive officers during the year ended December 31, 2009 and whose annual compensation exceeded \$100,000 for that year.

Other annual compensation in the form of perquisites and other personal benefits has been omitted as the aggregate amount of those perquisites and other personal benefits was less than \$10,000 for each person listed.

<b>Name and Principal Position</b>	<b>Year</b>	<b>Salary (\$)</b>	<b>Bonus (\$ (3))</b>	<b>Option Awards (\$ (4))</b>	<b>All other compensation (\$)</b>	<b>Total (\$)</b>
Harry S. Palmin (1) President, Chief Executive Officer	2009	\$ 270,000	\$ 40,500	\$ 131,650	\$ 0	\$ 442,150
	2008	\$ 270,000	\$ 40,500	\$ 110,560	\$ 0	\$ 421,060
Christopher J. Pazoles (1) Vice President of Research and Development	2009	\$ 235,000	\$ 35,250	\$ 105,320	\$ 0	\$ 375,570
	2008	\$ 235,000	\$ 35,250	\$ 55,280	\$ 0	\$ 325,530
Elias B. Nyberg (1) (2) Vice President of Regulatory, Quality and Compliance	2009	\$ 225,000	\$ 33,750	\$ 78,990	\$ 0	\$ 337,740
	2008	\$ 168,750	\$ 25,313	\$ 93,160	\$ 0	\$ 287,223

(1) There has been no increase to executive base salaries for 2010.

(2) Dr. Nyberg's employment with the Company commenced on April 1, 2008.

(3) Bonus amounts for 2009 were paid in 2010. Bonus amounts for 2008 were paid in 2009.

(4) The fair value of each stock award was estimated on the grant date using the Black-Scholes option-pricing model. See Note 7 to the financial statements for a description of the assumptions used in estimating the fair value of stock options.

### Employment Agreements

On January 31, 2006, we entered into an employment agreement with Harry Palmin effective January 1, 2006, whereby he agreed to serve as our president and chief executive officer for an initial term of two years at an annual salary of \$225,000. The agreement is automatically renewed for successive one-year terms unless notice of termination is provided by either party at least 90 days prior to the end of such term. The agreement was renewed for an additional one-year term on January 1, 2010 in accordance with its terms. On December 17, 2007, the Board of Directors approved an increase in Mr. Palmin's annual salary to \$270,000 effective January 1, 2008. He is eligible to receive an annual cash bonus at the discretion of the compensation committee and he is entitled to participate in our employee fringe benefit plans or programs generally available to our senior executives. The agreement provides that in the event that we terminate Mr. Palmin without cause or he resigns for good reason (as defined below), we will (i) pay Mr. Palmin his pro rata share of the average of his annual bonus paid during the two fiscal years preceding his termination; (ii) pay Mr. Palmin his base salary for 11 months after the date of termination; (iii) continue to provide him benefits for 11 months after the date of termination; and (iv) fifty percent of his unvested stock options will vest. The agreement also contains a non-compete provision, which prohibits Mr. Palmin from competing with us for one year after termination of his employment with us.

“Cause” means (i) gross neglect of duties for which employed; (ii) committing fraud, misappropriation or embezzlement in the performance of duties as our employee; (iii) conviction or guilty or nolo plea of a felony or misdemeanor involving moral turpitude; or (iv) willfully engaging in conduct materially injurious to us or violating a covenant contained in the employment agreement.

“Good Reason” means (i) the failure of our board of directors to elect Mr. Palmin to the offices of president and chief executive officer; (ii) the failure by our stockholders to continue to elect Mr. Palmin to our board of directors; (iii) our failure to pay Mr. Palmin the compensation provided for in the employment agreement, except for across-the-board cuts applicable to all of our officers on an equal percentage basis, provided that such reduction is approved by our board of directors; (iv) relocation of Mr. Palmin’s principal place of employment to a location beyond 50 miles of Newton, Massachusetts; (v) a reduction of base salary or material reduction in other benefits or any material change by us to Mr. Palmin’s function, duties, authority, or responsibilities, which change would cause Mr. Palmin’s position with us to become one of lesser responsibility, importance, or scope; and (vi) our material breach of any of the other provisions of the employment agreement.

