

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

**FORM 10-KSB**

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

For the Fiscal Year Ended: December 31, 2006

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)

Issuer'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:

**Common Stock, par value \$0.00001 per share**

(Title of class)

Check whether the issuer is required to file reports pursuant to Section 13 or 15(d) of the Exchange Act. Yes  No

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

Check if there is no disclosure of delinquent filers in response to Item 405 of Regulation S-B contained in this form, and no disclosure will 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-KSB or any amendment to this Form 10-KSB.

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

The issuer's revenues for its most recent fiscal year were \$0.

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 sold, or the average bid and asked price of such common equity, as of a specified date within the past 60 days. (See definition of affiliate in Rule 12b-2 of the Exchange Act.) was: \$29,425,670.

As of March 12, 2007 there were 39,235,272 shares of the issuer's common stock outstanding.

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

NOVELOS THERAPEUTICS, INC.

FORM 10-KSB

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*This annual report on Form 10-KSB 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 Form 10-KSB 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-KSB. We will not update these forward-looking statements unless the securities laws and regulations require us to do so.*

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This Annual Report on Form 10-KSB contains trademarks and service marks of Novelos Therapeutics, Inc. Unless otherwise provided in this Annual Report on Form 10-KSB, 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. DESCRIPTION OF BUSINESS

#### Business of the Issuer

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 company was Novelos Therapeutics, Inc.

We are a biopharmaceutical company commercializing oxidized glutathione-based compounds for the treatment of cancer and hepatitis. NOV-002, our lead compound, is currently in Phase 3 development for lung cancer under a Special Protocol Assessment and Fast Track. NOV-002 is also in Phase 2 development for chemotherapy-resistant ovarian cancer and early-stage breast cancer, and is also being developed for acute radiation injury. NOV-205, our second compound, is in Phase 1b development for chronic hepatitis C non-responders. Both compounds have completed clinical trials in humans and have been approved for use in Russia where they were originally developed.

NOV-002, our lead compound, acts as a chemoprotectant and an immunomodulator. It is marketed in Russia by ZAO BAM under the trade name Glutoxim®, and has been administered to over 10,000 patients, demonstrating clinical efficacy and excellent safety. ZAO BAM is a company, controlled by one of our former directors, from which we acquired certain rights in the oxidized glutathione technology. The U.S.-based Phase 1/2 clinical trial of NOV-002 for non-small cell lung cancer (NSCLC) was completed in August 2005 and the treated group demonstrated improved objective tumor response (defined as greater than 50% tumor shrinkage) and higher tolerance of chemotherapy versus the control group. In May 2006, we finalized a Special Protocol Assessment with the FDA for a single pivotal Phase 3 trial and obtained Fast Track designation in August 2006. The primary endpoint of this trial is improvement in median overall survival, and we commenced patient enrollment in November 2006. In a 1996-98 Russian non-small cell lung cancer trial, NOV-002 increased the one-year survival rate from 17% to 63% when used in combination with chemotherapy. This result represents an 80% improvement over the U.S. survival rate of 35% that results from the current standard of care.

NOV-002 is also being developed to treat chemotherapy-resistant ovarian cancer. A U.S. Phase 2 trial is ongoing at Massachusetts General Hospital and Dana-Farber Cancer Institute. In a 1998 Russian review of case studies, NOV-002 sensitized previously platinum-resistant ovarian cancer patients to chemotherapy. In combination with NOV-002, 40% of the women responded favorably (partial or complete response) to the same chemotherapy that they had failed previously (compared to the 10% response rate that is typically seen upon such re-treatment).

NOV-002 is also being developed to treat early-stage breast cancer. These patients are often treated with chemotherapy to minimize surgical intervention. A planned U.S. Phase 2 trial will evaluate the ability of NOV-002 to enhance the effectiveness of such chemotherapy while diminishing dose-limiting side-effects.

NOV-002 is also being developed to treat acute radiation injury.

NOV-205, our second compound, acts as a hepatoprotective agent with immunomodulating and anti-inflammatory properties. Russian clinical studies completed in 1999 in hepatitis B and C patients showed that after treatment with NOV-205, serum viral load was undetectable in a high proportion of patients and serum biochemical markers of liver damage were significantly decreased. Our Investigational New Drug Application for NOV-205 as monotherapy for chronic hepatitis C was accepted by the FDA 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 is ongoing.

Our intellectual property portfolio of issued patents includes four U.S. patents (plus a fifth notice of allowance), two European patents and one Japanese patent. Overall, we have filed more than thirty patent applications filed worldwide, with coverage including composition of matter, method of use and manufacturing. The breadth of our intellectual property will also allow us to expand our product pipeline by claiming and commercializing additional compounds that are based on oxidized glutathione.

We have devoted substantially all of our efforts towards the research and development of our product candidates. We have incurred approximately \$11.6 million in research and development expense from our inception through December 31, 2006. We have had no revenue from product sales to date and have funded our operations through the sale of equity securities and debt financings. From our inception through December 31, 2006, we have raised approximately \$29.0 million in equity and debt (subsequently paid off or converted into equity) financings. We have never been profitable and have incurred an accumulated deficit of \$23.7 million as of December 31, 2006.

## **Business Strategy**

Our primary objective is to fully exploit our proprietary scientific and intellectual property portfolio in oxidized glutathione-based therapeutics. NOV-002, currently in Phase 3 development in the U.S., has demonstrated an excellent safety and efficacy profile in Russia as an adjunctive treatment to chemotherapy for a number of different cancers. The Russian data is particularly compelling in non-small cell lung cancer and platinum-resistant ovarian cancer, indications with large and growing unmet medical needs. Positive results in a controlled U.S.-based Phase 1/2 non-small cell lung cancer study completed in August 2005 reinforced the positive results obtained in earlier Russian clinical studies.

We also intend to explore the commercial potential of NOV-002 for treatment of acute radiation injury in the U.S. and abroad to address the growing concern over catastrophic radiation exposure from, for example, a nuclear weapon, a “dirty bomb” or an accident at a nuclear power plant. Significantly, animals treated with NOV-002 demonstrated substantially increased survival rates (two- to three-fold, measured at thirty days post-radiation) compared to the irradiated control animals. In addition, NOV-002-treated animals did not experience severe neutropenia (loss of white blood cells used for fighting off infections) and demonstrated significantly higher bone marrow cell counts than the control (bone marrow is the source of white blood cells). In February 2006, we submitted a proposal to the Department of Health and Human Services (“HHS”) for the use of NOV-002 to treat subjects that may develop Acute Radiation Syndrome (“ARS”) after exposure to high levels of penetrating radiation. In June 2006, HHS notified us that our proposal was within the competitive range for discussion and further evaluation. In October 2006, HHS notified us that NOV-002 was not eligible for procurement under this specific award. In March 2007, HHS cancelled its solicitation prior to making any award.

We expect to obtain a U.S. marketing partner for NOV-002 after the non-small cell lung cancer Phase 3 clinical trial results are available (mid-2009). In the nearer term, we plan to out-license NOV-002 in Europe and/or Japan and use resources from these potential arrangements to offset, in part, the expense of our development.

In Russian clinical studies, NOV-205 has demonstrated the ability to substantially decrease the serum viral load of patients with either hepatitis B or C as well as to restore normal liver function as evidenced by blood biochemical markers. In the U.S., both hepatitis B and C are relatively large markets, but hepatitis B is reasonably well served. Therefore, we will concentrate clinical development efforts on chronic hepatitis C, which should represent a more direct path to regulatory approval as well as providing patients with an improved therapy regimen. A U.S. Phase 1b clinical trial commenced in September 2006 and we will explore out-license opportunities for NOV-205 once U.S. data becomes available (mid-2007).

## **Technology Overview**

Glutathione is a naturally occurring substance present in nearly all cells of the body. The glutathione pathway consists of oxidized glutathione, the primary component of NOV-002, and associated metabolic enzymes. It is considered to be the most important cellular system for protection against the toxic effects of a variety of cell-damaging molecules. More recently, it has become evident that in addition to this cell protective role, a key function of the glutathione system is to dynamically regulate cell function by reversibly altering the structure of proteins via a process termed glutathionylation. The resulting activation/inhibition of protein function is analogous to the much-studied role of protein phosphorylation as a cellular regulatory mechanism.

Thus, changes in the ratio of intracellular reduced and oxidized glutathione can trigger glutathionylation, affecting cell signaling pathways that govern a variety of critical cell functions including gene expression, cell proliferation, growth arrest and apoptosis (programmed cell death). Importantly, it has been shown that oxidized glutathione itself is capable of causing protein glutathionylation leading to changes in cell signaling pathway function. Examples of effects of oxidized glutathione on gene expression include regulation of gene transcription factors such as NFkB and AP-1, which have been shown to have pivotal roles in the regulation of many genes involved in immune and inflammatory responses, including cytokines and growth factors. Findings with NOV-002 in animals and humans (e.g., cell protection; effects on cytokine production and blood cell proliferation; immune system modulation) are consistent with the hypothesis that it may act, at least in part, by such a mechanism.

Pharmacological manipulation of reduced and oxidized glutathione (e.g., including protein glutathionylation) can have multiple and parallel effects on cells, with the overall impact on cell function being dependent upon the type of cell and its physiological state (i.e., normal or diseased). In light of this complexity, identification of the precise molecular targets of NOV-002, which account for its clinical effects, is the subject of ongoing study.

## **Products in Development**

Our current developmental pipeline of drugs is based on oxidized glutathione, a natural metabolite, that has shown excellent safety as well as clinical efficacy in numerous cancers, hepatitis B and C, HIV, psoriasis, tuberculosis and certain other diseases. The lead products are believed to act via modulation of critical regulatory molecules that mediate immune function, tumor progression (in combination with chemotherapy), and drug detoxification.

### **NOV-002**

NOV-002 is an injectable, small-molecule formulation of a natural metabolite that is being developed in combination with chemotherapy for treatment of lung, ovarian and breast cancer.

#### ***NOV-002 for Non-Small Cell Lung Cancer***

In the U.S., NOV-002 is in Phase 3 development for non-small cell lung cancer under a Special Protocol Assessment with Fast Track designation. NOV-002 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 340 patients in Russia across several types of cancer including: non-small cell lung cancer, colorectal cancer, pancreatic cancer, breast cancer and ovarian cancer. Since the Russian Ministry of Health approval in 1998, it is estimated that NOV-002 has been administered to over 10,000 patients.

According to the American Cancer Society, about 1.4 million U.S. men and women were expected to be diagnosed with cancer in 2006. Over 550,000 U.S. cancer patients were expected to die, in 2006, which makes cancer the second leading cause of death in the U.S., exceeded only by deaths related to heart disease. Lung cancer is the leading cause of cancer death in the U.S. Approximately 175,000 people were expected to be diagnosed with lung cancer in 2006, with over 160,000 deaths. According to a Rodman and Renshaw report dated December 2006, there are currently approximately 405,000 cases of lung cancer among industrial nations and the pharmaceutical market for treating lung cancer is currently approximately \$800 million in the U.S. and \$1.8 billion worldwide, expected to grow to greater than \$8 billion by 2011. Non-small cell lung cancer accounts for more than 80% of lung cancer. Only about 15% of non-small cell lung cancer patients are diagnosed early enough to be eligible for surgery.

Platinum-based chemotherapy regimens are standard first-line treatment for advanced non-small cell lung cancer patients, since these patients are not eligible for surgery. Carboplatin and paclitaxel are the most common combination therapy in the U.S., while cisplatin and gemcitabine are more common in Europe. During treatment, patients continue to be subject to serious adverse effects. According to December 2003 Credit Suisse First Boston and UBS reports and Phase 3 clinical trials conducted prior to 1999, the one-year survival rate for first-line therapy is typically only about 35%, median survival is approximately 8.5 months and the objective tumor response rate is about 20%. Overall, fewer than 5% of advanced non-small cell lung cancer patients survive five years. Docetaxel is approved for use as second-line treatment of non-small cell lung cancer. New regimens with existing cytotoxic drugs are expected to provide only incremental improvements in efficacy and/or safety, and are very expensive. Newly emerged targeted biologic therapies, such as Astra Zeneca's IRESSA®, OSI's TARCEVA® and Genentech's AVASTIN®, may offer some limited benefit for certain patients, but overall efficacy has remained low, there are safety concerns and the costs are very high. Thus, there is a lack of effective treatments for non-small cell lung cancer, particularly for late stage patients.

NOV-002, unlike any other marketed drug or product in development, appears to increase both toleration and efficacy of chemotherapy in that it allows the patient to safely undergo more cycles of chemotherapy (demonstrated in both U.S. and Russian studies), produces a clinical survival benefit (63% and 52% one-year survival in Russian studies versus 35% typical in the U.S.) and demonstrated better tumor shrinkage (69% of the patients treated with NOV-002 plus chemotherapy had 50% or greater tumor shrinkage versus only 33% of the patients treated with chemotherapy alone). We expect that NOV-002 will be used in combination with first-line chemotherapy treatments and may be complementary to second-line and recently emerging third-line products. Furthermore, we expect that NOV-002 may have utility in all stages of non-small cell lung cancer and in other solid tumor types as well.

The Russian non-clinical and clinical data set (including clinical safety and efficacy, extensive animal toxicology studies and a comprehensive chemistry and manufacturing package) was accepted by the FDA as the basis of an Investigational New Drug (IND) application, leading to a Novelos-sponsored Phase 1/2 clinical trial in advanced non-small cell lung cancer in late 1999. The aim of the Phase 1/2 clinical study was to demonstrate safety, detect trends towards efficacy, compare routes of administration and support initiation of a Phase 3 study. We finalized a Special Protocol Assessment with the FDA in May 2006 for a single pivotal Phase 3 trial in advanced non-small cell lung cancer in combination with first-line chemotherapy, and obtained Fast Track designation in August 2006. The primary endpoint of this trial is improvement in median overall survival and we commenced enrollment in November 2006. We expect the pivotal Phase 3 trial to conclude mid-2009.

