

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, 2005

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:

<u>Title of Class</u>	<u>Name of each exchange on which registered</u>
None	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 \$12,584.

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: \$43,965,318

As of March 21, 2006, there were 39,130,272 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.

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## 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 June 2005, we merged with Common Horizons, Inc., a Nevada corporation, and the surviving company was Novelos Therapeutics, Inc.

We are a biotechnology company commercializing two promising oxidized glutathione-based compounds, NOV-002, currently in Phase 3 development for lung cancer, and NOV-205. We believe these compounds could have clinical value in the treatment of a number of cancers and both hepatitis B and C. Both compounds have completed clinical trials in humans and have been approved for use in the Russian Federation where they were developed. NOV-002, marketed in Russia by ZAO BAM, a company controlled by one of our directors, Mark Balazovsky, under the trade name GLUTOXIM<sup>®</sup>, has been administered to over 5,000 patients, demonstrating clinical efficacy and excellent safety. For more information regarding ZAO BAM, see the section entitled, "Certain Relationships and Related Transactions." The FDA advised us in December 2005 that they agreed with us that advancing NOV-002 into a pivotal Phase 3 trial in advanced non-small cell lung cancer, in combination with first-line chemotherapy, is warranted. We will seek to finalize the pivotal Phase 3 trial design under a Special Protocol Assessment during the first half of 2006. The primary endpoint of this trial will be overall survival and we expect enrollment to begin in the third quarter of 2006. In March 2006, we filed an Investigational New Drug Application with the FDA for NOV-205 as a mono-therapy for hepatitis C, and expect to initiate a U.S.-based Phase 1b clinical trial in the second quarter of 2006.

NOV-002 is designed to act as a chemoprotectant and an immunomodulator. 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. A U.S.-based Phase 1/2 clinical trial of NOV-002 in non-small cell lung cancer has been completed in which the treated group demonstrated improved objective tumor response (defined as greater than 50% tumor shrinkage) and higher tolerance of chemotherapy versus the control group.

We are also developing NOV-002 to treat ovarian cancer. 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 had failed previously. We expect to initiate a U.S.-based Phase 2 clinical trial in chemotherapy-resistant ovarian cancer in the second quarter of 2006.

We are also developing NOV-002 for the treatment of acute radiation injury. Russian animal models have shown that NOV-002 may provide a significant survival advantage if administered following a catastrophic radiation exposure from, for example, a nuclear weapon, a "dirty bomb" or an accident at a nuclear power plant.

We are developing NOV-205 to treat chronic hepatitis C in the U.S. NOV-205 is designed to act as a hepatoprotective agent with immunomodulating and antiviral activity. In Russian clinical studies completed in 1999, NOV-205 was shown to greatly reduce or eliminate viral loads and to vastly improve liver function.

From January 1, 2004 to December 31, 2005, we spent approximately \$1,400,000 on research and development activities and expect to increase our expenditures on research and development activities over the next 18 months.

### Business Strategy

Our primary objective is to fully exploit our proprietary scientific and intellectual property position in oxidized glutathione-based therapeutics. NOV-002, currently in Phase 3 development in the

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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 (i.e., resistant to initial chemotherapy) ovarian cancer, and the current as well as projected unmet medical need in these types of cancer is great. Positive results in a controlled U.S.-based Phase 1/2 lung cancer study suggest that the Russian experience can be replicated here. Therefore, we are implementing a focused program in each of these indications designed in hope of gaining FDA approval in the shortest amount of time with a reasonable amount of expense.

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 December

2004, we responded with a Capability Statement to the U.S. Department of Health and Human Services' Request for Information seeking drugs to mitigate radiation treatment and submitted a formal proposal in February 2006. The government is expected to announce contract awards in 2006.

NOV-205 has demonstrated the ability to substantially decrease the 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. We will seek to out-license the hepatitis B indication in the Far East where the incidence of the disease is very high.

For both NOV-002 and NOV-205, we plan to develop the product in the U.S. to the point where initiation of a pivotal trial is possible for strategic indications. At that point, we plan to out-license the drug and indication in Europe and/or Japan and use resources from these arrangements to offset, in part, the expense of the pivotal trials. In addition, we plan to out-license non-strategic indications, like hepatitis B, in markets like the Far East (including China and India). We further plan to leverage the Small Business Technology Transfer program and U.S. State Department grants, which support Russian scientific employment in the biomedical sciences, to provide additional funding for preclinical development initiatives. Through the date of this filing we have not as yet received any funding under these programs.

### **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

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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 preclinical and 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 derivative of a natural metabolite that is being developed in combination with chemotherapy for treatment of lung and ovarian 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. 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. Efficacy and excellent safety have been demonstrated in trials with 340 patients in Russia with 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, NOV-002 has been administered to over 5,000 patients.

According to the American Cancer Society, in 2006 about 1.4 million U.S. men and women are expected to be diagnosed with cancer. In 2006 over 550,000 U.S. cancer patients are expected to die, 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. It is expected that in 2006 approximately 175,000 people will be diagnosed with lung cancer and more than 160,000 will die as a result. According to Globocan, there were 900,000 cases of lung cancer worldwide and 800,000 resulting deaths in 2002. According to Needham & Company, the pharmaceutical market for treating lung cancer in the U.S. was approximately \$800 million in 2003. 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 an objective response rate is about 20%. Overall, less than 5% of the 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, but are very expensive. Newly emerged targeted biologic therapies, such as Astra Zeneca's IRESSA<sup>®</sup>, OSI's TARCEVA<sup>®</sup> and Genentech's AVASTIN<sup>®</sup>, 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 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 55% 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 chemotherapy alone treated patients). 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 be used in all disease stages for non-small cell lung cancer and other solid tumors.

The Russian preclinical 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. The FDA advised us in December 2005 that they agreed that advancing NOV-002 into a pivotal Phase 3 study in advanced non-small cell lung cancer, in combination with first-line chemotherapy, is warranted. We will seek to finalize the pivotal Phase 3 study design under a Special Protocol Assessment during the first half of 2006. The primary endpoint of this study will be overall survival, and we expect enrollment to begin in the third quarter of 2006.

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 to evaluate the safety and efficacy of NOV-002 in patients with advanced non-small cell lung cancer. The overall results of the Russian

non-small cell lung cancer study were impressive. 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. 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, 55% of the patients treated with NOV-002 survived for one year.

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

According to the American Cancer Society, in 2006 approximately 20,000 U.S. women are expected to be diagnosed with ovarian cancer and 15,000 women are expected to die from it. According to Needham & Company, the pharmaceutical market for treating ovarian cancer was estimated to be \$280 million in 2003. There is a lack of effective treatment, particularly in the case of refractory patients (those who do not respond to 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 combination. Doxorubicin and topotecan alternate as second- and third-line chemotherapy treatments.

Refractory 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 Berkenclit, J.Repro. Med., 2005.

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 compares very favorably to current alternatives. 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., we plan to pursue development of NOV-002 for ovarian cancer via the open Investigational New Drug Application. A Phase 2 protocol trial in platinum-refractory ovarian cancer patients is under design, and we plan to initiate the trial in the second quarter of 2006.

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

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 a nuclear power plant facilities.

Current 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 only effective 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 already 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 several thousand 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. The control group received no treatment. The treated group received daily injections of NOV-002. The NOV-002 treated animals did not experience severe neutropenia and demonstrated increased survival.

We also 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. In December 2004, we submitted a Capability Statement in response to a U.S. Department of Health and Human Services' Request for Information for Therapeutics to Treat Neutropenia and Thrombocytopenia Associated with the Acute Radiation Syndrome. We are currently planning animal experiments with Shriners Hospital, Boston, MA to confirm the radiation injury treatment results from Russia. In February 2006 we submitted a proposal to the Department of Health and Human Services for the use of NOV-002 to treat the potentially lethal blood cell reductions (neutropenia, thrombocytopenia, lymphopenia) that are part of the Acute Radiation Syndrome seen in subjects exposed to high levels of ionizing radiation. The government is expected to announce contract awards in the second half of 2006.

## **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 PharmaWeek November 2005, the U.S. market alone was believed to be \$800 million in 2004, the current global market is believed to be in excess of \$2 billion per year, growing to \$4 billion by 2007 and possibly \$10 billion by 2012. 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 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.

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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, Novelos filed an Investigational New Drug Application with the FDA for NOV-205 as monotherapy in chronic hepatitis C in March 2006. We expect to begin a Phase 1b clinical study with NOV-205 in the second quarter of 2006.

### **Preclinical Research Program**

Our preclinical 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. 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, as well as with the U.S. State Department to continue research and development efforts in Russia. Through an ongoing effort, the U.S. State Department has committed over \$30 million to convert former Russian bioweapons facilities into research medical institutions with technologies and products suitable for commercialization. We hope to launch several mechanistic and oral formulation experiments as well as host-defense animal studies through this effort. We have also funded Dr. Gelfand's new laboratory at Shriners Hospitals to conduct studies in animal models to confirm 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 of the glutathione pathway, 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 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 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 (Albany, OR) in a single, very cost effective synthetic step and then lyophilized into a powder at Oregon Freeze Dry (Albany, OR). It is then filled, finished and packaged at Dalton Pharma Services (Toronto, Canada) as a sterile filtered, aseptically processed solution for intravenous, intramuscular and/or subcutaneous use. NOV-002 Clinical Trial Material, API and vials, 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 and then lyophilized into a powder at Oregon Freeze Dry. It is then filled, finished and packaged at Dalton Pharma Services.