On July 15, 2005, we entered into an employment agreement with Christopher J. Pazoles whereby he agreed to serve as our vice president of research and development for an initial term of two years. The agreement is automatically renewed for successive one-year terms unless notice of termination is provided by either party at least 60 days prior to the end of such term. The agreement was renewed for an additional one-year term on July 15, 2009 in accordance with its terms. The agreement provides for minimum salary and bonus amounts during the first two years of his employment. These minimum amounts have been satisfied. Dr. Pazoles’ agreement provides that he is entitled to participate in our employee fringe benefit plans or programs generally available to our senior executives. The agreement further provides that in the event that we terminate Dr. Pazoles without cause or he resigns for good reason (as defined below), we will (i) pay Dr. Pazoles his base salary through the remainder of the term of his employment agreement in monthly installments; (ii) continue to provide him benefits for 12 months after the date of termination; and (iii) pay, on a prorated basis, any minimum bonus or other payments earned.

Dr. Pazoles also entered into a nondisclosure and development agreement with us, which prohibits him from competing with us and soliciting our employees or customers during the term of his employment and for two years thereafter. If we terminate his employment without cause, this prohibition will only extend for six months after his termination.

“Cause” means Dr. Pazoles (i) has willfully failed, neglected, or refused to perform his duties under the employment agreement; (ii) has been convicted of or pled guilty or no contest to a crime involving a felony; or (iii) has committed any act of dishonesty resulting in material harm to us.

“Good Reason” means that Dr. Pazoles has resigned due to our failure to meet any of our material obligations to him under the employment agreement.

### **Phase 3 Clinical Trial Bonus Plan**

On December 8, 2009, our board of directors approved a special bonus plan for all employees of the Company, including our named executive officers. The bonus plan provided for the payment of contingent cash bonuses in three equal installments in aggregate amounts ranging from 80% to 150% of annual 2009 salaries for each employee. All payments under the bonus plan were conditioned upon the achievement of favorable results for our Phase 3 Trial. As a result of the negative results of the Phase 3 Trial, as announced on February 24, 2010, no amounts will become payable under the special bonus plan.

## Outstanding Equity Awards at Fiscal Year-End

The following table sets forth certain information regarding stock options held as of December 31, 2009 by the executive officers named in the summary compensation table.

Name	Year of Grant	Individual Grants		Exercise or base price (\$/share)	Expiration date
		Number of securities underlying unexercised options (#) exercisable	Number of securities underlying unexercised options (#) unexercisable		
Harry S. Palmin	2009(1)	—	250,000	\$ 0.75	12/8/2019
	2008(2)	133,333	266,667	0.43	12/15/2018
	2007(2)	133,333	66,667	0.45	12/17/2017
	2006(2)	150,000	—	0.91	12/11/2016
	2005(3)	250,000	—	0.01	1/31/2015
	2005(3)	150,000	—	0.01	3/31/2015
	2004(4)	330,000	—	0.01	4/1/2014
	2003(5)	7,130	—	0.70	8/1/2013
Christopher J. Pazoles	2009(1)	—	200,000	\$ 0.75	12/8/2019
	2008(2)	66,666	133,334	0.43	12/15/2018
	2007(2)	83,333	41,667	0.45	12/17/2017
	2006(2)	100,000	—	0.91	12/11/2016
	2005(6)	200,000	—	0.01	4/8/2015
	2004(7)	16,667	—	0.01	4/1/2014
Elias B. Nyberg	2009(1)	—	150,000	\$ 0.75	12/8/2019
	2008(2)	33,333	66,667	0.43	12/15/2018
	2008(8)	100,000	—	0.58	4/1/2018

- (1) These shares vest quarterly in increments of one-twelfth over three years from the date of grant. The exercise price equals the closing price on the date of grant.
- (2) These shares vest annually in increments of one-third over three years from the date of grant. The exercise price equals the closing price on the date of grant.
- (3) These shares initially vested over a two-year period. Pursuant to their terms, the shares fully vested upon the completion of a non-bridge loan financing, which occurred in the second quarter of 2005. The exercise price equals the fair market value of our common stock on the date of grant as determined by our board of directors.
- (4) These shares initially vested one-third upon grant and one-third annually over the following two years. Pursuant to their terms, one additional year of vesting occurred upon the completion of a non-bridge loan financing, which occurred in the second quarter of 2005. The exercise price equals the fair market value of our common stock on the date of grant as determined by our board of directors.
- (5) These shares vest annually in increments of one-third over three years from the date of grant. The exercise price equals the fair market value of our common stock on the date of grant as determined by our board of directors.
- (6) These shares vested in increments of one-fourth every six months over two years from the date of grant. The exercise price equals the fair market value of our common stock on the date of grant as determined by our board of directors.
- (7) These shares represent the fully vested portion of an option grant made to Mr. Pazoles in consideration of consulting services delivered during 2004. Pursuant to their terms, the shares vested at the completion of the consulting engagement and expire ten years from the date of grant.
- (8) These shares were fully vested upon grant. The exercise price equals the closing price on the date of grant.