In the U.S. Phase 1/2 non-small cell lung cancer clinical trial of NOV-002, 44 chemotherapy-naive late-stage lung cancer patients who had not received prior chemotherapy were randomized to one of three groups for six months of treatment:

- Group A: NOV-002, administered intravenously and intramuscularly, in combination with cytotoxic chemotherapy (carboplatin + paclitaxel).
- Group B: NOV-002, administered intravenously and subcutaneously, in combination with cytotoxic chemotherapy.
- Group C: Cytotoxic chemotherapy alone was administered to this control group.

Based on the study protocol, the intent-to-treat analysis of the best overall objective tumor response (e.g., complete or partial tumor shrinkage) showed that eleven out of sixteen (69%) NOV-002-treated patients in Group B demonstrated greater than 50% tumor shrinkage versus only five out of fifteen (33%) in the control group (C). Six out of thirteen (46%) patients in Group A demonstrated an objective response. The difference between groups B and C was statistically significant ( $p=0.044$ ).

Further, NOV-002-treated patients better tolerated cytotoxic chemotherapy as evidenced by their ability to receive more cycles of chemotherapy compared to the control group (C). 100% of patients in Group B and 85% in Group A were able to complete four cycles of chemotherapy, while only 50% of control group patients (C) were able to do so. The differences between groups was statistically significant ( $p=0.004$ ).

In St. Petersburg, Russia, a multi-center, randomized, open-label study was conducted more than ten years ago to evaluate the safety and efficacy of NOV-002 in patients with advanced non-small cell lung cancer. NOV-002, used in combination with chemotherapy, dramatically and significantly increased the one-year survival rate (63% treated group vs. 17% control,  $p<0.05$ ). NOV-002 significantly improved patients' ability to conduct daily activities and quality of life, increased tolerance to chemotherapy, improved hematologic parameters and improved or normalized kidney/liver toxicity markers. As in the U.S. Phase 1/2 trial, patients receiving NOV-002 were able to receive significantly more cycles of chemotherapy. Importantly, no NOV-002-associated adverse effects were observed. In addition, in an independent study in advanced non-small cell lung cancer study of similar design in Moscow in 2000, 52% of the patients treated with NOV-002 survived for one year.

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

According to the American Cancer Society, approximately 20,000 U.S. women were expected to be diagnosed with ovarian cancer in 2006 and 15,000 women are expected to die from it. According to a Rodman and Renshaw report dated December 2006, the pharmaceutical market for treating ovarian cancer is currently estimated to be \$300 million. 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 the same in ovarian cancer as in non-small cell lung cancer. Standard first-line treatment for ovarian cancer patients is 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 are faced with inadequate therapeutic options. According to a Lehman Brothers report dated September 2002, response rates from second-line treatments, such as doxorubicin and topotecan, are typically less than 12%. 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 a June 2005 issue of the Journal of Reproductive Medicine.

In Russia in 1998, twenty ovarian cancer case studies were analyzed. All of these patients were treated for three cycles with platinum-based chemotherapy but continued with progressive disease according to qualitative assessments and Cancer Antigen 125. The patients were then treated with NOV-002 for three to four weeks, followed by three more cycles of the same platinum-based chemotherapy (which they previously failed to respond to) in conjunction with NOV-002. The observed 40% objective response rate across these case studies is much higher than would be expected in such patients. Objective response is defined as partial (50% or greater tumor reduction) or complete response; it does not include stabilization of the disease or small reductions in tumor size. An additional 40% of patients in the Russian analysis displayed stable disease.

In the U.S., a Phase 2 trial in chemotherapy-resistant ovarian cancer patients commenced in July 2006 and is ongoing at Massachusetts General Hospital and Dana-Farber Cancer Institute. We expect interim results from this trial by mid-2007.

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

We are also developing NOV-002 to treat early-stage breast cancer in combination with chemotherapy. These patients are often treated with chemotherapy to minimize surgical intervention. A planned U.S. Phase 2 trial, expected to commence early to mid-2007, will evaluate the ability of NOV-002 to enhance the effectiveness of such chemotherapy while diminishing dose-limiting side-effects.

#### ***NOV-002 for Treatment of Acute Radiation***

Significant market opportunity and unmet need exist for a drug that may safely treat the effects of acute radiation injury. In today's world, there appears to be more concern than ever about an attack by a nuclear weapon, a "dirty bomb" or an attack or accident at a nuclear power plant. The majority of deaths following such an attack do not result from the explosion itself, but from bone marrow suppression, which in turn leads to neutropenia (severe loss of white blood cells, neutrophils, leaving the body defenseless against infections) and depletion of platelets (key clotting factors that stop bleeding). The window of opportunity to treat radiation injury is short, thus the drug would need to be stockpiled at the local level in high risk areas, such as military bases, major population centers and within a 10-50 mile radius of nuclear power plant facilities.

Currently, post-radiation exposure treatment options are essentially non-existent. Potassium iodide is the only pharmaceutical agent that has been stockpiled in the event of radiation exposure. However, it is effective only in reducing the risk of thyroid cancer, and does not protect the body from acute radiation injury. Similarly, the FDA recently approved pentetate calcium trisodium injection and pentetate zinc trisodium injection, which have been in use for decades to treat radiation contamination caused by industrial accidents. The goal of treatment with these agents is to help remove the radioactive elements from the body and reduce the risk of the development of illnesses such as cancer that can occur years after exposure, but they do not address acute radiation injury.

NOV-002 has been safely administered to many thousands of Russian patients since the mid-1990s and to a limited number of subjects in a U.S. Phase 1/2 lung cancer trial. Further, NOV-002 has already demonstrated the ability to restore hematological parameters and boost immune function in cancer patients receiving cytotoxic chemotherapy. In Russian preclinical experiments in 2003, groups of mice and rats were exposed to lethal levels of ionizing radiation. The animals treated with NOV-002 post-exposure demonstrated an increased survival of two- to three-fold (measured at thirty days post-exposure) compared to the irradiated control animals. Moreover, there was a 2.5-fold increase in the number of hematopoietic colony-forming units in the spleens of mice receiving NOV-002 after radiation compared to those receiving radiation alone. In another experiment, two groups of rats were irradiated at sub-lethal levels of exposure. The control group received no treatment. The treated group received daily injections of NOV-002. Unlike the control group, NOV-002-treated animals did not experience severe neutropenia and demonstrated increased survival compared to the control group.

We intend to explore the commercial potential of NOV-002 for radiation protection in the U.S. and abroad to address the growing concern over catastrophic radiation exposure from a nuclear weapon, a “dirty bomb”, or an attack/accident at a nuclear power plant. Meanwhile, we are working with Shriners Hospitals to conduct studies in animal models to confirm and expand on the positive results in treatment of acute radiation injury with NOV-002 demonstrated in Russian experiments.

## **NOV-205**

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

NOV-205 is a unique, injectable, small-molecule proprietary formulation of oxidized glutathione and inosine. We are developing NOV-205 in the U.S. for the treatment of chronic hepatitis C.

According to the World Health Organization, chronic hepatitis C affected 170 million people worldwide in 2003, and up to four million people are newly infected each year. Chronic infection can progress to cirrhosis and end-stage liver disease. While there are varying estimates about the size of the global market for hepatitis C drugs, according to a September 2006 publication of *Nature Reviews Drug Discovery* the current global market is believed to be in excess of \$3 billion per year, growing to more than \$8 billion by 2010. In the U.S., according to the Centers for Disease Control and Prevention, an estimated 3.9 million persons were infected with hepatitis C, and 2.7 million persons in the U.S. had chronic infection in 2003. Further, hepatitis C infections account for approximately 30,000 new infections and 8,000-10,000 deaths each year in the U.S.

NOV-205 was approved in Russia by the Ministry of Health in 2001 as monotherapy for the treatment of hepatitis B and C. The Russian approval of NOV-205 was supported by a Russian New Drug Application, which included studies in hepatitis B and C totaling 90 treated patients. An additional 88 patients were treated in previous anecdotal studies. After relatively short treatment periods (1-2 months), the drug was shown to eliminate the serum viral load in hepatitis B patients and to decrease viral load below detection in 40-60% of hepatitis C subjects. Importantly, these reductions were largely maintained during 1-3 months of post-treatment follow-up. In addition, NOV-205 improved liver function as evidenced by significant reductions in serum biochemical markers of liver toxicity. No NOV-205-related adverse events were reported among any of the 178 patients treated in these studies.

The therapeutic profile of NOV-205 contrasts sharply 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, anemia). Furthermore, these drugs are effective in only a fraction of the patient population and are very expensive. Other new products for hepatitis C, beyond variations of ribavirin and interferon (e.g., HCV protease inhibitors), are at early stages of development and could potentially be used in combination with NOV-205.

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 Investigational New Drug Application with the FDA for NOV-205 as monotherapy in chronic hepatitis C in March 2006. The FDA accepted our Investigational New Drug Application 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. We expect this trial to conclude by mid-2007.

## **Non-clinical Research Program**

Our non-clinical research program is aimed at (a) gaining a better understanding of the mechanism(s) of action of our oxidized glutathione-based drug products and (b) adding to the Russian non-clinical data information that will be required for ultimate FDA filing of our products. This research is being performed via a network of academic and commercial (i.e., contract research organizations) laboratories.

We are engaged in 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 drug products, particularly with respect to their molecular and cellular mechanism(s) of action and to facilitate: (1) the design and execution of clinical studies, (2) the interactions with the FDA and (3) the interactions with others in the scientific community.

We are also working with Jeffrey Gelfand, M.D., senior advisor for international medical affairs at Partners Healthcare System (Massachusetts General Hospital, Harvard Medical School, Dana-Farber Cancer Institute, Brigham and Women's Hospital) and director of the Center for Integration of Medicine and Innovative Technology. In his new laboratory at Shriners Hospitals, Dr. Gelfand is conducting studies in animal models to confirm and expand upon the positive results in treatment of acute radiation injury with NOV-002 demonstrated in Russian experiments.

We also intend to continue to collaborate, through ZAO BAM, with leading Russian research institutions in Moscow and St. Petersburg, to enhance the basic science around oxidized glutathione, support development of NOV-002 and NOV-205 and develop additional products and product forms. Further, through our other contacts in Russia, we believe we may have access to products and technologies developed by other Russian research institutions and scientists.

## **Manufacturing**

Our proprietary manufacturing process is well-established, simple, inexpensive 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 is manufactured in the U.S. in compliance with current Good Manufacturing Principles at Synthetech, Inc. (Albany, OR) in a single, very cost-effective synthetic step and then lyophilized into a powder at Oregon Freeze Dry, Inc. (Albany, OR). It is then filled, finished and packaged at Hyaluron (Burlington, MA) as a sterile filtered, aseptically processed solution for intravenous, intramuscular and/or subcutaneous use. NOV-002 clinical trial material (vials containing the active pharmaceutical ingredient and solution) has successfully completed 36-month stability studies.

Similar to NOV-002, NOV-205's active pharmaceutical ingredient is manufactured in compliance with current Good Manufacturing Principles in a single, very cost effective, synthetic step at Synthetech, Inc. and then lyophilized into a powder at Oregon Freeze Dry, Inc. It is then filled, finished and packaged at Dalton Pharma Services Inc. (Toronto, Canada).

## **Intellectual Property**

We own all intellectual property rights worldwide (excluding Russia and other states of the former Soviet Union) related to both clinical-stage compounds (i.e., NOV-002 and NOV-205) and other pre-clinical compounds based on oxidized glutathione. We have four issued patents in the U.S., and received a notice of allowance for a fifth U.S. patent in September 2006. We also have two issued patents in Europe and one in Japan. Overall, we have filed more than 30 patent applications worldwide.

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

## **Employees**

As of March 1, 2007 we have seven employees, all of whom are 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 United States and other countries. We anticipate that these regulations will apply separately to each drug and compound in our drug therapy technology. We believe that complying with these regulations will involve a considerable level of time, expense and uncertainty.

In the United States, drugs 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 drugs. Drug development and approval within this regulatory framework is difficult to predict and will take a number of years and involve the expenditure of substantial resources.

The steps required before a pharmaceutical agent may be marketed in the United States include:

- Pre-clinical laboratory tests, *in vivo* pre-clinical studies, and formulation studies;
- The submission to the FDA of an Investigational New Drug Application 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 or Biologic Drug License Application to the FDA; and
- FDA approval of the New Drug Application or Biologic Drug License Application prior to any commercial sale or shipment of the product.

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 drug 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. Although there are some procedures for unified filings for certain European countries, in general, each country at this time has its own procedures and requirements.

## **Item 2. Description of Property**

We lease our executive office in Newton, Massachusetts. Our office consists of approximately 2,200 square feet and is rented for approximately \$5,700 per month. This lease expires in August 2007. 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**

We are not a party to any legal proceedings the outcome of which, in the opinion of our management, would have a material adverse effect on our business, financial condition, or results of operations.

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

No matters were submitted to a vote of our security holders during the fourth quarter of the fiscal year ended December 31, 2006.