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## **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., two in Europe, one in Japan and one in Canada. We have also filed over 30 patent applications worldwide.

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 10, 2006, we have six 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, record keeping, 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 offices in Newton, Massachusetts. Our office consists of approximately 2,200 square feet and is rented for approximately \$4,830 per month. This lease expires in August 2006. 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, 2005.

## 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 13, 2005 when trading began. 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.

Fiscal Year 2005	High	Low
Second Quarter (beginning June 13, 2005)	\$ 2.80	\$ 2.20
Third Quarter	\$ 4.47	\$ 2.16
Fourth Quarter	\$ 3.65	\$ 1.53

On March 21, 2006, we had approximately, 203 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 capital 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 all accrued dividends on our Series A preferred stock.

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

### Overview

We were established in 1996 to commercialize two promising oxidized glutathione-based compounds, NOV-002, currently in Phase 3 development, and NOV-205, for the treatment of cancer and hepatitis. Both compounds have completed clinical trials in humans and have been approved for use in the Russian Federation where they were developed. NOV-002, marketed in Russia by ZAO BAM, a company controlled by one of our directors, Mark Balazovsky, under the trade name GLUTOXIM<sup>®</sup>, has been administered to over 5,000 patients, demonstrating, what we believe to be, clinical efficacy and excellent safety data. The FDA advised us in December 2005 that they agreed with us that advancing NOV-002 into a pivotal Phase 3 trial in advanced non-small cell lung cancer, in combination with first-line chemotherapy, is warranted. We will seek to finalize the pivotal Phase 3 trial design under a Special Protocol Assessment during the first half of 2006. The primary endpoint of

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this trial will be overall survival and we expect enrollment to begin in the third quarter of 2006. We filed in March 2006 an Investigational New Drug Application with the FDA for NOV-205 as monotherapy for hepatitis C, and expect to initiate a U.S.-based Phase 1b clinical trial in the second quarter of 2006.

We have devoted substantially all of our efforts towards the research and development of our product candidates. As of December 31, 2005, we had incurred approximately \$5.0 million in research and development expense since our inception. We have had no revenue from product sales to date and have funded our operations through the sale of equity securities and debt financings. From our inception through December 31, 2005, we have raised approximately \$12.8 million in equity and debt financings. We have never been profitable and have incurred an accumulated deficit of \$15.4 million as of December 31, 2005.

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

On May 26, 2005, we also revised a certain royalty obligation with a related party. As a result, we issued 2,016,894 shares of our common stock with an aggregate deemed value of \$2,521,118.

On May 27, 2005, June 29, 2005, July 29, 2005 and August 9, 2005, we completed private placements of units, each unit initially consisting of 20,000 shares of our common stock and warrants to purchase 10,000 shares of our common stock. We sold an aggregate of 200 units for net cash proceeds of \$3,714,468 for 178 of these units and the conversion of \$550,000 of convertible debt for 22 of these units.

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

### **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 monitors; data management organizations and investigators in conjunction with clinical trials; fees paid to contract manufacturers in conjunction with the production of clinical materials; consulting fees; 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 low or too high. The date on which

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certain services commence, the level of services performed on or before a given date and the cost of such services are often determined based on subjective judgments. We make these judgments based upon the facts and circumstances known to us in accordance with generally accepted accounting principles.

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

Accounting for equity instruments granted by us under APB 25, SFAS 123 and EITF 96-18 requires fair-value estimates of the equity instrument granted. 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 in exchange for the receipt of goods or services, we estimate the fair value of the equity instruments based upon consideration of factors that we deem to be relevant at that time. Because shares of our common stock were not publicly traded prior to the corporate restructuring described in Note 3 to our financial statements, market factors historically considered in valuing stock and stock option grants included comparative values of public companies discounted for the risk and limited liquidity provided for in the shares we are issuing; pricing of private sales of our convertible preferred stock; prior valuations of stock grants and the effect of events that occurred between the time of such grants; economic trends; and the comparative rights and preferences of the security being granted compared to the rights and preferences of our other outstanding equity.

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

## **Results of Operations**

### ***Years Ended December 31, 2005 and 2004***

*Revenue.* Revenue for the year ended December 31, 2005 was \$12,584 compared to \$4,962 for the year ended December 31, 2004. The 2005 amount represented the recognition of a prior year's deferred revenue on sales of bulk drug samples to facilitate research activities. This revenue represents recognition of the remaining installment due on bulk drug sample sales. In lieu of cash, we accepted research and development services as final payment.

*Research and Development.* Research and development expense for the year ended December 31, 2005 was \$1,136,217 compared to \$261,768 for the year ended December 31, 2004. Research and development expense consists of expenses incurred in identifying, developing and testing product candidates, which primarily consist of salaries and related expenses for personnel, fees paid to professional service providers for independent monitoring and analysis of our clinical trials, costs of

contract research and manufacturing, and costs of facilities. The \$874,449, or 334%, increase in research and development expense was primarily due to increased funding of our preclinical, clinical and contract manufacturing activities, an increase in compensation costs due to an increase in headcount, and an increase in stock-based compensation. The private placement transactions, corporate restructuring and issuance of promissory notes during the year ended December 31, 2005 allowed us to engage outside consultants and organizations to further research, develop and test our product candidates.

*General and Administrative.* General and administrative expense for the year ended December 31, 2005 was \$1,442,749 compared to \$368,413 for the year ended December 31, 2004. General and administrative expense consists primarily of salaries and other related costs for personnel in executive, finance, investor relations, accounting, business development, and human resource functions. Other costs include facility costs not otherwise included in research and development expense, insurance, costs for public and investor relations and

professional fees for legal and accounting services. The \$1,074,336, or 292%, increase in general and administrative expense was primarily due to our periodic filing obligations and increases in professional and consulting fees, public and investor relations and public company recordkeeping. We also incurred additional legal and consulting costs during the year ended December 31, 2005 in translating and filing our European patent applications. As described in Note 4 to our financial statements, we also recorded a \$33,000 expense during the year ended December 31, 2005 relating to the late filing of a registration statement associated with our sale of units.

*Consulting Revenue.* Consulting revenue for the year ended December 31, 2005 was \$0 compared to \$13,374 for the year ended December 31, 2004. Consulting revenue recorded during the year ended December 31, 2004 primarily related to one consulting engagement that ended during the quarter ended June 30, 2004.

*Interest Income.* Interest income for the year ended December 31, 2005 was \$49,876 compared to \$95 for the year ended December 31, 2004. The increase in interest income during the year ended December 31, 2005 over the comparable period in 2004 related to higher average cash balances in 2005, as a result of the financings described in Notes 3 and 5 to our financial statements, being placed in interest-bearing accounts.

*Interest Expense.* Interest expense for the year ended December 31, 2005 was \$109,102 compared to \$208,741 for the year ended December 31, 2004. The \$99,639, or 48%, decrease was due to lower average debt balances during the 2005 period.

*Gain on Forgiveness of Debt.* Gain on forgiveness of debt for the year ended December 31, 2005 was \$2,087,531 compared to \$0 for the year ended December 31, 2004. On May 26, 2005, we exchanged indebtedness of \$3,139,185 for 586,352 shares of our common stock with an aggregate deemed value of \$732,940 and \$318,714 in cash, which resulted in forgiveness of debt income of \$2,087,531.

*Restructuring Expense.* Restructuring expense for the year ended December 31, 2005 was \$2,521,118 compared to \$0 for the year ended December 31, 2004. On May 26, 2005, we revised an arrangement that requires us to pay future royalties, which resulted in the issuance of 2,016,894 shares of our common stock with an aggregate deemed value of \$2,521,118.

## **Liquidity and Capital Resources**

We have financed our operations since inception through the sale of equity securities and the issuance of debt. As of December 31, 2005, we had approximately \$4,267,000 in unrestricted cash and equivalents.

During the year ended December 31, 2005, cash of \$2,399,000 was used in operations, primarily due to a net loss of \$3,053,000, a \$2,088,000 non-cash gain attributable to the forgiveness of debt, a decrease in prepaid expenses and other current assets of \$97,000, and a decrease in accounts payable and accrued expenses of \$137,000, offset by stock-based compensation expense of \$399,000 and non-cash restructuring expenses of \$2,521,000.

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During the year ended December 31, 2005, cash of \$252,000 was used in investing activities due to \$26,000 in purchases of property and equipment, an increase in restricted cash of \$195,000, an increase in deferred financing costs of \$25,000 and an increase in deposits of \$5,000.

During the year ended December 31, 2005, financing activities provided cash of \$6,908,000 consisting of net proceeds of \$2,864,000 from the sale of preferred stock, net proceeds of \$3,715,000 from the sale of units (each unit initially consisting of 20,000 shares of common stock and a warrant to purchase 10,000 shares of common stock), and \$850,000 from the issuance of promissory notes, partially offset by \$521,000 in payments on promissory notes payable to certain stockholders and holders of our long-term debt.

We believe that our available cash and cash equivalents, including the proceeds from the March 7, 2006 private placement (described below under the caption "Subsequent Events"), will be sufficient to meet our working capital requirements, including operating losses, and capital expenditure requirements through September 2007, assuming that our business plan is implemented successfully.

However, we believe that we will need to raise additional capital during 2007 in order to support the planned growth of our business. We may seek additional funding through collaborative arrangements and public or private financings. Additional funding may not be available to us on acceptable terms or at all. In addition, the terms of any financing may adversely affect the holdings or the rights of our stockholders. For example, if we raise additional funds by issuing equity securities, further dilution to our existing stockholders may result. If we are unable to obtain funding 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; and
- the timing, receipt, and amount of milestone and other payments, if any, from collaborators.