Options granted pursuant to the 2006 Stock Incentive Plan will become fully vested upon a termination event within one year following a change in control, as defined. A termination event is defined as either termination of employment other than for cause or constructive termination resulting from a significant reduction in either the nature or scope of duties and responsibilities, a reduction in compensation or a required relocation.

## Director Compensation

*Summary Compensation:* The following table sets forth certain information about the compensation we paid or accrued with respect to our directors who served during the year ended December 31, 2009.

<u>Name and Principal Position</u>	<u>Year</u>	<u>Director Fees (\$ (2))</u>	<u>Option Awards (\$ (3))</u>	<u>All other compensation (\$)</u>	<u>Total (\$)</u>
Stephen A. Hill, Chairman (1)	2009	\$ 39,500	\$ 42,128	\$ —	\$ 81,628
Michael J. Doyle, Director (1)	2009	32,500	42,128	—	74,628
Sim Fass, Director (1)	2009	33,250	42,128	—	75,378
James S. Manuso, Director (1)	2009	25,250	42,128	—	67,378
David B. McWilliams, Director (1)	2009	26,000	42,128	—	68,128
Howard M. Schneider, Director (1)	2009	38,250	42,128	—	80,378

- (1) As of December 31, 2009, outstanding options to purchase common stock held by directors were as follows: Dr. Hill 350,000; Mr. Doyle 350,000; Dr. Fass 350,000; Dr. Manuso 300,000; Mr. McWilliams 402,778; Mr. Schneider 250,000.
- (2) Director fees include all fees earned for director services including quarterly fees, meeting fees and committee chairman fees.
- (3) The fair value of each stock award was estimated on the grant date using the Black-Scholes option-pricing model. See Note 7 to the financial statements for a description of the assumptions used in estimating the fair value of stock options.

During 2009, we paid our non-employee directors a cash fee of \$5,000 per quarter. The non-employee directors also received a fee of \$1,500 for any board or committee meeting attended and \$750 for each telephonic board or committee meeting in which the director participated. We also paid our chairman an additional annual fee in the amount of \$15,000, our non-employee director who serves as the chair of the audit committee an additional annual fee of \$10,000 and our non-employee director who serves as the chairman of the compensation and nominating and corporate governance committees an additional annual fee of \$5,000. We reimbursed directors for reasonable out-of-pocket expenses incurred in attending board and committee meetings and undertaking certain matters on our behalf. Directors who are our employees do not receive separate fees for their services as directors. There has been no change to cash fees payable to non-employee directors for 2010.

On December 8, 2009, options to purchase 80,000 shares of our common stock were granted to each of our non-employee directors at the closing price of our common stock on that day. These grants vest on a quarterly basis over a two-year period.

## ITEM 11. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

At the close of business on March 22, 2010, there were issued and outstanding 90,385,939 shares of our common stock. The following table provides information regarding beneficial ownership of our common stock as of March 22, 2010:

- Each person known by us to be the beneficial owner of more than five percent of our common stock;
- Each of our directors;
- Each executive officer named in the summary compensation table; and
- All of our current directors and executive officers as a group.

The address of each executive officer and director is c/o Novelos Therapeutics, Inc., One Gateway Center, Suite 504, Newton, Massachusetts 02458. The persons named in this table have sole voting and investment power with respect to the shares listed, except as otherwise indicated. The inclusion of shares listed as beneficially owned does not constitute an admission of beneficial ownership. Shares included in the “Right to Acquire” column consist of shares that may be purchased through the exercise of options that vest within 60 days of March 22, 2010 .