**PART II****Item 5. Market for Common Equity, Related Stockholder Matters and Small Business Issuer Purchases of Equity Securities**

Our common stock has been quoted on the OTC Electronic Bulletin Board of The National Association of Securities Dealers, Inc. under the symbol "NVL.T.OB" 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 2005</b>	High	Low
First quarter	\$ N/A	\$ N/A
Second quarter (beginning June 14, 2005)	2.90	2.00
Third quarter	4.47	2.15
Fourth quarter	3.65	1.53

  

<b>Fiscal Year 2006</b>	High	Low
First quarter	\$ 2.25	\$ 1.60
Second quarter	1.95	0.85
Third quarter	1.05	0.63
Fourth quarter	1.02	0.60

On December 31, 2006 there were 179 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 currently expect to retain future earnings, if any, for the development of our business. Dividends may be paid on our common stock only if and when declared by our board of directors after payment of any accrued dividends on our Series A 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**

During 2006, we issued a total of 85,000 shares of our common stock to investor relations consultants as compensation for services on the following dates and in the following amounts: January 23, 2006 20,000 shares; February 27, 2006 15,000 shares; February 28, 2006 20,000 shares; March 28, 2006 10,000 shares; June 22, 2006 10,000 shares; September 22, 2006 10,000 shares.

On March 27, 2006 we issued 75,000 shares of our common stock to Dr. Kenneth Tew, a member of our Scientific Advisory Board, upon exercise of his stock option at a price per share of \$0.01 for total consideration of \$750, pursuant to an option granted in April 2004.

These issuances were exempt from registration under the Securities Act of 1933 pursuant to an exemption under Section 4(2) thereof as a sale of securities not involving a public offering.

## **Item 6. Management's Discussion and Analysis or Plan of Operation**

### **Overview**

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

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

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

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

### **Plan of Operation**

Our plan of operation for the next twelve months is to continue the clinical development of our two product candidates. We expect our principal expenditures during those 12 months to include the costs associated with clinical trials. We will continue to maintain a low number of permanent employees and utilize senior advisors, consultants, contract research and manufacturing organizations and third parties to perform certain aspects of product development, including clinical and non-clinical development, manufacturing and, in some cases, regulatory and quality assurance functions. Based on our current and anticipated spending, we anticipate that we will be able to fund these activities with existing working capital into the third quarter of 2007. We plan to seek additional capital in the first half of 2007. If we are unable to obtain funding on a timely basis, we may be required to significantly curtail or terminate one or more of our research or development programs or take other steps that could significantly impact the execution of our strategy.

### **Capital Structure and Financings**

In 2005 following the settlement of certain of our indebtedness, we completed a two-step reverse merger with Common Horizons, Inc. ("Common Horizons"), a Nevada-based developer of web portals, and its wholly owned subsidiary Nove Acquisition, Inc. In the first step, Nove Acquisition was merged into Novelos with all outstanding shares of Novelos (net of shares of treasury stock) being converted into an equal number of shares of common stock of Common Horizons and all outstanding options and warrants to purchase shares of Novelos common stock were converted into an equal number of options and warrants to purchase shares of Common Horizons with the same terms and conditions as the original options and warrants. In connection with the merger all but 4,500,000 shares of outstanding common stock of Common Horizons were canceled. In the second step, Common Horizons merged into Novelos, changing its state of incorporation, by-laws, certificate of incorporation and fiscal year to that of Novelos, which became the surviving corporation. The business of Common Horizons, which was insignificant, was abandoned and the business of Novelos was adopted. The transaction was therefore treated as a reverse acquisition recapitalization with Novelos as the acquiring party and Common Horizons as the acquired party for accounting purposes. Accordingly, all historical information in these financial statements is that of the Novelos business. The results of operations of Common Horizons prior to the merger were not material for purposes of pro forma presentation. The 4,500,000 remaining shares of Common Horizons outstanding at the completion of the merger, net of cancellations, were deemed, for accounting purposes, to be an issuance by Novelos. Since Common Horizons had no remaining financial assets or liabilities, the merger with Common Horizons did not have any significant effect on our assets or liabilities or on our results of operations subsequent to the date of the merger.

During 2005 and 2006 we completed various private placements of securities. In May through August of 2005 we sold an aggregate of 4,000,000 shares of common stock and warrants to purchase 2,000,000 shares of common stock for net cash proceeds of \$3,715,000 and the conversion of \$550,000 of convertible debt and accrued interest. In September and October 2005, we sold in a private placement 3,200 shares of Series A preferred stock and warrants to purchase 969,696 shares of common stock for aggregate net proceeds of \$2,864,000. The preferred stock was initially convertible into 1,939,393 shares of common stock, and is currently convertible into 2,370,370, shares of common stock due to certain adjustments to the conversion price. On March 7, 2006, we sold 11,154,073 shares of our common stock and warrants to purchase 8,365,542 shares of our common stock for net proceeds of \$13,847,000.

## **Results of Operations**

**Research and development expense.** Research and development expense consists of costs incurred in identifying, developing and testing product candidates, which primarily consist of salaries and related expenses for personnel, fees paid to professional service providers for independent monitoring and analysis of our clinical trials, costs of contract research and manufacturing and costs to secure intellectual property. We currently have two 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, 2006 and 2005**

**Research and Development.** Research and development expense for the year ended December 31, 2006 was \$6,441,000 compared to \$1,261,000 for the year ended December 31, 2005. The \$5,180,000, or 411%, increase in research and development expense was primarily due to increased funding of our clinical, contract manufacturing and non-clinical activities. The overall increase resulted principally from activities relating to the commencement of our pivotal Phase 3 clinical trial of NOV-002 for non-small cell lung cancer. The increase includes \$2,677,000 in additional contract research and consulting services and an increase of \$433,000 in drug manufacturing costs. We also purchased \$1,291,000 of chemotherapy drugs during 2006 to be used in the Phase 3 clinical trial, specifically for clinical sites in Eastern and Western Europe. Since we do not anticipate recovering any of the costs of the chemotherapy and we do not have a reliable method for tracking the drugs that have been administered to patients or evaluating any losses associated with spoilage, we recorded the entire amount as an expense in the period purchased. As disclosed in Note 10, we have a commitment to purchase an additional \$1,300,000 million of chemotherapy drugs at specified intervals through March 2008. Additionally, as a result of hiring that occurred during the third quarter of 2005, research and development salaries and related costs also increased \$644,000 during 2006 compared to 2005. Lastly, stock compensation expense increased \$135,000 during 2006 compared to 2005 principally resulting from the adoption of SFAS 123R in January 2006 and the associated compensation expense related to stock options granted to research and development personnel. For the next year, we expect research and development spending to continue to increase as our clinical trials progress.

**General and Administrative.** General and administrative expense for the year ended December 31, 2006 was \$2,488,000 compared to \$1,318,000 for the year ended December 31, 2005. The \$1,170,000, or 89%, increase in general and administrative expense was primarily due to increased costs associated with corporate governance and periodic filing requirements as a public company, increased overhead costs to support the research activities described above and expanded investor relations activities. The total increase includes an increase of \$464,000 in compensation and directors' fees; an increase of \$257,000 in public and investor relations costs and public company recordkeeping costs (including a \$123,000 increase in non-cash stock compensation related to restricted stock awards); an increase of \$169,000 related to professional and consulting fees; and an increase of \$36,000 in insurance costs. We also incurred an increase of \$196,000 in non-cash stock compensation expense related to stock option grants and an increase of \$107,000 in travel and overhead expenses. These increases were offset in 2006 by a reduction in accrued registration filing penalties that were recorded during 2005.

*Interest Income.* Interest income for the year ended December 31, 2006 was \$638,000 compared to \$50,000 for the year ended December 31, 2005. The increase in interest income during 2006 related to higher average cash balances in 2006, as a result of the financings described in Note 5 being placed in interest-bearing accounts.

*Interest Expense.* Interest expense for the year ended December 31, 2006 was \$0 compared to \$109,000 for the year ended December 31, 2005. The decrease was due to all interest-bearing debt balances being paid off during 2005.

*Gain on Forgiveness of Debt.* Gain on forgiveness of debt for the year ended December 31, 2006 was \$0 compared to \$2,087,000 for the year ended December 31, 2005. On May 26, 2005, we exchanged indebtedness of \$3,139,000 for 586,352 shares of our common stock with an aggregate deemed value of \$733,000 and \$319,000 in cash, which resulted in forgiveness of debt income of \$2,087,000.

*Restructuring Expense.* Restructuring expense for the year ended December 31, 2006 was \$0 compared to \$2,521,000 for the year ended December 31, 2005. On May 26, 2005, we revised an arrangement that requires us to pay future royalties, which resulted in the issuance of 2,016,894 shares of our common stock with an aggregate deemed value of \$2,521,000.

*Preferred Stock Dividends and Deemed Dividend.* During the year ended December 31, 2006 we paid cash dividends to preferred stockholders of \$261,000. In 2005, we issued additional shares of preferred stock with a deemed value of \$64,000 in payment of dividends. During the year ended December 31, 2005, we recorded a deemed dividend to preferred stockholders of \$2,077,000. This amount represents the value attributed to the beneficial conversion feature of the Series A 8% Cumulative Convertible Preferred Stock issued in September and October 2005. There were no deemed dividends in the year ended December 31, 2006. The deemed dividend and cash dividends have been included in the calculation of net loss attributable to common stockholders for the respective periods.

### **Liquidity and Capital Resources**

We have financed our operations since inception through the sale of equity securities and the issuance of debt (which was subsequently paid off or converted into equity). As of December 31, 2006, we had \$11,594,000 in cash and equivalents, including \$1,655,000 of restricted cash that is reserved for research and development activities.

During the year ended December 31, 2006, cash of approximately \$6,469,000 was used in operations, primarily due to a net loss of \$8,286,000, offset by non-cash stock-based compensation expense of \$588,000, depreciation and amortization of \$10,000, a decrease in prepaid expenses of \$123,000 and an increase in accounts payable and accrued expenses of \$1,096,000. During the year ended December 31, 2006, cash of approximately \$1,446,000 was used in investing activities primarily due to the pledge of \$1,550,000, included in restricted cash and equivalents, associated with a letter of credit agreement with a bank as described in Note 10.

During the year ended December 31, 2006, cash of approximately \$13,586,000 was provided by financing activities representing net proceeds of \$13,847,000 from the sale of common stock and warrants, reduced by the payment of \$261,000 in cash dividends on the Series A cumulative convertible preferred stock.

We believe that our available cash and equivalents will be sufficient to meet our working capital requirements, including operating losses, and capital expenditure requirements into the third quarter of 2007, assuming that our business plan is implemented successfully.

We believe that we will need to raise additional capital during 2007 in order to support the pivotal Phase 3 clinical trial for NOV-002 and other research and development activities. Furthermore, we may license or acquire other compounds that will require capital for development. We may seek additional funding through collaborative arrangements and public or private financings. Additional funding may not be available to us on acceptable terms or at all. In addition, the terms of any financing may adversely affect the holdings or the rights of our stockholders. For example, if we raise additional funds by issuing equity securities, further dilution to our existing stockholders may result. If we are unable to obtain funding on a timely basis, we may be required to significantly curtail one or more of our research or development programs. We also could be required to seek funds through arrangements with collaborators or others that may require us to relinquish rights to some of our technologies, product candidates, or products which we would otherwise pursue on our own.

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

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

### Commitments

In July, 2006, the Company entered into a contract with a supplier of pharmaceutical products that will provide chemotherapy drugs to be used in connection with Phase 3 clinical trial activities outside of the United States. Payments under the contract will be made in Euros and will be funded with available working capital. The minimum commitment under the contract is approximately as follows as of December 31, 2006:

	Payments Due by Period				
	Total	0-12 Months	1 - 3 Years	3 - 5 Years	After 5 Years
Chemotherapy purchase commitment	\$ 1,300,000	\$ 1,200,000	\$ 100,000	\$ —	—

### Critical Accounting Policies

The preparation of financial statements and related disclosures in conformity with accounting principles generally accepted in the United States (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 Expenses.* As part of the process of preparing financial statements, we are required to estimate accrued expenses. This process involves identifying services that have been performed on our behalf, and estimating the level of service performed and the associated cost incurred for such service as of each balance sheet date in our financial statements. Examples of estimated expenses for which we accrue include: contract service fees such as amounts paid to clinical 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 upon the facts and circumstances known to us in accordance with generally accepted accounting principles.

*Stock-based Compensation.* Commencing on January 1, 2006 we began applying the provisions of Statement of Financial Accounting Standards (SFAS) 123R, *Share-Based Payment*, or SFAS 123R, in accounting for stock-based compensation. SFAS 123R 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). Prior to January 1, 2006, we followed Accounting Principles Board (APB) Opinion No. 25, *Accounting for Stock Issued to Employees*, or APB 25, and related interpretations, in accounting for our stock-based compensation plans, rather than the alternative fair-value method provided for under SFAS No. 123, *Accounting for Stock-Based Compensation*, or SFAS 123. In the notes to our financial statements, we provide pro-forma disclosures in accordance with SFAS 123 for periods prior to the adoption of SFAS 123R. We account for transactions in which services are received from non-employees in exchange for equity instruments based on the fair value of such services received or of the equity instruments issued, whichever is more reliably measured, in accordance with SFAS 123 and the Emerging Issues Task Force (EITF) Issue 96-18, *Accounting for Equity Instruments That Are Issued to Other than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*, or EITF 96-18.

Accounting for equity instruments granted or sold by us under APB 25, SFAS 123, SFAS 123R and EITF 96-18 requires fair-value estimates of the equity instrument granted or sold. If our estimates of the fair value of these equity instruments are too high or too low, our expenses may be over- or understated. 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. Because shares of our common stock were not publicly traded prior to the corporate restructuring described in Note 3 to the financial statements, market factors historically considered in valuing stock and stock option grants included corresponding values of comparable public companies discounted for the risk and limited liquidity provided for in the shares we are issuing; pricing of private sales of our convertible preferred stock; prior valuations of stock grants and the effect of events that occurred between the times of such grants; economic trends; and the comparative rights and preferences of the security being granted compared to the rights and preferences of our other outstanding equity.