### **Recently Issued Accounting Pronouncement**

On December 16, 2004, the Financial Accounting Standards Board issued SFAS 123(R), *Share-Based Payment*, which is a revision of SFAS 123 (SFAS 123R). SFAS 123R supersedes APB 25 and amends SFAS No. 95, *Statement of Cash Flows*. Generally, the approach in SFAS 123R is similar to the approach described in SFAS 123, detailed below. However, SFAS 123R requires all share-based payments to employees, including grants of employee stock options, to be recognized in the statement of operations based on their fair values at the date of grant. Pro forma disclosure is no longer an alternative. SFAS 123R is effective for public entities that file as small business issuers as of the beginning or the first interim or annual reporting period that begins after December 15, 2005. Early adoption is permitted in periods in which financial statements have not yet been issued. We have adopted SFAS 123R as of January 1, 2006, and its effects will be reflected in our quarterly report for the first quarter of fiscal 2006.

The Company will apply SFAS 123R using the "modified prospective" method. Under this transition method, compensation cost is recognized on or after the required effective date for the portion of outstanding awards for which the requisite service has not yet been rendered, based on the grant-date fair value of those awards calculated under SFAS 123 for either recognition or pro forma disclosures.

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As permitted by SFAS 123, we currently account for share-based payments to employees using APB 25's intrinsic value method and, as such, generally recognize no compensation cost for employee stock options issued with an exercise price greater than or equal to the fair value of the underlying stock on the grant date. Accordingly, the adoption of SFAS 123R's fair-value method may have a significant impact on our reported results of operations. Management is still evaluating the impact of the adoption of SFAS 123R.

### **Subsequent Events**

On March 7, 2006, we issued 11,154,073 shares of our common stock and warrants to purchase 8,365,542 shares of our common stock pursuant to a securities purchase agreement dated March 2, 2006 with 39 accredited investors for aggregate gross proceeds of \$15,058,005. The warrants are exercisable until March 7, 2011 at an exercise price of \$2.50 per share.

We are required to register the resale of the shares of common stock sold in the offering and issuable upon exercise of the warrants. We are required to file the registration statement with the Securities and Exchange Commission (SEC) within 30 days after the closing and use our best efforts to cause the registration statement to be declared effective under the Securities Act of 1933, as amended, within 120 days after the closing of the offering. We are required to use our best efforts to keep the registration statement continuously effective under the Securities Act until the earlier of the date when all the registrable securities covered by the registration statement have been sold or the second anniversary of the closing. In the event that the registration statement is not filed or declared effective when due, we are obligated to pay the investors liquidated damages in the amount of 1% of the purchase price for each month in which we are in default.

Oppenheimer & Co., Inc. acted as the placement agent and Rodman & Renshaw, LLC acted as the sub-placement agent in connection with the offering. The aggregate commissions payable to Oppenheimer and Rodman & Renshaw in connection with the private placement were approximately \$1,000,000. In addition, we issued them warrants to purchase 669,244 shares of common stock identical to those sold to the investors.

The sale of common stock and warrants described above, resulted in an anti-dilution adjustment to the exercise price of our outstanding warrants. Such adjustment reduced the exercise price of such warrants from \$1.65 to \$1.35 per share of common stock. The sale also resulted in an anti-dilution adjustment to the conversion price of our Series A preferred stock from \$1.65 to \$1.35.

### **Factors Affecting Future Performance**

#### **We may not have adequate funds to sustain our operations.**

For the year ended December 31, 2004, our independent registered public accounting firm issued an opinion on our financial statements which included an explanatory paragraph expressing substantial doubt about our ability to continue as a going concern. As of August 9, 2005, we had restructured or repaid substantially all of our

debt and closed private placements of common stock and common stock purchase warrants that resulted in aggregate net cash proceeds of \$3,714,868 to us. On September 30, 2005, we sold 3,000 shares of our Series A 8% cumulative convertible preferred stock resulting in net proceeds of \$2,680,000. On October 3, 2005 we sold 200 shares of our Series A 8% cumulative convertible preferred stock resulting in net proceeds of \$184,000. On March 7, 2006, we sold 11,154,073 shares of our common stock and warrants to purchase 8,365,542 shares of our common stock pursuant to a securities purchase agreement dated March 2, 2006 with 39 accredited investors for aggregate gross proceeds of \$15,058,005. Currently, we believe that we have available cash sufficient to meet our working capital requirements through September 2007, assuming our expense levels do not exceed our current plan. However, 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.

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**The failure to complete development of our therapeutic technology, obtain government approvals, including required FDA approvals, or to comply with ongoing governmental regulations could prevent, delay or limit introduction or sale of proposed products and result in failure to achieve revenues or maintain 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 time-frame 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:

- the 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 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 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

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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 and, in fact, NOV-002 has been approved for use there as an immunostimulant in combination with chemotherapy and antimicrobial therapy in indications such as tuberculosis, and NOV-205 has been approved there as a monotherapy agent for the treatment of hepatitis B and C. However, 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 anticipate commencing a Phase 3 study of NOV-002 for non-small cell lung cancer in 2006. We also anticipate completing a Phase 2 clinical study for NOV-002 for chemotherapy-resistant ovarian cancer and a Phase 1b clinical study for NOV-205 for chronic hepatitis C in early 2007. There can be no assurance, however, 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.

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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 alternative research, development and 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 liability, clinical and preclinical liability risks which could create a substantial financial burden should we be sued because we do not currently have product liability insurance above and beyond our general insurance coverage.**

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 maintained product liability insurance coverage during the time of the NOV-002 Phase 1/2 clinical study, we do not currently have any product liability insurance or other liability insurance relating to clinical trials or any products or compounds. Currently, no clinical trials are ongoing, but we expect to be starting clinical trials in the second quarter of 2006. It is our intention to secure such insurance once new clinical trials are initiated. We cannot give assurances that we will be able to obtain or maintain adequate product liability insurance on acceptable terms, if at all, or that such insurance will provide adequate coverage against our potential liabilities. Furthermore, our

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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 upon 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.

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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 upon 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 product(s) 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

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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.**

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.

**We may have difficulty raising needed capital in the future because of our limited operating history and business risks associated with us.**

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 funds are unavailable from any available source, 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;

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- market acceptance of our products;
  - costs for recruiting and retaining management, employees and consultants; and
  - costs for training physicians.

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.

**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 has heretofore operated with limited day-to-day business management, operating as a vehicle to hold certain technology for possible future exploration, and has been and will continue to be engaged in the development of new drugs and therapeutic technologies. As a result, 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

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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. Third-party payers are increasingly challenging the prices charged for medical drugs and services. Also, the trend toward managed health care in the United States and the concurrent growth of organizations such as health maintenance organizations, which could control or significantly influence the purchase of health care services and drugs, as well as legislative proposals to reform health care or reduce government insurance programs, may all result in lower prices for or rejection of our drugs. The cost containment measures that health care payers and providers are instituting and the effect of any health care reform could materially harm our ability to operate profitably.

**We depend upon 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.

**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 32% of our outstanding voting stock. They have the ability to determine our direction and decisions. The interests of our current officers and directors may differ from the interests of other stockholders. As a result, our current officers and directors would have the ability to exercise control over all corporate actions requiring stockholder approval, irrespective of how the other stockholders may vote, 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 and 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.

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**Our common stock could be further diluted as the result of our issuing convertible securities, warrants or options.**

In the past, we have issued convertible securities, such as our Series A 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 issuing additional convertible securities, options and warrants could affect the rights of our stockholders, and could reduce the market price of

our common stock.

**We sold shares of our Series A preferred stock and common stock purchase warrants in violation of certain provisions of our securities purchase agreement and registration rights agreement executed in connection with our private placement of units. While we have received waivers from such investors representing approximately 96% of the outstanding units as of March 21, 2006 (83% as of December 31, 2005), other investors who do not waive such rights could sue us seeking damages arising from the breach of such agreements.**

On May 27, 2005, June 29, 2005, July 29, 2005 and August 9, 2005, we sold units, consisting of shares of our common stock and common stock purchase warrants pursuant to a securities purchase agreement and registration rights agreement.

The registration rights agreement required that:

- We file a registration statement with the SEC to register the shares of common stock and the shares of common stock issuable upon the exercise of the warrants.
- Each of these investors was entitled to liquidated damages in an amount equal to two percent (2%) of the purchase price of the shares of common stock and the common stock purchase warrants if we failed to file a registration statement with the SEC on or before October 8, 2005 and if we failed to pay any partial liquidated damages within seven days after the date payable, we were required to pay interest thereon at a rate of fifteen percent (15%) per annum to such investors until such amounts are paid in full.
- Neither we nor any of our security holders include our securities in a registration statement other than the shares of common stock and shares of common stock issuable upon exercise of the warrants.

The securities purchase agreement required that:

- From the date of the purchase agreement until February 13, 2006, we were generally prohibited from issuing shares of common stock or common stock equivalents.
- From the date of the purchase agreement until the two year anniversary of such agreement, we were prohibited from effecting or entering into an agreement to effect any financing involving a variable rate transaction.

We filed a registration statement on Form SB-2 with the SEC on November 16, 2005 to register for resale the shares of common stock and shares of common stock issuable upon exercise of the warrants, which became effective on December 15, 2005. We have recorded an accrued liability of \$33,000 as of December 31, 2005 for payments in connection with this late filing.