<u>Name and Address of Beneficial Owner</u>	<u>Shares Beneficially Owned (4)</u>			
	<u>Outstanding</u>	<u>Right to Acquire</u>	<u>Total</u>	<u>Percentage</u>
Purdue Pharma, L.P. (1) One Stamford Forum 201 Tresser Blvd. Stamford, CT 06901-3431	13,636,364	0	13,636,364	15.1
Knoll Capital Management (2) 1114 Avenue of the Americas, 45 <sup>th</sup> Floor New York, NY 10036	4,462,234	9,247,776	13,710,010	13.8
Harry S. Palmin (3)	641,118	1,174,629	1,815,747	2.0
Christopher J. Pazoles	0	483,332	483,332	*
Elias B. Nyberg	0	145,832	145,832	*
Stephen A. Hill	0	250,000	250,000	*
Michael J. Doyle	0	250,000	250,000	*
Sim Fass	0	250,000	250,000	*
James S. Manuso	0	200,000	250,000	*
David B. McWilliams	0	302,778	302,778	*
Howard M. Schneider	100,000	150,000	250,000	*
All directors and officers as a group (11 persons)	741,118	3,798,234	4,539,352	4.8

\* Less than one percent.

(1) Following the financing transactions completed on August 25, 2009 and November 10, 2009 Purdue transferred its shares of common stock and warrants to purchase common stock to Beacon Company (c/o Whitely Chambers, Don Street, St. Helier, Jersey JE49WG, Channel Islands) and Rosebay Medical Company L.P. (c/o Northbay Associates, 14000 Quail Springs Parkway #2200, Oklahoma City, OK 73134), which are independent associated companies of Purdue. The “Right to Acquire” column excludes shares issuable on conversion of Series E preferred stock and upon exercise of warrants issued in February, August and November 2009 as described in the table below.

(2) Includes holdings of Knoll Special Opportunities II Master Fund Limited and Europa International, Inc. (the “Knoll-affiliated Funds”). Shares in the “Right to Acquire” column include shares of common stock issuable upon conversion of Series E preferred stock, excluding accumulated unpaid dividends. On February 26, 2010, the Knoll-affiliated Funds provided to the Company notice of waiver of the conversion limitations on the Series E preferred stock held by them. Such limitations are described in footnote 4 to this table.

(3) Shares owned by H. Palmin include 94,000 shares owned by his wife, Deanna Palmin.

(4) The terms of our Series E preferred stock and common stock purchase warrants issued to the holders of Series E preferred stock provide that the number of shares of common stock to be obtained by each of the holders of Series E preferred stock and common stock purchase warrants, upon conversion of the Series E preferred stock or exercise of the common stock purchase warrants, cannot exceed the number of shares that, when combined with all other shares of our common stock and securities owned by each of them, would result in any one of them owning more than 4.99% or 9.99%, as applicable in the certificate of designations and warrant agreement, of our outstanding common stock, provided, however that this limitation may be revoked by the stockholder upon 61 days' prior notice to us. For this reason, holders of our Series E preferred stock who might otherwise have the right to acquire 5% or more of our common stock have been omitted from this table to the extent that they have not provided such a waiver. Such limitations do not apply in the event of automatic conversion of Series E preferred stock. Similar blocking provisions apply to outstanding shares of our Series C preferred stock and common stock purchase warrants issued to the holders of Series C preferred stock and therefore holders of our Series C preferred stock who might otherwise have the right to acquire 5% or more of our common stock have also been omitted from this table.

**Pro Forma Holdings Upon Automatic Conversion of Series E Preferred Stock**

The following table illustrates the pro forma beneficial ownership of our common stock that would result in the event of an automatic conversion of all of the outstanding shares of our Series E preferred stock into common stock. All outstanding shares of Series E preferred stock automatically convert in the event the volume weighted average price of our common stock, calculated in accordance with the terms of the Series E preferred stock, exceeds \$2.00 for 20 consecutive trading days, provided there is an effective registration statement covering the resale of the shares of common stock so issuable. At the current conversion price of \$0.65, the automatic conversion of all shares of Series E preferred stock outstanding as of March 22, 2010, excluding any accumulated dividends, would result in the issuance of 31,404,920 shares of common stock. In the table below, share holdings have been presented in total for groups of associated funds or companies. Such presentation is not intended to represent that such funds or companies are under common control.