Prior to the reverse merger and subsequent financing that occurred in May 2005, the fair value of our common stock was determined by our board of directors contemporaneously with the grant. In the absence of a public trading market for our common stock, our board of directors considered numerous objective and subjective factors in determining the fair value of our common stock. At the time of option grants and other stock issuances, our board of directors considered the liquidation preferences, dividend rights, voting control and anti-dilution protection attributable to our then-outstanding convertible preferred stock; the status of private and public financial markets; valuations of comparable private and public companies; the likelihood of achieving a liquidity event such as an initial public offering; our existing financial resources; our anticipated continuing operating losses and increased spending levels required to complete our clinical trials; and a general assessment of future business risks.

#### **Factors Affecting Future Performance**

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

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

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

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

We may consume available resources more rapidly than currently anticipated, resulting in the need for additional funding. We may seek to raise any necessary additional funds through the issuance of warrants, equity or debt financings or executing collaborative arrangements with corporate partners or other sources, which may be dilutive to existing stockholders or otherwise have a material effect on our current or future business prospects. In addition, in the event that additional funds are obtained through arrangements with collaborative partners or other sources, we may have to relinquish economic and/or proprietary rights to some of our technologies or products under development that we would otherwise seek to develop or commercialize by ourselves. If adequate funds are not available, we may be required to significantly reduce or refocus our development efforts with regard to our drug compounds. Currently, we believe that we have available cash sufficient to meet our working capital requirements into the third quarter of 2007, assuming our expense levels do not exceed our current plan. If we do not generate revenues or raise additional capital, we will not be able to sustain our operations at existing levels beyond that date or earlier if expense levels increase.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We have initiated a portion of our clinical trial activities in Europe. Significant depreciation in the value of the U.S. Dollar against principally the Euro could adversely affect our ability to complete the trials, particularly if we are unable to redirect funding or raise additional funds. Since the timing and amount of foreign-denominated payments are uncertain and dependent on a number of factors, it is difficult to cost-effectively hedge the potential exposure. Therefore, to date, we have not entered into any foreign currency hedges to mitigate the potential exposure.

**The market for our products is rapidly changing and competitive, and new therapeutics, new drugs and new treatments which 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. Many of these entities have significantly greater research and development capabilities and budgets than we do, as well as substantially more marketing, manufacturing, financial and managerial resources. These entities represent significant competition for us. Acquisitions of, or investments in, competing pharmaceutical or biotechnology companies by large corporations could increase such competitors' financial, marketing, manufacturing and other resources.

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

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

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

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

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

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

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

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

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

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

Our directors, officers and 5% stockholders beneficially own, in the aggregate, approximately 17% of our outstanding voting stock. The interests of our current officers and directors may differ from the interests of other stockholders. Further, our current officers and directors 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 effecting other financing arrangements; or
- the approval of certain mergers and other significant corporate transactions, including a sale of substantially all of our assets, or merger with a publicly-traded shell or other company.

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

In the past, we have issued common stock, convertible securities, such as our Series A cumulative 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 a substantial number of shares of common stock reserved for issuance upon the conversion and exercise of these securities. Our issuance of additional common stock, convertible securities, options and warrants could affect the rights of our stockholders, and could reduce the market price of our common stock.

**The use of the prospectus included in the Post-Effective Amendment No. 1 to the Registration Statement on Form SB-2 (previously declared effective on April 3, 2006) and the prospectus included in the Registration Statement on Form SB-2 (previously declared effective on April 19, 2006) were suspended on October 24, 2006.**

On October 24, 2006, we filed a Current Report on Form 8-K which described an error in the financial statements and related notes to financial statements for the quarter ended September 30, 2005 and the year ended December 31, 2005 relating to the accounting and disclosure of the beneficial conversion feature of the Company's Series A 8% Cumulative Convertible Preferred Stock. On November 1, 2006 we filed amendments to the Annual Report on Form 10-KSB for the year ended December 31, 2005 and the Quarterly Report on Form 10-QSB for the quarter ended September 30, 2005. Following the filing of the Form 8-K on October 24, 2006, we advised the selling stockholders named in two registration statements related to the resale of securities purchased in private placement transactions in 2005 and 2006 that the use of the respective prospectuses had been suspended. The registration statements were amended through the filing of a combined registration statement that was filed on November 17, 2006 and became effective on November 21, 2006. Pursuant to the registration rights associated with the private placement of securities that occurred from May through August of 2005, we exceeded the allowable grace period for suspension of use of an effective prospectus. As a result, we may become obligated to these selling stockholders in the event that any remaining holders submit a claim for liquidated damages. As of December 31, 2006, we have concluded that it is not probable that we will incur any liability associated with the suspension of the prospectus.

**ITEM 7. FINANCIAL STATEMENTS**

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## 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, 2006 and 2005 and the related statements of operations, stockholders' equity (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.

As discussed in Note 6, effective January 1, 2006, the Company adopted Statement of Financial Accounting Standards (SFAS) No. 123(R), *Share-Based Payment*.

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, 2006 and 2005 and the results of its operations, changes in stockholders' equity (deficiency) and cash flows for the years then ended in conformity with accounting principles generally accepted in the United States.

/s/ Stowe & Degon

Worcester, Massachusetts  
March 19, 2007

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

	<u>December 31,</u> <u>2006</u>	<u>December 31,</u> <u>2005</u>
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and equivalents	\$ 9,938,428	\$ 4,267,115
Restricted cash	1,655,251	196,908
Prepaid expenses and other current assets	294,995	337,902
Total current assets	<u>11,888,674</u>	<u>4,801,925</u>
FIXED ASSETS, NET	23,810	22,610
DEFERRED FINANCING COSTS	—	24,612
PREPAID EXPENSES	—	79,896
DEPOSITS	10,875	9,656
<b>TOTAL ASSETS</b>	<u>\$ 11,923,359</u>	<u>\$ 4,938,699</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable and accrued liabilities	\$ 1,088,041	\$ 217,156
Accrued compensation	225,384	—
Total current liabilities	<u>1,313,425</u>	<u>217,156</u>
<b>COMMITMENTS AND CONTINGENCIES</b>		
<b>STOCKHOLDERS' EQUITY:</b>		
Preferred Stock, \$0.00001 par value; 7,000 shares authorized: Series A 8% cumulative convertible preferred stock; 3,264 shares issued and outstanding (liquidation preference \$3,264,000)	—	—
Common stock, \$0.00001 par value; 100,000,000 shares authorized; 39,235,272 and 27,921,199 shares issued and outstanding at December 31, 2006 and December 31, 2005, respectively	392	279
Additional paid-in capital	34,294,154	20,119,820
Accumulated deficit	(23,684,612)	(15,398,556)
Total stockholders' equity	<u>10,609,934</u>	<u>4,721,543</u>
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<u>\$ 11,923,359</u>	<u>\$ 4,938,699</u>

*See notes to financial statements.*

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

	Year Ended December 31,	
	2006	2005
<b>REVENUES:</b>		
Sales of samples	\$ —	\$ 12,584
Total revenues	<u>—</u>	<u>12,584</u>
<b>COSTS AND EXPENSES:</b>		
Research and development	6,441,394	1,260,682
General and administrative	2,488,414	1,318,284
Total costs and expenses	<u>8,929,808</u>	<u>2,578,966</u>
<b>OTHER INCOME (EXPENSE):</b>		
Interest income	637,752	49,876
Interest expense	—	(109,102)
Miscellaneous	6,000	5,796
Gain on forgiveness of debt	—	2,087,531
Restructuring expense	—	(2,521,118)
Total other income (expense)	<u>643,752</u>	<u>(487,017)</u>
<b>NET LOSS</b>	<b>(8,286,056)</b>	<b>(3,053,399)</b>
<b>PREFERRED STOCK DIVIDEND</b>	<b>(261,120)</b>	<b>(64,000)</b>
<b>PREFERRED STOCK DEEMED DIVIDEND</b>	<b>—</b>	<b>(2,077,321)</b>
<b>NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS</b>	<b>\$ (8,547,176)</b>	<b>\$ (5,194,720)</b>
<b>BASIC AND DILUTED NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS PER COMMON SHARE</b>		
	<b>\$ (0.23)</b>	<b>\$ (0.24)</b>
<b>SHARES USED IN COMPUTING BASIC AND DILUTED NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS PER COMMON SHARE</b>		
	<b>37,179,878</b>	<b>21,757,424</b>

*See notes to financial statements.*

**NOVELOS THERAPEUTICS, INC.**  
**STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIENCY)**

	Common Stock		Series A Cumulative Convertible Preferred Stock		Additional Paid-in Capital	Accumulated Deficit	Treasury Stock	Total Stockholders' Equity (Deficiency)
	Shares	Amount	Shares	Amount				
BALANCE AT JANUARY 1, 2005	4,426,126	\$ 44	—	\$ —	7,998,110	\$ (12,345,157)	\$ (1,956)	\$ (4,348,959)
Issuance of common stock for financing commitment	10,500,000	105	—	—	—	—	—	105
Issuance of common stock upon conversion of convertible debt	1,760,000	18	—	—	1,099,982	—	—	1,100,000
Issuance of common stock in settlement of unsecured debt	586,351	6	—	—	732,935	—	—	732,941
Issuance of common stock in restructuring of royalty arrangement	2,016,894	20	—	—	2,521,098	—	—	2,521,118
Issuance of common stock in merger	4,500,000	45	—	—	(45)	—	—	—
Retirement of treasury stock in merger	(195,672)	(2)	—	—	(1,954)	—	1,956	—
Issuance of common stock and warrants in private placement, net of issuance costs of \$891,383	4,000,000	40	—	—	4,108,577	—	—	4,108,617
Issuance of common stock for placement agent services	125,000	1	—	—	156,249	—	—	156,250
Issuance of common stock for services	202,500	2	—	—	527,798	—	—	527,800
Compensation expense associated with options issued to non-employees	—	—	—	—	113,070	—	—	113,070
Issuance of cumulative convertible preferred stock, net of issuance costs of \$336,000	—	—	3,200	—	—	—	—	—
Issuance of warrants in connection with preferred stock	—	—	—	—	786,679	—	—	786,679
Beneficial conversion feature on preferred stock	—	—	—	—	2,077,321	—	—	2,077,321
Issuance of cumulative convertible preferred stock in payment of dividends	—	—	64	—	—	—	—	—
Net loss	—	—	—	—	—	(3,053,399)	—	(3,053,399)
BALANCE AT DECEMBER 31, 2005	27,921,199	279	3,264	—	20,119,820	(15,398,556)	—	4,721,543
Exercise of stock options	75,000	1	—	—	749	—	—	750
Issuance of common stock for services	85,000	1	—	—	144,049	—	—	144,050
Issuance of common stock and warrants in private placement, net of issuance costs of \$1,211,232	11,154,073	111	—	—	13,846,663	—	—	13,846,774
Compensation expense associated with options issued to employees	—	—	—	—	268,281	—	—	268,281
Compensation expense associated with options issued to non-employees	—	—	—	—	175,712	—	—	175,712
Dividends paid on preferred stock	—	—	—	—	(261,120)	—	—	(261,120)
Net loss	—	—	—	—	—	(8,286,056)	—	(8,286,056)
BALANCE AT DECEMBER 31, 2006	<u>39,235,272</u>	<u>\$ 392</u>	<u>3,264</u>	<u>\$ —</u>	<u>34,294,154</u>	<u>\$ (23,684,612)</u>	<u>\$ —</u>	<u>\$ 10,609,934</u>

*See notes to financial statements.*

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

	Year Ended December 31,	
	2006	2005
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$ (8,286,056)	\$ (3,053,399)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	9,516	3,244
Stock-based compensation	588,043	399,461
Gain on forgiveness of debt	—	(2,087,531)
Common stock issued for restructuring expense	—	2,521,118
Increase (decrease) in:		
Accounts receivable	—	12,584
Prepaid expenses and other current assets	122,803	(96,653)
Accounts payable and accrued liabilities	870,885	(136,538)
Accrued compensation	225,384	—
Accrued interest	—	51,451
Deferred revenue	—	(12,584)
Deferred rent	—	(250)
Cash used in operating activities	<u>(6,469,425)</u>	<u>(2,399,097)</u>
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Purchases of property and equipment	(10,716)	(25,854)
Change in restricted cash	(1,458,343)	(196,908)
Deferred financing costs	24,612	(24,612)
Deposits	(1,219)	(4,798)
Cash used in investing activities	<u>(1,445,666)</u>	<u>(252,172)</u>
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from issuance of common stock, net	13,846,774	3,714,868
Proceeds from issuance of Series A 8% cumulative convertible preferred stock, net	—	2,864,000
Dividends paid to preferred stockholders	(261,120)	—
Proceeds from exercise of stock option	750	—
Payments of long-term debt	—	(1,840)
Proceeds from issuance of promissory notes	—	850,000
Payment of promissory notes	—	(519,000)
Cash provided by financing activities	<u>13,586,404</u>	<u>6,908,028</u>
<b>INCREASE (DECREASE) IN CASH AND EQUIVALENTS</b>	<b>5,671,313</b>	<b>4,256,759</b>
<b>CASH AND EQUIVALENTS AT BEGINNING OF YEAR</b>	<b>4,267,115</b>	<b>10,356</b>
<b>CASH AND EQUIVALENTS AT END OF YEAR</b>	<b>\$ 9,938,428</b>	<b>\$ 4,267,115</b>
<b>SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION</b>		
Cash paid during the year for interest	\$ —	\$ 57,461
<b>SUPPLEMENTAL DISCLOSURES OF NON-CASH ACTIVITIES</b>		
Deemed dividend on preferred stock	\$ —	\$ 2,077,321
Preferred stock issued in payment of dividends	\$ —	\$ 64,000
Common stock issued for services	\$ 144,050	\$ 156,250
Common stock issued on conversion of promissory notes	\$ —	\$ 1,100,000
Common stock issued to repay notes payable	\$ —	\$ 638,719
Common stock issued in exchange for accounts payable	\$ —	\$ 544,221
Common stock issued for accrued interest	\$ —	\$ 100,000
Common stock issued for prepaid expenses	\$ —	\$ 426,450
Demand notes payable forgiven	\$ —	\$ 621,931
Accounts payable forgiven	\$ —	\$ 761,880
Accrued compensation forgiven	\$ —	\$ 360,357
Accrued interest forgiven	\$ —	\$ 343,363

*See notes to financial statements.*

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

**1. NATURE OF BUSINESS**

Novelos Therapeutics, Inc. (“Novelos” or on or after June 13, 2005, the “Company”) is a drug development company, originally established in 1996 as AVAM International, focused on the development of therapeutics for the treatment of various cancers and infectious diseases. See Note 3 regarding the reverse merger that occurred during 2005. Novelos owns exclusive worldwide intellectual property rights (excluding Russia and other states of the former Soviet Union) related to certain clinical compounds and other pre-clinical compounds based on oxidized glutathione. The Company operates in one business segment.