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## 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, 2005 and 2004, and the related statements of operations, stockholders' deficiency and cash flows for the years then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Novelos Therapeutics, Inc. as of December 31, 2005 and 2004 and the results of its operations, changes in stockholders' deficiency and cash flows for the years then ended in conformity with accounting principles generally accepted in the United States.

/s/ Stowe & Degen  
 Worcester, Massachusetts  
 March 22, 2006

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**NOVELOS THERAPEUTICS, INC.**  
**BALANCE SHEETS**  
**DECEMBER 31, 2005 and 2004**

<b>ASSETS</b>	<b>2005</b>	<b>2004</b>
<b>CURRENT ASSETS:</b>		
Cash and equivalents	\$ 4,267,115	\$ 10,356
Restricted cash	196,908	—
Accounts receivable	—	12,584
Prepaid expenses and other current assets	337,902	79,631
Total current assets	4,801,925	102,571
<b>FIXED ASSETS, net</b>	<b>22,610</b>	<b>—</b>
<b>DEFERRED FINANCING COSTS</b>	<b>24,612</b>	<b>—</b>
<b>PREPAID EXPENSES</b>	<b>79,896</b>	
<b>DEPOSITS</b>	<b>9,656</b>	<b>6,000</b>
<b>TOTAL ASSETS</b>	<b>\$ 4,938,699</b>	<b>\$ 108,571</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIENCY)</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable and accrued liabilities	\$ 211,456	\$ 2,026,421
Accrued interest	5,700	397,612
Notes payable to stockholders	—	2,017,931
Current portion of long-term debt	—	1,840
Total current liabilities	217,156	4,443,804

DEPOSIT ON CONVERTIBLE PREFERRED STOCK, SERIES B	—	1,142
DEFERRED REVENUE	—	12,584
Total liabilities	<u>217,156</u>	<u>4,457,530</u>
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' EQUITY (DEFICIENCY):		
Series A 8% convertible preferred stock; \$0.00001 par value; 7,000 shares authorized; 3,264 and 0 shares issued and outstanding in 2005 and 2004, respectively	—	—
Common stock; \$0.00001 par value; 100,000,000 shares authorized; 27,921,199 and 4,426,126 shares issued and outstanding in 2005 and 2004, respectively	279	44
Additional paid-in capital	20,119,820	7,998,110
Accumulated deficit	(15,398,556)	(12,345,157)
Treasury stock (195,672 shares), at cost	—	(1,956)
Total stockholders' equity (deficiency)	<u>4,721,543</u>	<u>(4,348,959)</u>
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIENCY)	<u>\$ 4,938,699</u>	<u>\$ 108,571</u>

See notes to financial statements.

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**NOVELOS THERAPEUTICS, INC.**  
**STATEMENTS OF OPERATIONS**  
**YEARS ENDED DECEMBER 31, 2005 AND 2004**

	2005	2004
REVENUES:		
Sales of samples	\$ 12,584	\$ 4,962
COSTS AND EXPENSES:		
Research and development	1,136,217	261,768
General and administrative	1,442,749	368,413
Total costs and expenses	<u>2,578,966</u>	<u>630,181</u>
OTHER INCOME (EXPENSE):		
Consulting revenue	—	13,374
Interest income	49,876	95
Interest expense	(109,102)	(208,741)
Miscellaneous	5,796	5,206
Gain on forgiveness of debt	2,087,531	—
Restructuring expense	<u>(2,521,118)</u>	<u>—</u>
Total other expense	<u>(487,017)</u>	<u>(190,066)</u>
NET LOSS	<u>(3,053,399)</u>	<u>(815,285)</u>
ACCRETION ON CONVERTIBLE PREFERRED STOCK, SERIES A	—	(69,541)
ACCRETION ON CONVERTIBLE PREFERRED STOCK SERIES B	—	(67,267)
NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS	<u>\$ (3,053,399)</u>	<u>\$ (952,093)</u>
BASIC AND DILUTED NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS PER COMMON SHARE	<u>\$ (0.14)</u>	<u>\$ (0.28)</u>
SHARES USED IN COMPUTING BASIC AND DILUTED NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS PER COMMON SHARE	<u>21,757,424</u>	<u>3,455,238</u>

See notes to financial statements.

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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	—	—	—	—	—	2,864,000	—	—	2,864,000
Issuance of cumulative convertible preferred stock in payment of dividends	—	—	64	—	—	—	—	—	—	—	—	—
Net loss	—	—	—	—	—	—	—	—	—	(3,053,399)	—	(3,053,399)
<b>BALANCE AT DECEMBER 31, 2005</b>	<b>27,921,199</b>	<b>\$ 279</b>	<b>3,264</b>	<b>\$ —</b>	<b>—</b>	<b>\$ —</b>	<b>—</b>	<b>\$ —</b>	<b>\$20,119,820</b>	<b>\$(15,398,556)</b>	<b>\$ —</b>	<b>\$ 4,721,543</b>

See notes to financial statements.

**NOVELOS THERAPEUTICS, INC.**  
**STATEMENTS OF CASH FLOWS**  
**YEARS ENDED DECEMBER 31, 2005 AND 2004**

	2005	2004
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$ (3,053,399)	\$ (815,285)
Adjustments to reconcile net loss to cash used for operating activities:		
Depreciation and amortization	3,244	2,538
Stock-based compensation	399,461	7,868
Gain on forgiveness of debt	(2,087,531)	—
Loss on cancellation of escrow agreement	—	1,957
Common stock issued for restructuring expense	2,521,118	—
Increase (decrease) in cash from:		
Accounts receivable	12,584	100
Prepaid expenses and other current assets	(96,653)	(75,219)
Accounts payable and accrued expenses	(136,538)	314,194
Accrued interest	51,451	174,520
Deferred revenue	(12,584)	(100)
Deferred rent	(250)	250
Cash used in operating activities	<u>(2,399,097)</u>	<u>(389,177)</u>
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Purchases of property and equipment	(25,854)	—
Increase in restricted cash	(196,908)	—
Deferred financing costs	(24,612)	—
Deposits	(4,798)	—
Cash used in investing activities	<u>(252,172)</u>	<u>—</u>
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from issuance of common stock, net	3,714,868	—
Proceeds from issuance of Series A 8% cumulative convertible preferred stock, net	2,864,000	—
Payments of long-term debt	(1,840)	(2,832)
Proceeds from issuance of promissory notes	850,000	219,000
Payment of promissory notes	(519,000)	—
Cash provided by financing activities	<u>6,908,028</u>	<u>216,168</u>
<b>INCREASE (DECREASE) IN CASH AND EQUIVALENTS</b>	<b>4,256,759</b>	<b>(173,009)</b>
<b>CASH AND EQUIVALENTS AT BEGINNING OF YEAR</b>	<b>10,356</b>	<b>183,365</b>

CASH AND EQUIVALENTS AT END OF YEAR	\$ 4,267,115	\$ 10,356
<b>SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION</b>		
Cash paid during the year for:		
Interest	\$ 57,461	\$ 33,750
<b>SUPPLEMENTAL DISCLOSURES OF NON-CASH ACTIVITIES</b>		
Common stock issued for placement agent services	\$ 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	\$ 610,212	\$ —
Accounts payable forgiven	\$ 773,599	\$ —
Accrued compensation forgiven	\$ 360,357	\$ —
Accrued interest forgiven	\$ 343,363	\$ —

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See notes to financial statements.

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## Novelos Therapeutics, Inc.

### Notes to Financial Statements

#### 1. NATURE OF BUSINESS

Novelos Therapeutics, Inc. ("Novelos" or on or after June 13, 2005, the "Company") was incorporated on June 21, 1996 as AVAM International, Inc. ("AVAM"). On October 6, 1998, Novelos Therapeutics, Inc., a newly incorporated entity, merged into AVAM, and the name of AVAM was changed to Novelos Therapeutics, Inc. See Note 3 regarding the merger and restructuring 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. Novelos focuses on therapeutics for the treatment of various cancers and infectious diseases.

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

**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 and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting periods. 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 represents cash placed in escrow as contractually required under an employment agreement with an officer.

**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.

**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 under collaborative research and development agreements will be recognized as research is

performed under the terms of the agreements, when there is an obligation to pay, and when no future performance obligations exist. Consideration received in advance, whether cash, equity securities or other instruments, is initially recorded as deferred revenue and recognized when earned. Revenue earned upon the attainment of research or product development milestones will be recognized over the terms of the related agreements, once all contingencies are eliminated, after taking into consideration the cost to date and the estimated total cost of the research activities.

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

**Income Taxes** — The Company accounts for income taxes under the provisions of Statement of Financial Accounting Standards ("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 carrying amounts and the tax bases of assets and liabilities using enacted tax rates in effect in the years in which the differences are expected to reverse.

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**Earnings (Loss) Per Share** — Basic earnings (loss) per share is computed by dividing income (loss) attributable to common stockholders by the weighted average number of common shares outstanding during the year. Diluted earnings per share is computed by dividing income attributable to common stockholders by the weighted average number of common shares outstanding during the period plus the number of additional common shares that would have been outstanding if the potentially dilutive common shares had been issued. Dilutive securities include stock options, convertible preferred stock and warrants. The Company's outstanding stock options and warrants are not included in the calculation of loss per share because their inclusion would be antidilutive.