<b>Name and Address of Beneficial Owner</b>	<b>Outstanding Shares of Common Stock</b>	<b>Shares of common stock issuable upon automatic conversion of Series E Preferred Stock</b>	<b>Total pro Forma Ownership (1)</b>	<b>Pro forma ownership Percentage (2)</b>
Xmark Funds (3) 90 Grove Street, Suite 201 Ridgefield, CT 06877	1,902,096	3,652,152	5,554,248	4.6%
OrbiMed affiliated funds (4) 767 Third Avenue, 30 <sup>th</sup> Floor New York, NY 10017	2,284,960	3,120,378	5,405,338	4.4%
Knoll affiliated funds (5) 666 Fifth Avenue, Suite 3702 New York, NY 10103	4,462,234	9,247,776	13,710,010	11.3%
Purdue Pharma, L.P. (6) One Stamford Forum 201 Tresser Blvd. Stamford, CT 06901-3431	13,636,364	15,384,614	29,020,978	23.8%

(1) Pro forma ownership does not include accumulated undeclared dividends totaling approximately \$1,633,000 at December 31, 2009 that had not yet been converted as of March 22, 2010. These accumulated undeclared dividends may be converted into approximately 2,512,000 shares of common stock in connection with the conversion of the associated remaining shares of Series E preferred stock.

- (2) Based on 121,790,859 shares of common stock outstanding, which reflects the number of shares of common stock outstanding as of March 22, 2010 plus the total number of shares issuable upon conversion of all of the outstanding shares of Series E preferred stock (excluding shares issuable upon conversion of accumulated undeclared dividends) at March 22, 2010.
- (3) Includes Xmark Opportunity Partners, LLC, Xmark Opportunity Fund, Ltd., Xmark Opportunity Fund, L.P., and Xmark JV Investment Partners, LLC.
- (4) Includes OrbiMed Advisors LLC, Caduceus Capital Master Fund Limited, Caduceus Capital II, LP, UBS Eucalyptus Fund, L.L.C., PW Eucalyptus Fund, Ltd., and Summer Street Life Sciences Investors LLC.
- (5) Includes Knoll Capital, Knoll Special Opportunities Fund II Master Fund, Ltd., and Europa International, Inc. As described in footnote 2 to the preceding table, on February 26, 2010, the Knoll-affiliated Funds provided to the Company notice of waiver of the conversion limitations on the Series E preferred stock held by them.
- (6) Following the financing transactions completed on February 11, 2009, August 25, 2009 and November 10, 2009, Purdue transferred its shares of Series E preferred stock, shares of common stock and warrants to purchase common stock of Novelos to Beacon Company and Rosebay Medical Company L.P., which are independent associated companies of Purdue. Pro forma ownership of Purdue excludes 14,003,499 shares of common stock issuable upon exercise of warrants issued to Purdue in February, August and November 2009 as a result of the blocker provisions described in footnote 4 to the preceding table.

### Equity compensation plans

The following table provides information as of December 31, 2009 regarding shares authorized for issuance under our equity compensation plans, including individual compensation arrangements.

We have two equity compensation plans approved by our stockholders: the 2000 Stock Option and Incentive Plan and the 2006 Stock Incentive Plan. We have also issued options to our directors and consultants that were not approved by our stockholders. These options are exercisable within a ten-year period from the date of the grant and vest at various intervals with all options being fully vested within three years of the date of grant. The option price per share is not less than the fair market value of our common stock on the date of grant.

#### Equity compensation plan information

Plan category	Number of shares to be issued upon exercise of outstanding options, warrants and rights (#)	Weighted-average exercise price of outstanding options, warrants and rights (\$)	Number of shares remaining available for future issuance under equity compensation plans (excluding shares reflected in column (a)) (#)
	(a)	(b)	(c)
Equity compensation plans approved by stockholders	6,766,047	\$ 0.65	3,290,000
Equity compensation plans not approved by stockholders	<u>2,453,778</u>	\$ 0.57	<u>0</u>
<b>Total</b>	<b><u><u>9,219,825</u></u></b>	<b>\$ 0.63</b>	<b><u><u>3,290,000</u></u></b>

### ITEM 12. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

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

If a royalty is not being paid to ZAO BAM on net sales of oxidized glutathione products, then we are required to pay ZAO BAM 3% of all license revenues. If license revenues exceed our cumulative expenditures including, but not limited to, preclinical and clinical studies, testing, FDA and other regulatory agency submission and approval costs, general and administrative costs, and patent expenses, then the Company would be required to pay ZAO BAM an additional 9% of the amount by which license revenues exceed the Company's cumulative expenditures. During 2008, we paid ZAO BAM \$15,000, which was 3% of license payments received under the collaboration agreement with Lee's Pharm, described in Note 5 to the financial statements.