The Company is devoting substantially all of its efforts toward the research and development of its products and has incurred operating losses since inception. The process of developing products will 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 and increasing operating losses in the foreseeable future. The Company plans to obtain capital to fund these activities through the sale of equity and debt securities and through collaborative arrangements with partners. If the Company is unable to obtain capital through these sources, it may have to seek other sources of capital or reevaluate its operating plans.

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

**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 management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue and expenses and disclosure of contingent assets and liabilities. Management’s estimates are based primarily on relevant historical experience and other assumptions that management believes to be reasonable. Actual results could differ from those estimates.

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

**Restricted Cash** — Restricted cash at December 31, 2005 represents cash placed in escrow as contractually required under an employment agreement with an officer. At December 31, 2006, restricted cash also includes \$1,550,000 of cash pledged as security on a letter of credit agreement with a bank. See Note 10.

**Property and Equipment** — 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** — At each balance sheet date, 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** — Effective January 1, 2006, the Company adopted the fair-value recognition provisions of Statement of Financial Accounting Standards (SFAS) No. 123(R), *Share Based Payment* (SFAS 123R) using the modified-prospective-transition method. During the year ended December 31, 2005, the Company accounted for stock option awards granted to directors and employees under the recognition and measurement principles of Accounting Principles Board Opinion (APB) No. 25, *Accounting for Stock Issued to Employees*, (APB 25). During 2006 and 2005 the Company accounted for share-based payments granted to non-employees in accordance with Emerging Issues Task Force (EITF) No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*. See Note 6 for a further description of the Company’s accounting policies related to stock-based compensation.

**Revenue Recognition** — Revenue from sales of samples 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.

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

**Income Taxes** — The Company accounts for income taxes under the provisions of SFAS No. 109, *Accounting for Income Taxes* (SFAS 109). SFAS 109 requires the recognition of deferred tax liabilities and assets for the expected future tax consequences of temporary differences between the financial reporting and tax bases of assets and liabilities using expected tax rates estimated to be in effect in the years in which the differences are expected to reverse. Valuation allowances are established, if necessary, to reduce the deferred tax asset to the amount that will, more likely than not, be realized.

**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** — SFAS No. 107, *Disclosures About Fair Value of Financial Instruments*, requires disclosure of the fair value of certain financial instruments. The Company's financial instruments consist of cash equivalents, accounts payable and accrued expenses. The estimated fair value of these 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 consists of cash and equivalents, on deposit with financial institutions, which may exceed federally insured limits. The Company's excess cash is invested on an overnight basis in securities that are fully collateralized. The Company maintains cash and equivalent balances with a stable and well-capitalized financial institution.

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

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

In February 2006, the FASB issued SFAS No. 155, *Accounting for Certain Hybrid Financial Instruments—an amendment of FASB Statements No. 133 and 140* (SFAS 155), to simplify and make more consistent the accounting for certain financial instruments. SFAS 155 amends SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities*, to permit fair-value remeasurement for any hybrid financial instrument with an embedded derivative that otherwise would require bifurcation, provided that the whole instrument is accounted for on a fair-value basis. SFAS 155 amends SFAS No. 140, *Accounting for the Impairment or Disposal of Long-Lived Assets*, to allow a qualifying special-purpose entity to hold a derivative financial instrument that pertains to a beneficial interest other than another derivative financial instrument. SFAS 155 applies to all financial instruments acquired or issued after the beginning of an entity's first fiscal year that begins after September 15, 2006, with earlier application allowed. This standard is not expected to have a significant effect on the Company's future reported financial position or results of operations.

Effective January 1, 2006, the Company adopted the provisions of SFAS No. 154, *Reporting Accounting Changes in Interim Financial Statements* ("SFAS 154"), which replaces APB Opinion No. 20, *Accounting Changes*, and SFAS No. 3, *Reporting Accounting Changes in Interim Financial Statement*. SFAS 154 changed the requirements for the accounting for and reporting of a change in accounting principle. SFAS 154 applies to all voluntary changes in accounting principle. It also applies to changes required by an accounting pronouncement in the unusual instance that the pronouncement does not include specific transition provisions. When a pronouncement includes specific transition provisions, those provisions should be followed. The adoption of SFAS 154 had no impact to the financial position or results of operations.

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

### 3. REVERSE MERGER AND REORGANIZATION

In May and June 2005, the Company completed a two-step reverse merger with Common Horizons, Inc. (“Common Horizons”), a Nevada-based developer of web portals, and its wholly owned subsidiary Nove Acquisition, Inc. In the first step, Nove Acquisition was merged into Novelos with all outstanding shares of Novelos (net of shares of treasury stock) being converted into an equal number of shares of common stock of Common Horizons and all outstanding options and warrants to purchase shares of Novelos common stock were converted into an equal number of options and warrants to purchase shares of Common Horizons with the same terms and conditions as the original options and warrants. In connection with the merger all but 4,500,000 shares of outstanding common stock of Common Horizons were cancelled. In the second step, Common Horizons merged into Novelos, changing its state of incorporation, by-laws, certificate of incorporation and fiscal year to that of Novelos, which became the surviving corporation. Following these transactions, Novelos shareholders owned approximately 83% of the combined company on a fully diluted basis after giving effect to the transactions. The business of Common Horizons, which was insignificant, was abandoned and the business of Novelos was adopted. The transaction was therefore treated as a reverse acquisition recapitalization with Novelos as the acquiring party and Common Horizons as the acquired party for accounting purposes. Accordingly, all historical information in these financial statements is that of the Novelos business. The results of operations of Common Horizons prior to the merger were not material for purposes of pro forma presentation. The 4,500,000 remaining shares of Common Horizons outstanding at the completion of the merger, net of cancellations, were deemed, for accounting purposes, to be an issuance by Novelos. Since Common Horizons had no remaining financial assets or liabilities, the merger with Common Horizons did not have any significant effect on our assets or liabilities or on our results of operations subsequent to the date of the merger.

### 4. FIXED ASSETS

Fixed assets consisted of the following at December 31:

	<u>2006</u>	<u>2005</u>
Office and computer equipment	\$ 52,537	\$ 49,717
Computer software	7,896	—
Leasehold improvements	2,500	2,500
Total fixed assets	62,933	52,217
Less accumulated depreciation and amortization	(39,123)	(29,607)
Fixed assets, net	<u>\$ 23,810</u>	<u>\$ 22,610</u>

Included in fixed assets is equipment under capital lease with a cost of \$13,061. Accumulated depreciation on such equipment was \$13,061 at both December 31, 2006 and 2005.

### 5. STOCKHOLDERS' EQUITY

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

**Series A Preferred** — On September 30, 2005 and October 3, 2005, the Company sold, in a private placement, a total of 3,200 shares of its Series A 8% Cumulative Convertible Preferred Stock (Series A Preferred) and 969,696 common stock warrants for net proceeds of \$2,864,000, net of issuance costs of \$336,000.

The Series A Preferred stockholders do not have voting rights. The holders of a majority of the Series A Preferred stock nominated Michael J. Doyle to the company's board of directors. The preferred stock has an annual dividend rate of 8%, payable quarterly in cash or additional shares of preferred stock. This dividend rate increases to 20% annually on the second anniversary of issuance or upon the occurrence of certain events of default. During 2006, the Company paid cash dividends of \$261,120 to preferred shareholders (\$80.00 per preferred share). During 2005, the Company issued 64 shares of preferred stock with a deemed value of \$64,000 in payment of dividends (\$20.00 per preferred share). The preferred stock is redeemable only at the option of the Company upon 30 days' notice at a 20% premium plus any accrued but unpaid dividends. The Series A Preferred stockholders have a preference in liquidation equal to the face value of the outstanding shares plus any accrued but any unpaid dividends. If there are insufficient assets to permit payment in full, the Company's assets will be distributed to the Series A Preferred stockholders on a pro rata basis.

The preferred shares were originally convertible at a price of \$1.65 per common share into 1,939,393 shares of common stock and the warrants were exercisable at \$2.00 per share. The fair value of the 969,696 warrants, determined on a relative fair-value basis, was \$786,679, which is included in additional paid-in capital. Since the conversion price of the preferred stock was less than the market value of the Company's common stock at the time of the closings, the Company determined that there was a beneficial conversion feature. After allocating the value of the warrants to paid-in-capital, the intrinsic value of the beneficial conversion feature was determined to be \$4,344,252. There were not sufficient net proceeds remaining to allocate the full intrinsic value to the beneficial conversion feature. Therefore, the remaining net proceeds of \$2,077,321 were allocated to the beneficial conversion feature and that amount was recorded as a deemed dividend in the year ended December 31, 2005.

The Series A Preferred stock and warrants have anti-dilution provisions that provide for adjustments to the conversion or exercise price, as applicable, upon the occurrence of certain events. Pursuant to these anti-dilution provisions, both the conversion price of the preferred stock and the exercise price of the warrants were subsequently adjusted to \$1.35 per share on March 7, 2006 in connection with a subsequent offering of common stock described below and the preferred stock then outstanding became convertible into 2,417,774 shares of common stock. The intrinsic value associated with this contingent beneficial conversion feature was \$1,501,686. However, the proceeds had been fully allocated to the warrants and initial beneficial conversion feature as described above and therefore no additional deemed dividend was recorded related to this adjustment to the conversion price.

In connection with the sale of the Series A Preferred stock and warrants, a stockholder, Margie Chassman, provided a financial enhancement to the investors in the form of an escrow of 2,133,000 shares of her common stock, to be drawn upon by the investors if their investment in the equity securities of the Company fails to provide a specified yield. In addition, the Company paid \$166,000 to Ms. Chassman and her designee, for providing such financial enhancement. This amount is included in the \$336,000 of issuance costs netted against the proceeds from the issuance of Series A Preferred stock as reported in the Statement of Stockholders' Equity (Deficiency).

**2006 PIPE** — On March 7, 2006, the Company completed a private offering of securities structured as a PIPE, exempt from registration under the Securities Act of 1933, in which it sold to accredited investors 11,154,073 shares of common stock at \$1.35 per share and warrants to purchase 8,365,542 shares of its common stock exercisable at \$2.50 per share for net cash proceeds of approximately \$13,847,000 (net of issuance costs of approximately \$1,211,000, including placement agent fees of approximately \$1,054,000). In connection with the private placement, the Company issued 669,244 common stock warrants (exercisable at \$2.50 per share) to the placement agents. The fair value of the warrants issued to investors and placement agents were included as a component of permanent equity upon issuance.

**Common Stock Warrants** — The following table summarizes information with regard to outstanding warrants issued in connection with equity and debt financings as of December 31, 2006:

<b>Offering</b>	<b>Outstanding (as adjusted)</b>	<b>Exercise Price (as adjusted)</b>	<b>Expiration Date</b>
2005 Bridge Loans (see Note 8)	720,000	\$ 0.625	April 1, 2010
2005 PIPE:			
Investors	3,333,275	\$ 1.35	August 9, 2008
Placement agents and finders	503,692	\$ 1.35	August 9, 2010
Series A Preferred :			
Investors – September 30, 2005 closing	909,090	\$ 1.35	September 30, 2010
Investors – October 3, 2005 closing	60,606	\$ 1.35	October 3, 2010
2006 PIPE :			
Investors	8,365,542	\$ 2.50	March 7, 2011
Placement agents	669,244	\$ 2.50	March 7, 2011
Total	<u>14,561,449</u>		

None of the above warrants have been exercised as of December 31, 2006.

**Registration Rights** — The shares of common stock sold in the 2005 PIPE and the 2006 PIPE and the shares of common stock issuable upon conversion of the preferred stock and exercise of outstanding warrants have been registered for resale with the Securities and Exchange Commission. Pursuant to the registration rights associated with the financings, if the Company fails to maintain the effectiveness of the registration statements for the periods specified in the agreements, the Company may become obligated to pay liquidated damages to the selling stockholders. The Company believes that an investor claim for liquidated damages relating to these registration rights is not probable and therefore has not accrued for such a contingency at December 31, 2006.