**Stock-Based Compensation** — The Company accounts for stock option awards granted to directors and employees (collectively, employees) under the recognition and measurement principles of Accounting Principles Board Opinion ("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 years ended December 31, 2005 and 2004, 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 applies the disclosure only provision of SFAS No. 123, *Accounting for Stock-based Compensation* ("SFAS 123"). The fair value of the Company's stock options used to compute pro forma net loss below is the estimated fair value at the grant date using the Black-Scholes option-pricing model with the following weighted-average assumptions for the year ended December 31, 2005:

Risk-free interest rate	3.95% - - 4.81%
Expected volatility	0% - 80%
Expected lives	2 - 10 years
Expected dividend	0

The per share, weighted-average grant date fair value of options granted during the years ended December 31, 2005 and 2004 was \$0.50 and \$0.01, respectively.

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

	Year Ended December 31,	
	2005	2004
Net loss attributable to common stockholders as reported	\$ (3,053,399)	\$ (952,093)
Stock-based employee compensation expense determined under fair-value-based method	(111,082)	(5,272)
Pro forma net loss attributable to common stockholders	<u>\$ (3,164,481)</u>	<u>\$ (957,365)</u>
Basic and diluted net loss attributable to common stockholders per share:		
As reported	\$ (0.14)	\$ (0.28)
Pro forma	<u>\$ (0.15)</u>	<u>\$ (0.28)</u>

In December 2004, the Financial Accounting Standards Board issued SFAS No. 123(R), *Share-Based Payment*, ("SFAS 123R"), which is effective for public entities that file as small business issuers as of the beginning of the first interim or annual reporting period that begins after December 15, 2005. SFAS 123R

requires a public entity to measure 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 will be 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). No compensation cost is recognized for equity instruments for which employees do not render the requisite service.

The Company will be required to apply SFAS 123R during the quarter ending March 31, 2006. SFAS 123R allows two methods for accounting for the effects of the transition: the modified prospective transition method and the modified retrospective method of transition. The Company has determined that it will implement SFAS 123R using the modified prospective method. Under the modified prospective transition method, the Company will use the fair value-based accounting method for all employee awards granted, modified, or settled after the effective date. As of the effective date, compensation cost related to the nonvested portion of awards outstanding as of that date will be based on the grant-date fair value of those awards as calculated under the original provisions of SFAS 123. The Company will not remeasure the grant-date fair value estimate of the unvested portion of awards granted prior to the effective date.

Stock or other equity-based compensation for non-employees is accounted for under the fair-value method as required by SFAS 123 and Emerging Issues Task Force ("EITF") No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction With Selling, Goods or Services*. Under this method, the equity-based instrument is valued at either the fair value of the consideration received or the equity instrument issued on the date of vesting. The resulting compensation cost is recognized and charged to operations over the service period. The measurement date is generally the issuance date for employees and the vesting date for consultants. The resulting non-cash expense is being recorded in the statements of operations over the vesting period of the stock option.

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

**Concentration of Credit Risk** — The Company maintains deposits in financial institutions, which occasionally exceed federally insured limits. Senior management continually reviews the financial stability of these institutions.

**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.

**New Accounting Pronouncements** — In May 2005, the Financial Accounting Standards Board issued 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 Statements*, and changes 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. SFAS 154 will be effective for the Company beginning January 1, 2006 and is not expected to have a material impact on the Company's financial position or results of operations.

**Reclassifications** — Certain accounts previously reported in the 2004 financial statements have been reclassified to facilitate comparability with the current year presentation. These reclassifications had no effect on 2004 net loss as previously reported.

### 3. MERGER AND RESTRUCTURING

On May 26, 2005, indebtedness of Novelos in the amount of \$3,139,185 was exchanged for 586,351 shares of common stock of Novelos with an aggregate deemed value of \$732,941 and cash in the amount of \$318,714, which resulted in forgiveness of debt income of \$2,087,531. Also on May 26, 2005, holders of convertible notes of Novelos in the principal amount of \$1,100,000 converted their

notes into 1,760,000 shares of common stock of Novelos at a price of \$0.625 per share. In addition, Novelos amended an arrangement for future royalty payments to a related party (see Note 11), which resulted in the issuance of 2,016,894 shares of its common stock with an aggregate deemed value of \$2,521,118. These amounts have been reflected in Novelos' Statements of Operations as "Gain on forgiveness of debt" and "Restructuring expense."

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

On May 27, 2005, Common Horizons sold 87 units, each unit consisting of 20,000 shares of common stock and warrants expiring on August 9, 2008 to purchase 10,000 shares of common stock at a purchase price of \$2.25 per share (a "Unit"), in a private placement transaction to accredited investors. As a result of the sale of these units, Common Horizons issued 1,740,000 shares of common stock and warrants to purchase 870,000 shares of common stock. Common Horizons received \$1,725,000 in cash as a result of such sale of Units. Holders of convertible debt of Common Horizons in the amount of \$450,000 converted the debt into 18 of the 87 Units. In connection with the closing, Common Horizons paid commissions and finders fees consisting of \$217,500 in cash and issued warrants expiring August 9, 2010 to purchase 152,000 shares of common stock of Common Horizons at a price of \$2.00 per share.

On May 27, 2005, as a result of the transactions described above, there were approximately 25,458,700 shares of common stock of Common Horizons issued and outstanding and options and warrants to purchase up to 2,202,651 and 1,764,000 shares, respectively, of common stock of Common Horizons issued and outstanding.

On June 13, 2005, Common Horizons merged with and into its wholly-owned subsidiary, Novelos. Each stockholder of Common Horizons received one share of common stock, par value \$0.00001 per share, of Novelos for each share of common stock, par value \$0.001 per share, of Common Horizons which resulted in the issuance of 4,500,000 shares of Novelos common stock. In addition, each option and warrant to acquire shares of common stock of Common Horizons was converted into the right to acquire an equal number of shares of common stock of Novelos at the exercise price stated in the original option or warrant.

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

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

On August 9, 2005, the Company completed a fourth closing of its private placement of Units. The Company sold 34 Units, receiving \$750,000 in cash as a result of such sale, and converted accrued interest of \$100,000 into Units. The Company issued to the accredited investors an aggregate of 680,000 shares of its common stock and warrants to purchase an aggregate of 340,000 shares of its

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common stock. In connection with this closing, the Company paid finders fees consisting of \$58,000 and issued warrants expiring August 9, 2010 to purchase 42,000 shares of common stock of the Company at a price of \$2.00 per share.

On August 9, 2005, the Company repaid certain stockholder loans in the principal amount of \$500,000 advanced in December 2004 and January 2005 and more fully described in Note 7 with proceeds from the private placement of Units.

In connection with the private placement of Units, vFinance Investments, Inc. and Mercer Capital, Ltd. acted as placement agents, on a best efforts basis. The placement agent agreement provided that the placement agents receive 8% of the gross proceeds of the Units sold by or through the efforts of the placement agents, a nonaccountable expense allowance of 2% of the gross proceeds of all Units sold in the offering, and reimbursement for additional expenses of up to \$40,000 to cover their due diligence investigation of the Company and their legal fees and expenses. In addition, the placement agents received warrants to purchase 218,000 shares of common stock of the Company representing 10% of the total number of shares of common stock of the Company sold by or through the efforts of the placement agents, all of which are included in the amounts described as warrants issued for commissions and finders fees for each closing above. These warrants have an exercise price of \$2.00 per share and expire on August 9, 2010. The placement agents also received 125,000 shares of common stock of Common Horizons upon the initial sale of Units. The Company also paid similar fees (cash and warrants) to finders who introduced the Company to certain investors.

The Company was obligated to file a registration statement covering the shares of common stock and common stock issuable in these private placements of Units by October 8, 2005 and to cause the registration

statement to be declared effective by February 5, 2006. The Company is obligated to pay the investors an amount equal to two percent (2%) of the purchase price of the Units purchased by them for each 30-day period following such date that the registration statement has not been filed or declared effective, as the case may be. The Company has obtained waivers of this requirement from unit holders representing approximately 83% of the shares of common stock sold in the private placement of Units and has recorded an accrued liability of \$33,000 as of December 31, 2005 for such payments. If the Company fails to pay any partial liquidated damages in full within seven days after the date payable, the Company will pay interest thereon at a rate of 15% per annum. The registration statement was filed on November 16, 2005 and was declared effective on December 15, 2005.

The sale of the Series A preferred stock and warrants described in Note 5, resulted in an anti-dilution adjustment to the exercise price of the outstanding warrants described above. Such adjustment reduced the exercise price of such warrants from \$2.00 and \$2.25 to \$1.65 per share of common stock.

The sale of common stock and warrants described in Note 12, resulted in a further anti-dilution adjustment to the exercise price of the outstanding warrants described above. Such adjustment reduced the exercise price of such warrants from \$1.65 to \$1.35 per share of common stock.

#### 4. FIXED ASSETS

Fixed assets consisted of the following at December 31:

	2005	2004
Office equipment	\$ 49,717	\$ 26,364
Leasehold improvements	2,500	—
Total fixed assets	52,217	26,364
Less accumulated depreciation and amortization	(29,607)	(26,364)
Fixed assets, net	\$ 22,610	\$ —

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, 2005 and 2004.

#### 5. STOCKHOLDERS' EQUITY

The Company's authorized capital stock consists of 100,000,000 shares of common stock, \$0.00001 par value per share, and 7,000 shares of preferred stock, \$0.00001 par value per share. As of December 31, 2005, 27,921,199 shares of common stock were issued and outstanding.