As a result of the assignment to Novelos of the exclusive worldwide intellectual property and marketing rights of oxidized glutathione (excluding the Russian Territory), Novelos is obligated to the Oxford Group, Ltd., or its assignees, for future royalties. Simyon Palmin, a founder of Novelos, a director until August 15, 2008 and the father of the Company's president and chief executive officer, is president of Oxford Group, Ltd. Mr. Palmin was also an employee of the Company and is now a consultant to the Company. Pursuant to the agreement, as revised May 26, 2005, Novelos is required to pay Oxford Group, Ltd. a royalty in the amount of 0.8% of the Company's net sales of oxidized glutathione-based products.

### Director Independence

Each member of the Audit Committee, the Compensation Committee and the Nominating and Corporate Governance Committee meets the independence requirements of the Nasdaq Stock Market for membership on the committees on which he serves. The board of directors considered the information included in transactions with related parties as outlined above along with other information the board considered relevant, when considering the independence of each director. Harry S. Palmin is not an independent director.

### ITEM 13. PRINCIPAL ACCOUNTING FEES AND SERVICES

Aggregate fees for professional services by Stowe & Degon LLC for the years ended December 31, 2009 and December 31, 2008 were:

	<u>2009</u>	<u>2008</u>
Audit	\$ 81,500	\$ 81,500
Audit Related	5,005	—
Tax	—	—
All Other	—	—
Total	<u>\$ 86,505</u>	<u>\$ 81,500</u>

*Audit Fees:* Audit fees were for professional services rendered for the audit of our annual financial statements, the review of quarterly financial statements and the preparation of statutory and regulatory filings.

*Audit-Related Fees:* Audit-related fees were for professional services rendered in connection with consents and assistance with review of registration statements filed with the SEC during 2009.

*Tax Fees:* Tax fees consist of fees billed for professional services for tax compliance, tax planning and tax advice. These services include assistance regarding federal, state and international tax compliance and planning, tax audit defense, and mergers and acquisitions. No such services were provided by Stowe & Degon LLC.

*All Other Fees:* All other fees include assistance with miscellaneous reporting requirements and interpretation of technical issues. No such services were provided by Stowe & Degon LLC.

***Policy on Audit Committee Pre-Approval of Audit and Permissible Non-Audit Services of Independent Registered Public Accounting Firm***

At present, our audit committee approves each engagement for audit and non-audit services before we engage Stowe & Degon LLC to provide those services.

Our audit committee has not established any pre-approval policies or procedures that would allow our management to engage Stowe & Degon LLC to provide any specified services with only an obligation to notify the audit committee of the engagement for those services. None of the services provided by Stowe & Degon LLC for 2009 or 2008 were obtained in reliance on the waiver of the pre-approval requirement afforded in SEC regulations.

**PART IV**

**ITEM 14. EXHIBITS**

<b>Exhibit No.</b>	<b>Description</b>	<b>Filed with this Form 10-K</b>	<b>Incorporated by Reference</b>		
			<b>Form</b>	<b>Filing Date</b>	<b>Exhibit No.</b>
2.1	Agreement and plan of merger among Common Horizons, Inc., Nove Acquisition, Inc. and Novelos Therapeutics, Inc. dated May 26, 2005		8-K	June 2, 2005	99.2
2.2	Agreement and plan of merger between Common Horizons and Novelos Therapeutics, Inc. dated June 7, 2005		10-QSB	August 15, 2005	2.2
3.1	Certificate of Incorporation		8-K	June 17, 2005	1
3.2	Certificate of Designations of Series E convertible preferred stock		8-K	February 18, 2009	4.1
3.3	Certificate of Designations of Series C cumulative convertible preferred stock		10-QSB	May 8, 2007	3.2
3.4	Certificate of Amendment of the Amended and Restated Certificate of Incorporation		8-K	November 4, 2009	3.1
3.5	Amended and Restated By-laws		8-K	August 26, 2009	3.1
10.1	Employment agreement with Christopher J. Pazoles dated July 15, 2005		10-QSB	August 15, 2005	10.4
10.2	Employment Agreement with Harry S. Palmin dated January 31, 2006		8-K	February 6, 2006	99.1
10.3	2000 Stock Option and Incentive Plan		SB-2	November 16, 2005	10.2
10.4	Form of 2004 non-plan non-qualified stock option		SB-2	November 16, 2005	10.3
10.5	Form of non-plan non-qualified stock option used from February to May 2005		SB-2	November 16, 2005	10.4