**Reserved Shares** — At December 31, 2006 and December 31, 2005 the following shares were reserved for future issuance upon exercise of stock options or warrants or conversion of preferred stock:

	<b>December 31,</b>	
	<b>2006</b>	<b>2005</b>
2000 Stock Option Plan	73,873	73,873
2006 Stock Incentive Plan	5,000,000	—
Options issued outside of formalized plans	2,578,778	2,653,778
Warrants (1)	16,820,135	4,829,008
Preferred stock (1)	2,696,283	3,393,938
Total shares reserved for future issuance	<u>27,169,069</u>	<u>10,950,597</u>

(1) The amount of reserved shares includes shares registered in excess of the number currently exercisable or convertible.

## 6. STOCK-BASED COMPENSATION

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

*2000 Stock Option Plan.* The Company's stock option plan established in August 2000 (the "2000 Plan") provides for grants of options to purchase up to 73,873 shares of common stock. Grants may be in the form of incentive stock options or nonqualified options. The board of directors determines exercise prices and vesting periods on the date of grant. Options generally vest annually over three years and expire on the tenth anniversary of the grant date. No options were granted, exercised or canceled under the 2000 Plan during 2005 or 2006.

*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 5,000,000 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 year ended December 31, 2006, stock options for the purchase of 840,000 shares of common stock were granted under the 2006 Plan. There have been no exercises or cancellations of options under the 2006 Plan. Options granted pursuant to the 2006 Stock Incentive 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 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.

*Other Stock Option Activity.* During 2005 and 2004, the Company issued a total of 3,061,000 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, 2006, options to purchase 75,000 shares were exercised. There have been no other exercises.

#### **Adoption of SFAS No. 123(R)**

Effective January 1, 2006, the Company adopted the fair-value recognition provisions of SFAS 123R, using the modified-prospective-transition method. SFAS 123R requires all share-based payments to employees, including grants of employee stock options, to be recognized in the financial statements based on their fair values. SFAS 123R did not change the accounting guidance for share-based payments granted to non-employees provided in SFAS No. 123, *Accounting for Stock Based Compensation* (SFAS 123), as originally issued and Emerging Issues Task Force (EITF) No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*. EITF 96-18 requires that companies recognize compensation expense based on the estimated fair value of options granted to non-employees over their vesting period, which is generally the period during which services are rendered by such non-employees.

Under the modified-prospective-transition method, compensation cost recognized for the year ended December 31, 2006 includes: (a) compensation cost for all stock-based payments granted, but not yet vested as of January 1, 2006, based on the grant-date fair value estimated in accordance with the original provisions of SFAS 123, and (b) compensation cost for all stock-based payments granted subsequent to January 1, 2006, based on the grant-date fair value estimated in accordance with the provisions of SFAS 123R. Results for prior periods have not been restated. As a result of the adoption of SFAS 123R, the Company recorded incremental stock-based compensation expense of \$268,281 (approximately \$0.01 per common share) in the year ended December 31, 2006.

During the year ended December 31, 2005, the Company accounted for stock option awards granted to directors and employees (collectively, employees) under the recognition and measurement principles of Accounting Principles Board Opinion (APB) No. 25, *Accounting for Stock Issued to Employees*, (APB 25). Under this method compensation cost is recognized for the amount by which the market price of the stock on the date of grant exceeds the exercise price of the option. For the year ended December 31, 2005, there was no stock-based employee compensation cost recorded for options granted to employees under the plan as none have been granted at exercise prices below the fair market value of the underlying stock. For those options granted at exercise prices equal to or greater than the fair market value of the underlying stock on the date of the grant, the Company applied the disclosure-only provision of SFAS 123.

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>2006</b>	<b>2005</b>
<b>Employee and director stock option grants:</b>		
Research and development	\$ 77,333	\$ —
General and administrative	190,948	—
	<u>268,281</u>	<u>—</u>
<b>Non-employee consultants stock option grants and restricted stock awards:</b>		
Research and development	11,435	67,215
General and administrative	308,327	332,246
	<u>319,762</u>	<u>399,461</u>
<b>Total stock-based compensation</b>	<b><u>\$ 588,043</u></b>	<b><u>\$ 399,461</u></b>

### 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.* Volatility is determined based on the Company's estimate of fluctuation in its common stock price and its review of comparable public company data due to the limited amount of time that the Company's common stock has been publicly traded.

*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 employee population. The expected term of options granted to employees prior to the Company's stock becoming publicly traded was generally longer (10 years) than is currently estimated.

*Forfeitures.* As required by SFAS 123R, the Company records share-based compensation expense only for those awards that are expected to vest. SFAS 123R 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, 2006 as the Company believes that there is insufficient history to develop an accurate estimate of future forfeitures. This analysis will be re-evaluated quarterly 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:

	<b>Year Ended December 31,</b>	
	<b>2006</b>	<b>2005</b>
Volatility	80%	0%-80%
Weighted-average volatility	80%	23%
Risk-free interest rate	4.50%-5.05%	3.95%-4.81%
Expected life (years)	5	2-10
Dividend	0	0
Weighted-average exercise price	\$ 0.99	\$ 0.78
Weighted-average grant-date fair value	\$ 0.62	\$ 0.49

### Pro-Forma Information Under SFAS 123 for Periods Prior to January 1, 2006

The following table illustrates the effect on net loss and net loss per share had the Company applied the fair-value recognition provisions of SFAS 123R in the periods prior to adoption. For purposes of this pro-forma disclosure, the value of the options is estimated using the Black-Scholes option-pricing model and amortized to expense over the options' vesting periods.

	<b>Year Ended December 31, 2005</b>
Net loss attributable to common stockholders as reported	\$ (5,194,720)
Stock-based employee compensation expense determined under fair-value-based method	(111,082)
Pro forma net loss attributable to common stockholders	<u>\$ (5,305,802)</u>
Basic and diluted net loss attributable to common stockholders per share:	
As reported	<u>\$ (0.24)</u>
Pro forma	<u>\$ (0.24)</u>

## 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, 2005	952,651	\$ 0.26		
Options granted	1,775,000	\$ 0.78		
Outstanding at December 31, 2005	2,727,651	\$ 0.60	8.9	\$ 4,294,257
Options granted	840,000	\$ 0.99		
Options exercised	(75,000)	\$ 0.01		
Outstanding at December 31, 2006	3,492,651	\$ 0.70	8.4	\$ 1,773,777
Exercisable at December 31, 2006	2,338,112	\$ 0.43	7.9	\$ 1,705,373

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, 2006, the total intrinsic value of options exercised was \$134,250 and the total amount of cash received from exercise of these options was \$750.

The following tables summarize information about stock options outstanding at December 31, 2006:

Exercise Price	Options Outstanding			Options Exercisable	
	Number of Shares	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Number of Shares	Weighted Average Exercise Price
\$ 0.01	2,053,778	7.8	\$ 0.01	1,974,239	\$ 0.01
\$ 0.70 – \$2.00	885,705	9.6	\$ 0.98	60,705	\$ 0.94
\$ 2.01 – \$3.22	525,000	8.6	\$ 2.63	275,000	\$ 2.65
\$ 7.01	28,168	5.5	\$ 7.01	28,168	\$ 7.01
	3,492,651	8.4	\$ 0.70	2,338,112	\$ 0.43

As of December 31, 2006, there was approximately \$716,000 of total unrecognized compensation cost related to unvested share-based compensation arrangements. Of this total amount, 63%, 22% and 15% is expected to be recognized during 2007, 2008 and 2009, respectively. The Company expects 1,154,539 in unvested options to vest in the future. The weighted average grant date fair value of vested and unvested options outstanding at December 31, 2006 was \$0.23 and \$0.79, respectively. The fair value of options that vested during 2006 and 2005 was approximately \$415,000 and \$82,000.

On January 3, 2007, options to purchase 30,000 shares of our common stock were granted for 2007 to each of our four non-employee directors at the closing price of our common stock on that day. These options vest on a quarterly basis over a two-year period.

## 7. INCOME TAXES

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

	2006	2005
Net operating loss carryforwards	\$ 3,700,000	\$ 3,331,000
Research and development expenses	3,581,000	1,556,000
Tax credits	550,000	282,000
Capital loss carryforward	403,000	403,000
Gross deferred tax asset	8,234,000	5,572,000
Valuation allowance	(8,234,000)	(5,572,000)
Net deferred tax asset	\$ —	\$ —

As of December 31, 2006, the Company had federal and state net operating loss carryforwards of approximately \$10,053,000 and

\$4,497,000, respectively, which expire through 2026. In addition, the Company has federal and state research and development and investment tax credits of approximately \$409,000 and \$214,000, respectively which expire through 2026. 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 occurred during 2005 or 2006 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.

## 8. SETTLEMENT OF OBLIGATIONS TO STOCKHOLDERS AND VENDORS

Prior to the reverse merger and reorganization that occurred in May and June 2005 (see Note 3), Novelos relied on private investors to fund its operations. Periodically, these investors advanced monies to Novelos evidenced by notes payable or other written agreements. Additionally, Novelos accumulated substantial overdue balances with certain key vendors. During 2005, Novelos repaid or otherwise settled all of its outstanding debt and overdue vendor obligations as summarized below.

During 2003 and 2004, Novelos entered into bridge loans with certain stockholders totaling \$1,100,000. The loans bore interest at 15% and matured on May 25, 2005. Under the terms of the loan agreements, the principal amount of the notes could be converted into common stock at the noteholder's option at one half the market value of the Company's stock, subject to a maximum conversion price of \$1.00 and a minimum conversion price of \$0.38 per share of common stock. In May 2005 these bridge loans were converted into 1,760,000 shares of common stock in accordance with the loan agreements. Of the total \$206,949 in accrued interest on the notes at the time of conversion, \$140,497 was paid in cash. The remaining \$66,452 was forgiven and the amount was included as a component of Gain on Forgiveness of Debt during the year ended December 31, 2005.

In December 2004 and January 2005 Novelos received loans totaling \$500,000 from an individual investor. The loans bore interest at 6% per annum and were repayable following the closing of one or more equity financings of minimum levels. These loans allowed Novelos to sustain its operations until the funding was obtained from the 2005 PIPE financing, as described in Note 5. In exchange for the loans and the investor's commitment to provide additional financing of up to \$500,000 through August 2005, designees of this individual received 10,500,000 shares of common stock of Novelos. The Company repaid these loans plus accrued interest on August 9, 2005 with proceeds from the 2005 PIPE financing.

In April 2005, Novelos issued \$450,000 bridge notes payable to private investors. In connection with the issuance of the notes, the investors received warrants, expiring in 5 years, to purchase 720,000 shares of Novelos common stock at \$0.625 per share. Since the Company's common stock was deemed to have substantially no value at the time of issuance of the warrants prior to the recapitalization described in Note 3, the fair value of the warrants was not material. Pursuant to their terms, the notes were converted into 360,000 shares of common stock and 3-year warrants to purchase 180,000 shares of common stock at \$2.25, in connection with the Company's 2005 PIPE financing.

On May 26, 2005, Novelos settled unsecured obligations with stockholders and vendors totaling \$3,139,185 in exchange for total consideration of \$1,051,654 consisting of 586,351 shares of common stock of Novelos with an aggregate deemed value of \$732,941 and cash in the amount of \$318,713. This settlement resulted in a gain on forgiveness of debt of \$2,087,531 in the year ended December 31, 2005. The components of the settlement are summarized as follows:

- Vendors with overdue balances totaling \$1,484,319 settled the outstanding balances in exchange for 435,376 shares of Novelos common stock with a deemed value of \$544,222 and cash of \$178,217, resulting in a gain on settlement of \$761,880;
- Unsecured demand notes totaling \$188,719 resulting from cash advances from stockholders were repaid by the issuance of 150,975 shares of common stock with a deemed value of \$188,719. The accrued interest of \$68,677 was forgiven;
- Unsecured demand notes to stockholders were forgiven totaling \$621,931 consisting of officers' accrued compensation and accrued consulting fees owed to a stockholder. The accrued interest of \$208,234 on these notes was also forgiven;
- Accrued interest on secured bridge loans to stockholders totaling \$66,452 (described above) was forgiven;
- Officers forgave accrued compensation of \$360,357.

## 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. Since the Company has a net loss for all periods presented, the inclusion of stock options and warrants 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:

	Year Ended	
	December 31,	
	2006	2005
Stock options	3,492,651	2,727,651
Warrants	14,561,449	4,829,008
Conversion of preferred stock	2,417,774	1,939,393

## 10. COMMITMENTS

On August 9, 2006, the Company entered into a one-year lease for office space, commencing September 1, 2006, at an annual rent of \$65,250. Rent expense was \$62,625 and \$45,355 in the years ended December 31, 2006 and 2005, respectively.

The Company is obligated to ZAO BAM under a royalty and technology transfer agreement. One of the Company's former directors 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.

The Company has also agreed to pay ZAO BAM 12% of all license revenues, as defined, in excess of the Company's expenditures associated therewith, including but not limited to, preclinical and clinical studies, testing, FDA and other regulatory agency submission and approval costs, general and administrative costs, and patent expenses, provided that such payment be no less than 3% of all license revenues.

On July 15, 2005, the Company entered into an employment agreement with Christopher J. Pazoles, Ph.D., 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 one-year terms unless 60-day notice is provided by either party. 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, Dr. Pazoles will receive his base salary for the remainder of the contract term as well as any minimum bonus on a prorated basis. In addition, his benefits will be paid for following twelve months.

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 one-year terms unless 90-day notice is provided by either party. 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, 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.