The Company is authorized to issue shares of preferred stock from time to time in one or more series without stockholder approval. As of December 31, 2005, the Company had designated 6,000 shares as Series A 8% cumulative convertible preferred stock, 3,264 of which were issued and outstanding.

All outstanding shares of common stock and preferred stock were duly authorized, validly issued, fully-paid and non-assessable.

##### Common Stock

On March 26, 2004, in accordance with the consent of Novelos's stockholders, Novelos effected a 71.3064 for 1 stock split in the form of a stock dividend of 70.3064 shares for stockholders of record on that date. In addition each then outstanding share of Series A preferred stock was converted into 473.33 shares of common stock and each outstanding share of Series B preferred stock was converted into 586.7233 shares of common stock. All shares of Series A and Series B preferred stock, and accrued dividends thereon, were cancelled upon exchange for common shares. Concurrent with the stock dividend and conversion of Series A and Series B preferred stock, the par value of Novelos's common stock was changed from \$.01 to \$.00001.

*Voting.* Holders of common stock are entitled to one vote per share held of record on all matters to be voted upon by stockholders. The common stock does not have cumulative voting rights. Persons who hold a majority of the outstanding common stock entitled to vote on the election of directors can elect all of the directors who are eligible for election.

*Dividends.* Subject to preferences that may be applicable to the holders of any outstanding shares of preferred stock, the holders of common stock are entitled to receive such lawful dividends as may be declared by the Company's board of directors.

*Liquidation and Dissolution.* In the event of the Company's liquidation, dissolution or winding up, and subject to the rights of the holders of any outstanding shares of preferred stock, the holders of shares of common stock will be entitled to receive *pro rata* all of the remaining assets available for distribution to the Company's stockholders.

*Other Rights and Restrictions.* The Company's charter prohibits the granting of preemptive rights to any of

the stockholders. All outstanding shares are fully paid and nonassessable.

*Listing.* The Company's common stock is traded on the over-the-counter bulletin board.

### **Series A 8% Cumulative Convertible Preferred Stock**

On September 30, 2005 and October 3, 2005, the Company sold 3,000 and 200 units, respectively, each unit consisting of a share of its Series A 8% cumulative convertible preferred stock, par value \$0.00001 per share, and warrants to purchase 303.03 shares of its common stock for a purchase price of \$1,000 per unit. As a result of these transactions, the Company issued 3,000 and 200 shares, respectively, of its Series A preferred stock and warrants to purchase 909,090 and 60,606 shares, respectively, of its common stock. The warrants expire in five years and have an exercise price of \$2.00 per share. The units were sold to four institutional investors, one of which was a previous investor in the Company, for aggregate net proceeds of \$2,864,000.

*Voting Rights:* The Series A preferred stock do not have voting rights. The holders of a majority of the Series A preferred stock, as a class, have the right to nominate one member for election to the Company's board of directors for so long as any shares of Series A preferred stock is outstanding. The preferred stockholders nominated Michael J. Doyle and he has been elected to the Company's board of directors.

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*Dividends:* The Series A preferred stock has a dividend rate of 8% per annum, payable quarterly, which rate increases to 20% per annum on the second anniversary of the date of issuance and upon the occurrence of certain events of default specified in the certificate of incorporation. Such dividends may be paid in cash or in additional shares of the Company's Series A preferred stock. The dividend due for the quarter ended December 31, 2005 in the amount of \$64,000 was paid by the issuance of 64 shares of Series A preferred stock with a deemed value of \$1,000 per share.

*Conversion:* Each share of Series A preferred stock is convertible into 606 shares of common stock. The Series A preferred stock can be converted only to the extent that the Series A stockholder will not, as a result of the conversion, hold in excess of 4.99% of the total outstanding shares of the Company's common stock.

*Antidilution:* Upon the occurrence of a stock split, stock dividend, combination of the Company's common stock into a smaller number of shares, issuance of any of the Company's shares or other securities by reclassification of the Company's common stock, merger or sale of substantially all of the Company's assets, the conversion rate shall be adjusted so that the conversion rights of the Series A preferred stock stockholders will be equivalent to the conversion rights of the Series A preferred stock stockholders prior to such event.

*Redemption:* The Series A preferred stock is not redeemable at the option of the holder. However, the Company may redeem the Series A preferred stock for \$1,200 per share plus any accrued but unpaid dividends upon 30 days' (during which time the Series A preferred stock may be converted) prior written notice if a registration statement has been filed with and declared effective by the Securities and Exchange Commission covering the shares of the Company's common stock issuable upon conversion of the Series A preferred stock.

*Dissolution:* In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company's affairs, the Series A preferred stock will be treated as senior to the Company's common stock. The Series A preferred stockholders will be entitled to receive first, \$1,000 per share and all accrued and unpaid dividends. If, upon any winding up of the Company's affairs, the Company's assets available to pay the holders of Series A preferred stock are not sufficient to permit the payment in full, then all the Company's assets will be distributed to the holders of the Company's Series A preferred stock on a *pro rata* basis.

The Company agreed to file a registration statement with the SEC to register 175% of the shares of common stock issuable upon conversion of the Series A preferred stock and 100% of the common stock issuable upon exercise of the warrants within 30 days of the date of issuance of the Series A preferred stock and cause it to become effective within 120 days of the date of such issuance. The Company is obligated to pay such investors two percent (2%) in cash of the purchase price of any Series A preferred stock not yet converted and the purchase price of shares issued upon conversion of the Series A preferred stock for each month or portion of a month during which the Company is delinquent with respect to these registration obligations. The Company obtained a waiver of this requirement provided that the required registration statement was filed on or before November 16, 2005. The registration statement was filed on November 16, 2005 and was declared effective on December 15, 2005.

In connection with the sale of the Series A preferred stock and warrants, a stockholder, Ms. 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 \$366,000 of issuance costs netted against the proceeds from the issuance of Series A preferred stock as reported in the Statement of Stockholders' Equity (Deficiency).

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

The sale of common stock and warrants described in Note 12, resulted in a further anti-dilution adjustment to the exercise price of the outstanding warrants of the Company. Such adjustment

reduced the exercise price of such warrants from \$1.65 to \$1.35 per share of common stock. This sale also resulted in an anti-dilution adjustment to the conversion price of the Company's Series A preferred stock from \$1.65 to \$1.35.

**Private Placement Registration** — The Company was obligated to file a registration statement covering the shares of common stock issued and issuable in the private placement described in Note 3 within 60 days (October 8, 2005) and to cause the registration statement to be declared effective within 180 days (February 5, 2006) following the last closing date of such sale of Units. The Company is obligated to pay the investors an amount equal to two percent (2%) of the purchase price of the Units purchased by them for each 30-day period following such date that the registration statement has not been filed or declared effective, as the case may be. The Company has obtained waivers of this requirement from approximately 96% of the unit holders and has recorded a liability of \$33,000 as of December 31, 2005 for such payments. If the Company fails to pay any partial liquidated damages in full within seven days after the date payable, the Company will pay interest thereon at a rate of 15% per annum. The registration statement was filed on November 16, 2005 and was declared effective on December 15, 2005.

**Stock Options** — During 2005 and 2004, the Company issued stock options to employees, directors and consultants outside of any formalized plan. These options, of which none have been exercised as of December 31, 2005, 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 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. The options granted in 2005 consist of 1,250,000 at an exercise price of \$0.01 per share and 525,000 with exercise price ranging from \$2.20 to \$3.22 per share and a weighted average exercise price of \$2.63 per share. At December 31, 2005, the weighted average remaining contractual life of the options granted with an exercise price of \$0.01 per share is 8.8 years and the weighted average remaining contractual life of the options granted with exercise prices ranging from \$2.20 to \$3.22 is 9.3 years.

Stock option activity for employees, directors and consultants outside of any formalized plan for the two-year period ended December 31, 2005 is as follows:

	Number of Options	Weighted- Average Exercise Price	Weighted- Average Fair Value
Balance at January 1, 2004	—	\$ —	
Options granted	1,286,000	0.01	\$ 0.003
Options forfeited	(407,222)	0.01	
Balance at December 31, 2004	878,778	0.01	
Options granted	1,775,000	0.78	\$ 0.500
Options forfeited	0	—	
Balance at December 31, 2005	2,653,778	\$ 0.53	
Exercisable at \$0.01 at December 31, 2005	1,855,172	\$ 0.01	
Exercisable at \$2.20 to \$3.22 at December 31, 2005	25,000	\$ 3.22	

Total non-cash compensation expense related to the above-mentioned option grants included in research and development expense was \$67,215 and \$0 for the years ended December 31, 2005 and 2004, respectively. Total non-cash compensation expense related to the above-mentioned option grants included in general and administrative expense was \$45,854 and \$7,868 for the years ended December 31, 2005 and 2004, respectively.

**Stock Option Plan** — The Company's incentive stock option plan (the "Plan"), established in August 2000, provides for grants of options to purchase up to 73,873 post split 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 exercised or cancelled during 2005 or 2004.



There was no stock option activity for the 2000 Stock Option Plan for the two-year period ended December 31, 2005. Options issued and outstanding under this plan are as follows:

	Number of Options	Exercise Prices Range	Weighted- Average Exercise Price	Weighted- Average Remaining Life
Balance December 31, 2004	73,873	\$ .70 - \$7.01	\$ 3.16	
Balance December 31, 2005	73,873	\$ .70 - \$7.01	\$ 3.16	7 Years
Exercisable at \$0.70 to \$1.70 at December 31, 2005	30,942		\$ 0.75	
Exercisable at \$7.01 at December 31, 2005	27,240		\$ 7.01	

**Warrants** — In connection with the sale of units described in Note 3, Novelos issued warrants to purchase 340,000 shares of common stock at \$2.00 per share to finders as compensation. The warrants expire on August 9, 2010, and had a weighted average fair value of \$1.94 per share. All of the warrants are exercisable at December 31, 2005.