Exhibit No.	Description	Filed with this Form 10-K	Incorporated by Reference		
			Form	Filing Date	Exhibit No.
10.6	Form of non-plan non-qualified stock option used after May 2005		SB-2	November 16, 2005	10.5
10.7	Form of common stock purchase warrant issued in March 2005		SB-2	November 16, 2005	10.6
10.8	Form of securities purchase agreement dated May 2005		8-K	June 2, 2005	99.1
10.9	Form of subscription agreement dated September 30, 2005		8-K	October 3, 2005	99.1
10.10	Form of Class A common stock purchase warrant dated September 30, 2005		8-K	October 3, 2005	99.3
10.12	Consideration and new technology agreement dated April 1, 2005 with ZAO BAM		10-QSB	August 15, 2005	10.2
10.13	Letter agreement dated March 31, 2005 with The Oxford Group, Ltd.		10-QSB	August 15, 2005	10.3
10.14	Form of securities purchase agreement dated March 2, 2006		8-K	March 3, 2006	99.2
10.15	Form of common stock purchase warrant dated March 2006		8-K	March 3, 2006	99.3
10.16	2006 Stock Incentive Plan, as amended		S-1/A	December 7, 2009	10.16
10.17	Form of Incentive Stock Option under Novelos Therapeutics, Inc.'s 2006 Stock Incentive Plan		8-K	December 15, 2006	10.1
10.18	Form of Non-Statutory Stock Option under Novelos Therapeutics, Inc.'s 2006 Stock Incentive Plan		8-K	December 15, 2006	10.2
10.19	Form of Non-Statutory Director Stock Option under Novelos Therapeutics, Inc.'s 2006 Stock Incentive Plan		8-K	December 15, 2006	10.3
10.20	Securities Purchase Agreement dated April 12, 2007		10-QSB	May 8, 2007	10.1
10.21	Letter Amendment dated May 2, 2007 to the Securities Purchase Agreement		10-QSB	May 8, 2007	10.2
10.22	Registration Rights Agreement dated May 2, 2007		10-QSB	May 8, 2007	10.3
10.23	Agreement to Exchange and Consent dated May 1, 2007		10-QSB	May 8, 2007	10.5
10.25	Form of Common Stock Purchase Warrant dated May 2, 2007 issued pursuant to the Securities Purchase Agreement dated April 12, 2007		10-QSB	May 8, 2007	4.1

10.26	Form of Common Stock Purchase Warrant dated May 2, 2007 issued pursuant to the Agreement to Exchange and Consent dated May 2, 2007	10-QSB	May 8, 2007	4.2
10.27	Securities Purchase Agreement dated March 26, 2008	8-K	April 14, 2008	10.1
10.28	Amendment to Securities Purchase Agreement dated April 9, 2008	8-K	April 14, 2008	10.2
10.29	Registration Rights Agreement dated April 11, 2008	8-K	April 14, 2008	10.3
10.30	Form of Common Stock Purchase Warrant dated April 11, 2008 issued pursuant to the Securities Purchase Agreement dated March 26, 2008	8-K	April 14, 2008	4.3
10.31	Warrant Amendment Agreement dated April 11, 2008	8-K	April 14, 2008	10.5
10.32	Amendment to Registration Rights Agreement dated April 11, 2008	8-K	April 14, 2008	10.4
10.33	Securities Purchase Agreement dated August 14, 2008	8-K	August 18, 2008	10.1
10.34	Securities Purchase Agreement dated February 11, 2009	8-K	February 18, 2009	10.1
10.35	Registration Rights Agreement dated February 11, 2009	8-K	February 18, 2009	10.2
10.36	Series D Preferred Stock Consent and Agreement to Exchange dated February 10, 2009	8-K	February 18, 2009	10.3
10.37	Warrant Amendment Agreements dated February 11, 2009	8-K	February 18, 2009	10.4
10.38	Amendment No. 2 to Registration Rights Agreement dated February 11, 2009	8-K	February 18, 2009	10.5
10.39*	Collaboration Agreement dated February 11, 2009	10-K	March 30, 2009	10.39
10.40	Form of Warrant Exchange Agreement dated August 21, 2009	8-K	August 26, 2009	10.5
10.41	Securities Purchase Agreement dated August 25, 2009	S-1	September 15, 2009	10.41
10.42	Registration Rights Agreement dated August 25, 2009	S-1	September 15, 2009	10.42
10.43	Common Stock Purchase Warrant dated August 25, 2009	S-1	September 15, 2009	10.43