In July, 2006, the Company entered into a contract with a supplier of pharmaceutical products that will provide chemotherapy drugs to be used in connection with Phase 3 clinical trial activities outside of the United States. Pursuant to the contract, the Company was obligated to purchase a minimum of approximately \$2,600,00 of chemotherapy drugs at specified intervals through March 2008. During 2006, the Company purchased approximately \$1,300,000 under the contract and as of December 31, 2006, approximately \$1,300,000 is remaining under that commitment. In connection with that agreement, the Company was required to enter into a standby letter of credit arrangement with a bank, expiring in August 2007. The balance on the standby letter of credit at December 31, 2006 equals the remaining purchase commitment of \$1,300,000. In connection with the letter of credit, the Company has pledged cash of approximately \$1,600,000 to the bank as collateral on the letter of credit. The pledged cash is included in restricted cash at December 31, 2006.

## **11. RELATED-PARTY TRANSACTIONS**

During the year ended December 31, 2005 Novelos paid a contract research organization that is also a stockholder of the Company \$200,611 for services performed during that year. During 2005 the Company issued 360,000 shares of common stock with a deemed value of \$450,000 to the same company in full settlement of a \$1,185,321 accounts payable balance that was outstanding from 2004. No remaining amounts were payable to the stockholder at December 31, 2005.

As a result of the assignment to Novelos of the exclusive worldwide intellectual property and marketing rights of oxidized glutathione (excluding Russia and the states of the former Soviet Union), Novelos is obligated to the Oxford Group, Ltd. for future royalties. The Company's Chairman of the Board of Directors is president of Oxford Group, Ltd. Effective May 26, 2005, Novelos amended the arrangement for future royalty payments to Oxford Group, Ltd. which resulted in the issuance of 2,016,894 shares of common stock, including 907,602 shares to each of two directors of the Company. Pursuant to the revised agreement, 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. The total share issuance had an aggregate deemed value of \$2,521,118 and is included in restructuring expense in the year ended December 31, 2005.

See also Note 8 regarding settlement of obligations with certain stockholders during 2005.

## **12. RESTATEMENT OF PREVIOUSLY ISSUED FINANCIAL STATEMENTS**

Subsequent to the initial filing of the Company's annual report on Form 10-KSB for the year ended December 31, 2005 and the 10-QSB for the three- and nine-month periods ended September 30, 2005 (the "Relevant Periods") and in connection with an internal review of the terms associated with the Company's historical financing transactions, the Company determined that the intrinsic value associated with the beneficial conversion feature (BCF) of the Company's Series A 8% Cumulative Convertible Preferred Stock had not been properly presented as a deemed (non-cash) dividend nor included in the calculation of net loss attributable to common stockholders in the Relevant Periods. In accordance with Emerging Issues Task Force Issue (EITF) No. 98-5, *Accounting for Convertible Securities with Beneficial Conversion Features or Contingently Adjustable Conversion Ratios*, and EITF No. 00-27, *Application of Issue No. 98-5 to Certain Convertible Instruments*, a conversion feature that is 'in-the-money' based on the market price of a company's common stock at the commitment date is considered a BCF. As the terms of the Series A 8% Cumulative Convertible Preferred Stock allowed immediate conversion, the deemed (non-cash) dividend related to the BCF should have been recorded upon issuance.

The following table sets forth the effects of the restatement on certain line items within the Company's Statements of Operations for the year ended December 31, 2005:

	<u>As Previously Reported</u>	<u>Revision</u>	<u>As Restated</u>
<b>Year Ended December 31, 2005:</b>			
Net Loss	\$ (3,053,399)	\$ —	\$ (3,053,399)
Preferred Stock (Non-cash) Dividend (1)	—	(64,000)	(64,000)
Preferred Stock Deemed (Non-cash) Dividend	—	(2,077,321)	(2,077,321)
<b>Net Loss Attributable to Common Stockholders</b>	<b><u>\$ (3,053,399)</u></b>	<b><u>\$ (2,141,321)</u></b>	<b><u>\$ (5,194,720)</u></b>
Basic and Diluted Net Loss Attributable to Common Stockholders Per Common Share	<u>\$ (0.14)</u>	<u>\$ (0.10)</u>	<u>\$ (0.24)</u>

(1) Represents a quarterly dividend paid to preferred stockholders in the quarter ended December 31, 2005 in the form of additional shares of preferred stock, as permitted pursuant to the terms of the related agreement. This amount was inadvertently not previously included as an adjustment in arriving at net loss attributable to common stockholders. The amount was not material in relation to net loss attributable to common stockholders and would not have changed the basic and diluted net loss attributable to common stockholders per common share as reported.

**ITEM 8. CHANGES AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE**

None.

**ITEM 8a. CONTROLS AND PROCEDURES**

*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 Securities Exchange Act of 1934, as amended, (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 2006 that would have materially affected, or would have been reasonably likely to materially affect, our internal control over financial reporting.

**ITEM 8B. OTHER INFORMATION**

None.

### Part III

#### ITEM 9. DIRECTORS, EXECUTIVE OFFICERS, PROMOTERS AND CONTROL PERSONS.

Our current directors and executive officers are:

Name	Age	Position
Simyon Palmin	62	Chairman of the Board
Harry S. Palmin	37	President, Chief Executive Officer, Director
George R. Vaughn	53	Chief Financial Officer and Chief Accounting Officer
M. Taylor Burtis	55	Vice President of Regulatory, Quality and Compliance
Christopher J. Pazoles, Ph.D.	56	Vice President of Research and Development
Michael J. Doyle (1) (2) (3)	48	Director
Sim Fass, Ph.D. (1) (2) (3)	65	Director
David B. McWilliams (2) (3)	63	Director
Howard M. Schneider (1) (3)	63	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. Simyon Palmin is the father of Harry Palmin.

**Simyon Palmin.** Mr. Palmin founded us in 1996. He has served as our chairman of the board and director of Russian relations since 1996. From 1996 to February 2004, he served as our chief executive officer. From 1984 to 1998, Mr. Palmin served as vice president of strategic planning and vice president of new product development of Design Components Inc. Mr. Palmin received a B.S. in naval instrumentation from St. Petersburg Navy Institute, St. Petersburg, Russia and a M.A. in aviation instrumentation from the Institute of Aviation Instrumentation, St. Petersburg, Russia. He also completed studies for a Ph.D. in electrical engineering.

**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, *magna cum laude*, 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.

**George R. Vaughn.** Mr. Vaughn has served as our chief financial officer and chief accounting officer since September 2005. Since April 2001, Mr. Vaughn has been the President of Vaughn & Associates, P.C., a professional services organization he founded in 1995 that provides interim and part-time chief financial officer, outsourced financial management, and tax advisory services for emerging and established businesses, including Novelos. From 1990 to 1995, Mr. Vaughn served as chief financial officer of XRL, Inc. Mr. Vaughn is a certified public accountant and is a member of the American Institute of Certified Public Accountants and the Massachusetts Society of Certified Public Accountants. He holds a B.S. in business administration from Stonehill College.

**Christopher J. Pazoles, Ph.D.** 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.

**M. Taylor Burtis.** Ms. Burtis has served as our vice president of regulatory, quality and compliance since July 2005. From October 2004 to June 2005, she served as a senior director of regulatory affairs at Therion Biologics. From November 2003 to September 2004, she served as a senior director of regulatory affairs at Antigenics. From May 2000 to October 2003, Ms. Burtis served as an associate director for worldwide regulatory affairs at Wyeth BioPharma. From 1996 to April 2000, she served as a senior manager of regulatory affairs at Genentech. From 1992 to 1996, Ms. Burtis was an FDA consumer safety officer in the Office of Compliance at the Center for Biologics Evaluation and Research. From 1991 to 1992, Ms. Burtis served as a medical research manager at Boston Veterans Administration Center. From 1987 to 1991, she served as a research lab manager at Children's Hospital, from 1985 to 1987, she served as a laboratory director at Brigham & Women's Hospital and from 1980 to 1985, she served as a technical specialist international liaison with the American Red Cross. Ms. Burtis earned a B.S. in biology from Framingham State College and a M.B.A. in operations and strategy from Simmons College.

**Michael J. Doyle.** Mr. Doyle has served as one of our directors since October 2005. Since April 2006, he has 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, where he was a Kaiser Fellow.

**Sim Fass, Ph.D.** Dr. Fass has served as one of our directors since February 2005. Dr. Fass 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. 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.

**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. Since August 2004, Mr. McWilliams has 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 Fairway Medical Technologies, Houston Technology Center and Texas Healthcare and Bioscience Institute. Mr. McWilliams received a M.B.A. in finance from the University of Chicago and a B.A. in chemistry, *Phi Beta Kappa*, from Washington and Jefferson College.

**Howard M. Schneider.** Mr. Schneider has served as one of our directors since February 2005. From January to December 2003, he served as chief executive officer of Metrosoft, Inc., and had been an advisor to such company from July 2002 to January 2003. 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., *magna cum laude*, in economics from Harvard College and a M.B.A. with distinction from New York University.

#### **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 chief 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, 2006 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.

**Summary Compensation Table**

<b>Name and Principal Position</b>	<b>Year</b>	<b>Salary (\$)</b>	<b>Bonus (\$ (4))</b>	<b>Option Awards (\$) (5)</b>	<b>All other compensation (\$ (6))</b>	<b>Total (\$)</b>
Harry S. Palmin (1) President, Chief Executive Officer	2006	\$ 225,000	\$ 50,000	\$ 91,410	\$ 0	\$ 366,410
	2005	148,000	29,600	1,295	0	178,895
Christopher J. Pazoles, Ph.D. (2) Vice President of Research and Development	2006	\$ 199,200	\$ 40,320	\$ 60,940	\$ 0	\$ 300,460
	2005	88,000	23,700	647	30,500	142,847
M. Taylor Burtis (3) Vice President of Quality, Regulatory and Compliance	2006	\$ 186,750	\$ 37,800	\$ 60,940	\$ 0	\$ 285,490
	2005	82,500	17,119	218,955	3,096	321,670

(1) On December 11, 2006, the board of directors approved an increase in Mr. H. Palmin's annual base salary to \$245,000, effective January 1, 2007.

(2) On December 11, 2006, the board of directors approved an increase in Dr. Pazoles' annual base salary to \$216,720, effective January 1, 2007.

(3) On December 11, 2006, the board of directors approved an increase in Ms. Burtis' annual base salary to \$203,175, effective January 1, 2007.

(4) Bonus amounts shown in this column relate to services performed in the year shown, but were paid in the subsequent year.

(5) The fair value of each stock award was estimated on the grant date using the Black-Scholes option-pricing model. Option grants to Messrs. H. Palmin and Pazoles were made prior to the reverse merger and recapitalization described in Note 3, while the option grant to Ms. Burtis was made subsequent to the reverse merger and recapitalization when there was a public market for our common stock. See Note 6 to the financial statements for a description of the assumptions used in estimating the fair value of stock options.

(6) Mr. Pazoles and Ms. Burtis employment with the Company began during 2005. All other compensation during 2005 represents amounts which they earned in their capacity as consultants prior to the commencement of their employment.

### 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. On December 11, 2006, the Board of Directors approved an increase in Mr. Palmin's annual salary to \$245,000 effective January 1, 2007. 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; (ii) continue to provide him benefits for 11 months after the date of termination; and (iii) 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, Ph.D, whereby he agreed to serve as our vice president of research and development for an initial term of two years. His annual salary is a minimum of \$192,000 for the first year and \$195,000 for the second year. On December 11, 2006, the Board of Directors approved an increase to Mr. Pazoles’ annual salary to \$216,720 effective January 1, 2007. Dr. Pazoles is also entitled to a minimum cash bonus of \$16,000 at the end of the first year and \$25,000 at the end of the second year. 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.

*Outstanding equity awards at Fiscal Year-End.* The following table sets forth certain information regarding stock options held as of December 31, 2006 by the executive officers named in the summary compensation table.

## Outstanding Equity Awards at Fiscal Year-End

Name	Individual Grants				
	Year of Grant	Number of securities underlying unexercised options (#) exercisable	Number of securities underlying unexercised options (#) unexercisable	Exercise or base price (\$/share)	Expiration date
Harry S. Palmin	2006(1)	—	150,000	\$ 0.91	12/11/2016
	2005(2)	250,000		0.01	1/31/2015
	2005(2)	150,000	—	0.01	3/31/2015
	2004(3)	330,000	—	0.01	4/1/2014
	2003(4)	7,130	—	0.70	8/1/2013
Christopher J. Pazoles, Ph.D.	2006(1)	—	100,000	\$ 0.91	12/11/2016
	2005(5)	150,000	50,000	0.01	4/8/2015
	2004(6)	16,667	—	0.01	4/1/2014
M. Taylor Burtis	2006(1)	—	100,000	\$ 0.91	12/11/2016
	2005(7)	75,000	75,000	2.20	7/1/2015

- (1) 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.
- (2) 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.
- (3) 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.
- (4) 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.
- (5) These shares vest 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.
- (6) 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 expire ten years from the date of grant.
- (7) These shares vest in increments of one-fourth every six months over two years from the date of 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, 2006.

Name and Principal Position	Year	Director Fees (\$ (2))	Option Awards (\$ (3))	All other compensation (\$)	Total (\$)
Simyon Palmin, Chairman and director of Russian relations (1)	2006	\$ —	\$ —	\$ 89,820	\$ 89,820
Michael J. Doyle, Director	2006	27,500	10,647	—	38,147
Sim Fass, Ph.D., Director	2006	26,500	10,647	—	37,147
David B. McWilliams, Director	2006	22,500	10,647	—	33,147
Howard M. Schneider, Director	2006	31,000	10,647	—	41,647

- (1) Other compensation for Simyon Palmin represents salary and bonus he received in his capacity as director of Russian relations for the Company.
- (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 6 to the financial statements for a description of the assumptions used in estimating the fair value of stock options.