The fair value of the warrants is the estimated fair value at the grant date using the Black-Scholes option-pricing model with the following assumptions:

Risk-free interest rate	3.77% - - 4.25%
Expected volatility	80%
Expected lives	5 years
Expected dividend	0

The sale of the Series A preferred stock and warrants described in Note 5, resulted in an anti-dilution adjustment to the exercise price of the outstanding warrants described above. Such adjustment reduced the exercise price of such warrants from \$2.00 to \$1.65 per share of common stock and increased the number of common shares that can be purchased to 412,112.

The sale of common stock and warrants described in Note 12, resulted in a further anti-dilution adjustment to the exercise price of the outstanding warrants described above. Such adjustment reduced the exercise price of such warrants from \$1.65 to \$1.35 per share of common stock and increased the number of common shares that can be purchased to 503,692.

**Reserved Shares** — At December 31, 2005, 73,873 shares of common stock were reserved for issuance upon exercise of options granted under the 2000 plan; 7,482,786 shares of common stock were reserved for issuance upon exercise of other outstanding options and warrants; and up to 3,393,938 shares of common stock were reserved for issuance pursuant to outstanding convertible preferred stock.

## 6. INCOME TAXES

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

	2005	2004
Net operating loss carryforwards	\$ 4,723,000	\$ 2,068,000
Depreciation and amortization	—	8,000
License fee	—	99,000
Research and development expenses	164,000	—
Accrued compensation	—	360,000
Accrued interest	—	320,000
Tax credits	282,000	380,000
Capital loss carryforward	403,000	380,000
Gross deferred tax asset	5,572,000	3,615,000
Valuation allowance	(5,572,000)	(3,615,000)
Net deferred tax asset	\$ —	\$ —

Because of the Company's limited operating history, management has provided a 100% reserve against the Company's net deferred tax assets for all periods. Management provided a valuation allowance due to the uncertainty associated with the utilization of the net operating loss carryforwards in the future. The valuation allowance was \$5,272,000 and \$3,615,000 at December 31, 2005 and 2004, respectively. As of December 31,

2005, the Company had net operating loss carryforwards of approximately \$10,400,000, which begin to expire in 2011 for federal purposes. The Company's research and development credits are available to offset future federal income tax, subject to limitations for alternative minimum tax. The research and development credit carryforwards begin to expire in 2011.

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

Under the provisions of the Internal Revenue Code, certain substantial changes in the Company's ownership may have limited, or may limit in the future, the amount of net operating loss carryforwards which could be utilized annually to offset future taxable income and income tax liabilities. The amount of any limitation is determined based on the Company's value and the long-term tax-exempt rate on the date of an ownership change.

## 7. NOTES PAYABLE TO STOCKHOLDERS

Since inception, Novelos has relied on private investors to fund its operations. Periodically, these investors have advanced monies to Novelos evidenced by notes payable or other written agreements.

Novelos had outstanding unsecured demand notes in the principal amount of \$817,931 at December 31, 2004. These notes bore interest at 6%. At December 31, 2004, these notes included \$521,931 of converted accrued compensation owed to officers, \$100,000 of converted accrued consulting expense owed to a stockholder of Novelos and \$196,000 in cash advances from stockholders. The notes related to converted compensation totaling \$621,931 were forgiven by the stockholders. The remaining notes were repaid through the issuance of stock with a deemed value of \$177,000 and cash of \$19,000. Therefore, there were no unsecured demand notes outstanding at December 31, 2005.

On May 25, 2004, Novelos obtained a bridge loan in the amount of \$100,000 from a stockholder. This loan bore interest at 15% and became due and payable on May 25, 2005. On November 25, 2003, Novelos received \$900,000 from certain stockholders in new secured debt financing through the issuance of "bridge loans," bearing interest at 15% and maturing on May 25, 2005. Novelos also converted an existing \$100,000 secured demand note payable into a bridge loan under the same terms. Under the terms of the loan agreements, the principal amount of the notes could be converted to common stock at \$1.00 per share, at the note holder's option. If the market value of the stock fell

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below \$2.00 per share, the conversion price would be adjusted downward to a price equal to one half of the market value of the stock, with a minimum conversion price of \$.38 per common share. In May 2005 these bridge loans were converted into 1,760,000 shares of common stock in accordance with the loan agreements. Therefore, there were no bridge loans outstanding at December 31, 2005.

In January 2005 Novelos received \$400,000 in the form of a loan from an individual stockholder. This loan bore interest at 6% per annum and was repayable following the closing of one or more equity financings that resulted in aggregate gross proceeds of at least \$5,000,000 to the Company. In December 2004 the Company had received a \$100,000 loan from the same individual stockholder. This loan bore interest at 6% per annum and was repayable upon the successful completion of a proposed "recapitalization" that raised at least \$3 million. In exchange for both of these loans and the individual's commitment to provide additional financing of up to \$500,000 through August 2005, this individual received in January 2005 10,000,000 shares of common stock of Novelos. These loans allowed Novelos to sustain its operations until permanent equity, as described in Note 3, was obtained. The Company closed equity financings by means of the private placements described in Note 3, which resulted in \$5,000,000 in aggregate gross proceeds to the Company. The Company repaid these loans on August 9, 2005 with proceeds from these equity financings. Therefore, there were no loans from stockholders outstanding at December 31, 2005.

## 8. COMPREHENSIVE INCOME (LOSS)

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

## 9. NET LOSS PER SHARE

The following table is the computation of basic and diluted net loss attributable to common stockholders per common share computed in the manner described in Note 2 for the years ended December 31:

	2005	2004
Net loss attributable to common stockholders	\$ (3,053,399)	\$ (952,093)
Weighted average basic and diluted common shares outstanding	21,757,424	3,455,238
Basic and diluted net loss attributable to common stockholders per common share	\$ (0.14)	\$ (0.28)

For the years ended December 31, 2005 and 2004, options to purchase 2,727,651 and 952,651 shares of common stock, respectively, were not included in the computation of diluted net loss per share since their inclusion would be antidilutive. At December 31, 2005 and 2004, warrants to purchase 4,829,008 and 0 shares of common stock, respectively, were not included in the computation of diluted net loss per share since their inclusion would be antidilutive.

## 10. COMMITMENTS

On May 11, 2005, the Company entered into a one-year lease for office space, commencing September 1, 2005, at an annual rent of \$58,000. As of December 31, 2004 and through August 31, 2005, the Company was a tenant-at-will under a prior sublease agreement with a third party. Monthly rent under this agreement was \$3,000. Rent expense was \$45,355 and \$36,100 for the years ended December 31, 2005 and 2004, respectively.

In connection with the restructuring of Novelos' debt described in Note 3, on May 6, 2005, Novelos agreed to reimburse a vendor, after the expiration of the 18-month holding period and the sale of its 50,000 shares of common stock of Novelos, the difference, if any, between the amount realized upon the sale of these shares and \$79,000.

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

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development for an initial term of two years. His annual salary is \$192,000 for the first year and \$195,000 for the second year. 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 the Company's employee fringe benefit plans or programs generally available to the Company's senior executives. The agreement further provides that in the event that the Company terminates Dr. Pazoles without cause or he resigns for good reason (as defined), the Company 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.

## 11. RELATED-PARTY TRANSACTIONS AND COMMITMENTS

Novelos engaged a contract research organization that is a stockholder of the Company to perform research and development services. During the years ended December 31, 2005 and 2004, \$200,611 and \$39,340 of expenses, respectively, were incurred under this arrangement. No amount was payable to the stockholder at December 31, 2005. At December 31, 2004, \$1,185,321 was payable to the stockholder and was included in accounts payable. The amount payable at December 31, 2004 was repaid through the issuance of common stock with a deemed value of \$450,000 and the remaining balance was forgiven by the stockholder.

The Company is obligated to ZAO BAM, a related party, under a royalty and technology transfer agreement. One of the Company's 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 however that such payment be no less than 3% of all license revenues.

Pursuant to an agreement that became effective on May 26, 2005, the Company revised its arrangement with Oxford Group, Ltd. and 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 Company's Chairman of the Board of Directors is president of Oxford Group, Ltd. As described in Note 3, the Company revised the arrangement for future royalty payments, which resulted in the issuance of 2,016,894 shares of common stock, including 907,602 shares to each of two directors of the Company, with an aggregate deemed value of \$2,521,118.

The obligations to ZAO Bam and Oxford Group resulted from their assignment of the exclusive intellectual property and marketing rights to a drug development platform technology, worldwide, excluding Russia and the Commonwealth of Independent States. The royalty payments will be recorded as royalty expense when the obligations are incurred. The payment for any new technologies will be accounted for as purchased technology and either capitalized or expensed at the time of payment, depending on the stage of completion of the related products.

See Notes 5 and 7 in regard to transactions with certain stockholders.