10.44	Letter Agreement with LP Clover Limited dated August 25, 2009		S-1	September 15, 2009	10.44
10.45	Letter Agreement with Mundipharma International Corporation Limited dated August 25, 2009		S-1	September 15, 2009	10.45
10.46	Summary of Phase 3 Clinical Trial Bonus Plan adopted on December 8, 2009		S-1/A	January 26, 2010	10.46
10.47	Consent and Amendment Agreement dated January 21, 2010		S-1/A	January 26, 2010	10.47
31.1	Certification of chief executive officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	X			
31.2	Certification of chief financial officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	X			
32.1	Certification of chief executive officer and chief financial officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	X			

\* Portions of this exhibit have been omitted pursuant to a confidential treatment order.

**SIGNATURES**

In accordance with Section 13 or 15(d) of the Exchange Act, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

**NOVELOS THERAPEUTICS, INC.**

By: /s/ Harry S. Palmin  
Harry S. Palmin  
Title: President, Chief Executive Officer

Date: March 30, 2010

In accordance with the Exchange Act, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

By: /s/ Harry S. Palmin  
Harry S. Palmin  
Title: Chief Executive Officer and Director (Principal Executive Officer)

Date: March 30, 2010

By: /s/ Joanne M. Protano  
Joanne M. Protano  
Title: Chief Financial Officer (Principal Accounting Officer)

Date: March 30, 2010

By: /s/ Stephen A. Hill  
Stephen A. Hill  
Title: Chairman of the Board of Directors

Date: March 30, 2010

By: /s/ Michael J. Doyle  
Michael J. Doyle  
Title: Director

Date: March 30, 2010

By: /s/ Sim Fass  
Sim Fass  
Title: Director

Date: March 30, 2010

---

By: /s/ James S. Manuso

James S. Manuso

Title: Director

Date: March 30, 2010

By: \_\_\_\_\_

David B. McWilliams

Title: Director

Date: \_\_\_\_\_

By: /s/ Howard M. Schneider

Howard M. Schneider

Title: Director

Date: March 30, 2010

---

**CERTIFICATION PURSUANT TO  
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Harry S. Palmin, Chief Executive Officer and President, Novelos Therapeutics, Inc., certify that:

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

Date: March 30, 2010

/s/ HARRY S. PALMIN

Harry S. Palmin  
Principal Executive Officer

---

**CERTIFICATION PURSUANT TO  
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Joanne M. Protano, Chief Financial Officer, Novelos Therapeutics, Inc., certify that:

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

Date: March 30, 2010

/s/ JOANNE M. PROTANO

Joanne M. Protano  
Principal Financial Officer

---

**CERTIFICATION PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report on Form 10-K of Novelos Therapeutics, Inc. (the "Company") for the year ended December 31, 2009, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Harry S. Palmin, Chief Executive Officer and President of the Company, and I, Joanne M. Protano, Chief Financial Officer of the Company, certify, to the best of our knowledge and belief, pursuant to 18 U.S.C. § 1350, adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that:

- 1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- 2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ HARRY S. PALMIN

Harry S. Palmin  
Principal Executive Officer

/s/ JOANNE M. PROTANO

Joanne M. Protano  
Principal Financial Officer

Dated: March 30, 2010

A signed original of this written statement required by Section 906, or other document authenticating, acknowledging, or otherwise adopting the signature that appears in typed form within the electronic version of this written statement required by Section 906, has been provided to Novelos Therapeutics, Inc. and will be retained by Novelos Therapeutics, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

---