During 2006, we paid our non-employee directors a cash fee of \$4,000 per quarter. The non-employee directors also received a fee of \$1,000 for any board or committee meeting attended or \$500 for each telephonic board or committee meeting in which the director participated. We also paid each non-employee director who serves as the chair of the audit committee an additional annual fee of \$5,000 and each non-employee director who serves as the chairman of the compensation and nominating and corporate governance committees an additional annual fee of \$3,000. We also 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 will not receive separate fees for their services as directors.

During 2006, non-employee directors received quarterly stock option grants of 5,000 shares of our common stock at the closing price of our common stock on the last day of the quarter. These options vest on a quarterly basis over a two-year period.

Effective January 1, 2007, the in-person and telephonic meeting fees were increased to \$1,500 and \$750, respectively. Also on that date, the annual fee for the chairman of the audit committee and chairman of both the compensation committee and the nominating and corporate governance committee were increased to \$10,000 and \$5,000, respectively. Directors who are our employees will not receive separate fees for their services as directors.

On January 3, 2007, options to purchase 30,000 shares of our common stock were granted for 2007 to each non-employee directors at the closing price of our common stock on that day. These options vest on a quarterly basis over a two-year period.

## Equity compensation plans

The following table provides information as of December 31, 2006 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	913,873	\$ 1.61	4,160,000
Equity compensation plans not approved by stockholders	2,578,778	\$ 0.54	0
<b>Total</b>	<b>3,492,651</b>	<b>\$ 0.70</b>	<b>4,160,000</b>

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

At the close of business on March 12, 2007, there were issued and outstanding 39,235,272 shares of our common stock. The following table provides information regarding beneficial ownership of our common stock as of March 12, 2007:

- 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 and warrants that vest within 60 days of March 12, 2007.

Name and Address of Beneficial Owner	Shares Beneficially Owned			
	Outstanding	Right to Acquire	Total	Percentage
Margie Chassman (1) 445 West 23 <sup>rd</sup> Street, Apt. 16E New York, NY 10011	2,553,185	66,666	2,619,851	6.7%
Harry S. Palmin	365,118	737,130	1,102,248	2.8%
Simyon Palmin (2)	1,947,481	487,826	2,435,307	6.1%
Christopher J. Pazoles, Ph.D.	0	216,667	216,667	*
M. Taylor Burtis	0	112,500	112,500	*
Michael J. Doyle	0	80,625	80,625	*
David McWilliams	0	158,403	158,403	*
Sim Fass	0	105,625	105,625	*
Howard Schneider	0	105,625	105,625	*
All directors and officers as a group (9 persons)	2,312,599	2,116,901	4,429,500	10.7%

\* Less than one percent.

(1) The number of shares in the "Outstanding" column is based on Ms. Chassman's record stock holdings as of March 12, 2007 as reported to us by our transfer agent, American Stock Transfer and Trust Company.

(2) Shares owned by S. Palmin include 208,542 shares owned by his wife, Alla Palmin.

## ITEM 12. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

In January 2005, we entered into an agreement with David Blech (the husband of Margie Chassman), which provided that he or his designees would lend us \$500,000 (inclusive of \$100,000 previously advanced to us in December 2004 by Ms. Chassman) for operating capital pending our debt restructuring and completion of our private placements of units, and up to an additional \$500,000 on the same terms if the private placement was delayed.

In 1990, Mr. Blech founded D. Blech & Company, which, until it ceased doing business in September 1994, was a registered broker-dealer involved in underwriting biotechnology issues. In May 1998, David Blech pled guilty to two counts of criminal securities fraud, and, in September 1999, he was sentenced by the U.S. District Court for the Southern District of New York to five years' probation, which was completed in September 2004. Mr. Blech also settled administrative charges by the Commission in December 2000 arising out of the collapse in 1994 of D. Blech & Co., of which Mr. Blech was president and sole stockholder. The settlement prohibits Mr. Blech from engaging in future violations of the federal securities laws and from association with any broker-dealer. In addition, the District Business Conduct Committee for District No. 10 of NASD Regulation, Inc. reached a decision, dated December 3, 1996, in a matter styled District Business Conduct Committee for District No. 10 v. David Blech, regarding the alleged failure of Mr. Blech to respond to requests by the staff of the NASD for documents and information in connection with seven customer complaints against various registered representatives of D. Blech & Co. The decision found that Mr. Blech failed to respond to such requests in violation of NASD rules and that Mr. Blech should, therefore, be censured, fined \$20,000 and barred from associating with any member firm in any capacity. Furthermore, Mr. Blech was discharged in bankruptcy in the United States Bankruptcy Court for the Southern District of New York in March 2000.

Mr. Blech did not lend us any money. Two loans were made under the agreement, both of which were made by Ms. Chassman, totaled \$500,000 and bore interest at 6% per annum. We repaid Ms. Chassman the entire \$500,000 out of proceeds of our private placements of units on August 9, 2005. According to the agreement, we also issued the following individuals the following number of shares of our common stock:

<b>Investor</b>	<b>Number of Shares of Common stock</b>
Margie Chassman	2,475,000
Wood River Trust	3,850,000
Esther Blech	1,225,000
Milton Chassman	1,225,000
Aaron Eiger	1,225,000
Mark Germain	500,000

Wood River Trust is a trust formed for the benefit of Evan Blech, the son of Ms. Chassman and Mr. Blech. The trustees of the trust are Harvey Kesner and Michael C. Doyle (no relation to our director, Michael J. Doyle). Esther Blech is the mother-in-law of Ms. Chassman. Milton Chassman is the brother of Ms. Chassman.

The Company understands that in January 2007, Wood River Trust sold approximately one half of their shares of Novelos common stock in a private transaction.

In connection with our 2005 PIPE financing, we paid Margie Chassman, an aggregate of \$52,000 as finders' fees. In connection with our Series A preferred stock financing during 2005, Ms. Chassman provided a financial enhancement to the investors in the form of an escrow of 2,133,000 share of her common stock, to be drawn upon by the investors if their investment in our equity securities fails to provide a specified yield. We paid Ms. Chassman and her brother \$166,000 for providing such financial enhancement.

As a result of the assignment to Novelos of the exclusive worldwide intellectual property and marketing rights of oxidized glutathione (excluding Russia and the states of the former Soviet Union), 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. Our Chairman of the Board of Directors is president of Oxford Group, Ltd.

We are obligated to ZAO BAM under a royalty and technology transfer agreement. One of our former directors, Mark Balazovsky, is the majority shareholder of ZAO BAM. Mr. Balazovsky resigned from the board of directors in November 2006. Pursuant to the royalty and technology transfer agreement between us 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.

We have also agreed to pay ZAO BAM 12% of all license revenues, as defined, in excess of our expenditures associated therewith, including but not limited to, preclinical and clinical studies, testing, FDA and other regulatory agency submission and approval costs, general and administrative costs, and patent expenses, provided that such payment be no less than 3% of all license revenues.

### ITEM 13. EXHIBITS

Exhibit No.	Description	Filed with this Form 10-KSB	Incorporated by Reference		Exhibit No.
			Form	Filing Date	
2.1	Agreement and plan of merger among Common Horizons, Inc., Nove Acquisition, Inc. and Novelos Therapeutics, Inc. dated May 26, 2005		8-K	June 2, 2005	99.2
2.2	Agreement and plan of merger between Common Horizons and Novelos Therapeutics, Inc. dated June 7, 2005		10-QSB	August 15, 2005	2.2
3.1	Certificate of Incorporation		8-K	June 17, 2005	1
3.3	Certificate of Designations of Series A cumulative convertible preferred stock		8-K	October 3, 2005	99.2
3.2	By-Laws		8-K	June 17, 2005	2
10.1 **	Employment agreement with Christopher J. Pazoles dated July 15, 2005		10-QSB	August 15, 2005	10.4
10.2 **	Employment agreement with Harry Palmin dated January 31, 2006		8-K	February 6, 2006	99.1

10.3 **	Compensation for independent directors	8-K	December 22, 2005	99.1
10.4 **	2000 Stock Option and Incentive Plan	SB-2	November 16, 2005	10.2
10.5 **	Form of 2004 non-plan non-qualified stock option	SB-2	November 16, 2005	10.3
10.6 **	Form of non-plan non-qualified stock option used from February to May 2005	SB-2	November 16, 2005	10.4
10.7 **	Form of non-plan non-qualified stock option used after May 2005	SB-2	November 16, 2005	10.5
10.8	Form of common stock purchase warrant issued in March 2005	SB-2	November 16, 2005	10.6
10.9	Form of securities purchase agreement dated May 2005	8-K	June 2, 2005	99.1
10.10	Form of subscription agreement dated September 30, 2005	8-K	October 3, 2005	99.1
10.11	Form of Class A common stock purchase warrant dated September 30, 2005	8-K	October 3, 2005	99.3
10.12	Form of share escrow agreement	8-K	November 3, 2005	10.3
10.13	Consideration and new technology agreement dated April 1, 2005 with ZAO BAM	10-QSB	August 15, 2005	10.2
10.14	Letter agreement dated March 31, 2005 with The Oxford Group, Ltd.	10-QSB	August 15, 2005	10.3
10.15	Form of securities purchase agreement dated March 2, 2006	8-K	March 3, 2006	99.2
10.16	Form of common stock purchase warrant dated March 2006	8-K	March 3, 2006	99.3
10.17	Placement Agent Agreement with Oppenheimer & Co. Inc. dated December 19, 2005	8-K	March 3, 2006	99.4
10.18 **	2006 Stock Incentive Plan	10-QSB	November 6, 2006	10.1
10.19	Form of Incentive Stock Option under Novelos Therapeutics, Inc.'s 2006 Stock Incentive Plan	8-K	December 15, 2006	10.1
10.20	Form of Non-Statutory Stock Option under Novelos Therapeutics, Inc.'s 2006 Stock Incentive Plan	8-K	December 15, 2006	10.2
10.21	Form of Non-Statutory Director Stock Option under Novelos Therapeutics, Inc.'s 2006 Stock Incentive Plan	8-K	December 15, 2006	10.3
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	

\*\* Management contract or compensatory plan.

#### ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Aggregate fees for professional services by Stowe & Degon for the years ended December 31, 2006 and December 31, 2005 were:

	2006	2005
Audit	\$ 79,500	\$ 80,775
Audit Related	—	9,700
Tax	—	—
All Other	—	—
Total	<u>\$ 79,500</u>	<u>\$ 90,475</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. The audit fees noted above for the year ended December 31, 2006 were for professional services rendered for the audit and reviews of our's 2006 annual and quarterly financial statements. The Audit fees noted above for the year ended December 31, 2005 were for professional services rendered for the audits and reviews of our's financial statements for 2005 (\$50,000) and 2004 (\$30,775).

*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, for consultations concerning financial accounting and reporting standards, and audits of business combinations.

*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.

*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.

#### ***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 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 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 for 2006 or 2005 were obtained in reliance on the waiver of the pre-approval requirement afforded in SEC regulations.

## 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 21, 2007

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

Date: March 21, 2007

By: /s/ George R. Vaughn  
George R. Vaughn  
Title: Chief Financial Officer

Date: March 21, 2007

By: /s/ Simyon Palmin  
Simyon Palmin  
Title: Chairman of the Board of Directors

Date: March 21, 2007

By: \_\_\_\_\_  
Michael J. Doyle  
Title: Director

Date: March 21, 2007

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

Date: March 21, 2007

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By: /s/ David B. McWilliams

David B. McWilliams

Title: Director

Date: March 21, 2007

By: /s/ Howard M. Schneider

Howard M. Schneider

Title: Director

Date: March 21, 2007

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**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-KSB 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 small business issuer as of, and for, the periods presented in this report;
4. The small business issuer's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15 (e) and 15d-15(e)) for the small business issuer and have:
  - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the small business issuer, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) evaluated the effectiveness of the small business issuer's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - c) disclosed in this report any change in the small business issuer's internal control over financial reporting that occurred during the small business issuer's most recent fiscal quarter (the small business issuer's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the small business issuer's internal control over financial reporting.
5. The small business issuer's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the small business issuer's auditors and the audit committee of small business issuer's board of directors (or persons performing the equivalent functions):
  - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the small business issuer's ability to record, process, summarize and report financial information; and
  - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the small business issuer's internal control over financial reporting.

Date: March 21, 2007

/s/ HARRY S. PALMIN

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Harry S. Palmin

Chief Executive Officer and President

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

I, George R. Vaughn, Chief Financial Officer, Novelos Therapeutics, Inc., certify that:

1. I have reviewed this Annual Report on Form 10-KSB 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 small business issuer as of, and for, the periods presented in this report;
4. The small business issuer's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15 (e) and 15d-15(e)) for the small business issuer and have:
  - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the small business issuer, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) evaluated the effectiveness of the small business issuer's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - c) disclosed in this report any change in the small business issuer's internal control over financial reporting that occurred during the small business issuer's most recent fiscal quarter (the small business issuer's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the small business issuer's internal control over financial reporting.
5. The small business issuer's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the small business issuer's auditors and the audit committee of small business issuer's board of directors (or persons performing the equivalent functions):
  - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the small business issuer's ability to record, process, summarize and report financial information; and
  - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the small business issuer's internal control over financial reporting.

Date: March 21, 2007

/s/ GEORGE R. VAUGHN

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George R. Vaughn

Chief Financial Officer

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

In connection with the Annual Report on Form 10-KSB of Novelos Therapeutics, Inc. (the "Company") for the year ended December 31, 2006, 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, George R. Vaughn, 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

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Harry S. Palmin  
Chief Executive Officer and President

/s/ GEORGE R. VAUGHN

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George R. Vaughn  
Chief Financial Officer

Dated: March 21, 2007

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.

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