## 12. SUBSEQUENT EVENTS

On January 31, 2006, 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 at an annual salary of \$225,000. He is eligible to receive an annual cash bonus at the discretion of the compensation committee and he is entitled to participate in the Company's employee fringe benefit plans or programs generally available to the Company's senior

executives. The agreement provides that in the event that the Company terminates Mr. Palmin without cause or he resigns for good reason (as defined), the Company will (i) pay Mr. Palmin his pro rata share of the average of his annual bonus paid during the two fiscal years preceding his termination; (ii) pay Mr. Palmin his base salary for 11 months after the date of termination; (iii) continue to provide him benefits for 11 months after the date of termination; and (iv) fifty percent of his unvested stock options will vest. The agreement also contains a non-compete provision, which prohibits Mr. Palmin from competing with the Company for one year after termination of his employment with the Company.

On March 7, 2006, the Company issued 11,154,073 shares of its common stock and warrants to purchase 8,365,542 shares of its common stock pursuant to a securities purchase agreement dated March 2, 2006 with 39 accredited investors for aggregate gross proceeds of \$15,058,005. The warrants are exercisable until March 7, 2011 at an exercise price of \$2.50 per share.

The Company is required to register the resale of the shares of common stock sold in the offering and issuable upon exercise of the warrants. The Company is required to file the registration statement with the Securities and Exchange Commission within 30 days after the closing and use its best efforts to cause the registration statement to be declared effective under the Securities Act of 1933, as amended, within 120 days after the closing of the offering. The Company is required to use its best efforts to keep the registration statement continuously effective under the Securities Act until the earlier of the date when all the registerable securities covered by the registration statement have been sold or the second anniversary of the closing. In the event that the registration statement is not filed or declared effective when due, the Company is obligated to pay the investors liquidated damages in the amount of 1% of the purchase price for each month in which the Company is in default.

Oppenheimer & Co., Inc. acted as the placement agent and Rodman & Renshaw, LLC acted as the sub-placement agent in connection with the offering. The aggregate commissions payable to Oppenheimer and Rodman & Renshaw in connection with the private placement were approximately \$1,000,000. In addition, the Company issued them warrants to purchase 669,244 shares of common stock identical to those sold to the investors.

The sale of common stock and warrants described above resulted in an anti-dilution adjustment to the exercise price of the outstanding warrants of the Company. Such adjustment reduced the exercise price of such warrants from \$1.65 to \$1.35 per share of common stock. This sale also resulted in an anti-dilution adjustment to the conversion price of the Company's Series A preferred stock from \$1.65 to \$1.35.

#### **Item 8. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure**

Not applicable.

#### **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 upon certain assumptions about the likelihood of future events. Because of these and other inherent limitations of control systems, there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions, regardless of how remote.

*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 2005 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.

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### Part III

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

Our current directors and executive officers are:

Name	Age	Position
Simyon Palmin	61	Chairman of the Board
Harry S. Palmin	36	President, Chief Executive Officer, Director
George R. Vaughn	52	Chief Financial Officer and Chief Accounting Officer
M. Taylor Burtis	55	Vice President of Regulatory, Quality and Compliance
Christopher J. Pazoles, Ph.D.	55	Vice President of Research and Development
Mark Balazovsky	68	Director
Michael J. Doyle (1) (2) (3)	47	Director
Sim Fass, Ph.D. (1) (2) (3)	63	Director
David B. McWilliams (2) (3)	62	Director
Howard M. Schneider (1) (3)	62	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 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

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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.

**Mark B. Balazovsky.** Mr. Balazovsky has served as one of our directors since 1996. In 1992, Mr. Balazovsky founded ZAO BAM, a Russian pharmaceutical company carrying out research, development and commercialization of drugs derived from oxidized glutathione, and has served as its general director since then. Since 1993, Mr. Balazovsky has also served as president of the Foundation for Medical-Pharmaceutical Programs. From 1965 to 1975, Mr. Balazovsky served as an engineer and deputy chief designer of the Radio-Technical Research and Development Facility. From 1960 to 1965, he served as an engineer at the Research and Development Facility of long-range communications. Mr. Balazovsky is also chairman of the board of Uyut, a private company. Mr. Balazovsky holds a B.S. and M.S. in radiocommunications and radiobroadcasting from the Institute of Communications, St. Petersburg, Russia.

**Michael J. Doyle.** Mr. Doyle has served as one of our directors since October 2005. Since January 2005, he has 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 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.

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**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.

#### **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. He is eligible to receive an annual cash bonus at the discretion of the compensation committee and he is entitled to participate in our employee fringe benefit plans or programs generally available to our senior executives. The agreement provides that in the event that we terminate Mr. Palmin without cause or he resigns for good reason (as defined below), we will (i) pay Mr. Palmin his pro rata share of the average of his annual bonus paid during the two fiscal years preceding his termination; (ii) pay Mr. Palmin his base salary for 11 months after the date of termination; (iii) continue to provide him benefits for 11 months after the date of termination; and (iv) fifty percent of his unvested stock options will vest. The agreement also contains a non-compete provision, which prohibits Mr. Palmin from competing with us for one year after termination of his employment with us.

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

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

On July 15, 2005, we entered into an employment agreement with Christopher J. Pazoles, 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 \$192,000 for the first year and \$195,000 for the second year. 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. However, 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.

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"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.

On March 21, 2006, our board of directors approved a 5% increase in Dr. Pazoles' base salary. This increase will become effective on April 1, 2006.

#### **Audit Committee**

The board of directors has an audit committee. Mr. Schneider, Mr. Doyle and Mr. Fass serve as members of the audit committee.

#### **Audit Committee Financial Expert**

The board of directors has determined that Mr. Schneider is an "audit committee financial expert." The audit committee financial expert is independent as defined by NASDAQ listing standards.

#### **Code of Conduct**

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

### **ITEM 10. EXECUTIVE COMPENSATION**

#### **Director Compensation**

As of January 1, 2006, we pay our non-employee directors a cash fee of \$4,000 per quarter. The non-

employee directors also receive 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 pay 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 will also reimburse 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. For the year ended December 31, 2005, the chairman of our audit committee was paid \$5,000 in fees. No other director received a cash fee during 2005.

Non-employee directors also receive stock option grants under our option plan. Commencing January 1, 2006, options to purchase 5,000 shares of our common stock are granted to each non-employee director per quarter at the closing price of our common stock on the day immediately prior to the board meeting date. These options vest on a quarterly basis over a two year period.

Mr. Schneider and Mr. Fass each received a non-qualified stock option to purchase 100,000 shares of our common stock in February 2005. Michael J. Doyle received a non-qualified stock option to purchase 100,000 shares of our common stock in October 2005. All options were granted at the fair market value on the date of grant.

### 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 most highly compensated officers (other than our chief executive officer) who served as executive officers during the year ended December 31, 2005 and whose annual compensation exceeded \$100,000 for the year ended December 31, 2005.

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 \$50,000 in the aggregate and constituted less than ten percent of the executive officers' respective total annual salary and bonus.

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### Summary Compensation Table

Name and Principal Position	Year	Annual Compensation	Long-Term Compensation
		Salary (\$)	Securities Underlying Options (#)
Harry S. Palmin	2005	\$ 148,000	400,000
President, Chief Executive Officer	2004	\$ 155,000(1)	330,000
Christopher J. Pazoles, Ph.D.	2005	\$ 118,500(2)	200,000
Vice President of research and Development	2004	\$ 26,000	16,667

(1) Mr. H. Palmin earned \$155,000; however, he forgave \$119,167 of this salary.

(2) On March 21, 2006, our board of directors approved a 5% increase in Dr. Pazoles' base salary. This increase will become effective on April 1, 2006.

*Option grants in last fiscal year.* The following table sets forth certain information about stock options granted during the year ended December 31, 2005 by us to the executive officers named in the summary compensation table.

### Option grants in last fiscal year

Name	Individual Grants			
	Number of securities underlying options granted (#) (1)	% of total options granted to employees in fiscal year	Exercise or base price (\$/share)	Expiration date
Harry S. Palmin	250,000(1)	14%	\$ 0.01	1/31/2015
	150,000(1)	8%	\$ 0.01	3/31/2015
Christopher J. Pazoles, Ph.D.	200,000(2)	11%	\$ 0.01	4/08/2015

(1) These shares initially vested over a two-year period. However, 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.

(2)



These shares vest 25% each six-month period over two years from date of grant.

*Fiscal year-end option table.* The following table sets forth certain information regarding stock options held as of December 31, 2005 by the executive officers named in the summary compensation table.

The value of unexercised in-the-money options is based on a price of \$2.00 per share, the fair market value of our stock on December 30, 2005, minus the per share exercise price, multiplied by the number of shares underlying the option. Actual gains, if any, will depend on the value of the common stock on the date of the sale of the shares.

#### Aggregated option exercises in last fiscal year and fiscal year-end option values

Name	Shares acquired on exercise (#)	Value realized (\$)	Number of securities underlying unexercised options at fiscal year-end		Value of unexercised in-the-money options at fiscal year-end	
			Exercisable (#)	Unexercisable (#)	Exercisable (\$)	Unexercisable (\$)
Harry S. Palmin	—	—	734,752	2,378	\$ 1,458,878	\$ 3,091
Christopher J. Pazoles, Ph.D.	—	—	66,667	150,000	132,667	298,500

#### Equity compensation plans

The following table provides information as of December 31, 2005 regarding shares authorized for issuance under our equity compensation plans, including individual compensation arrangements.

The equity compensation plan approved by our stockholders is our 2000 stock option and incentive plan. We issued options to our directors and consultants that were not approved by our

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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)) (#)
Equity compensation plans approved by stockholders	73,873	\$ 3.16	0
Equity compensation plans not approved by stockholders	2,653,778	\$ 0.53	0
<b>Total</b>	<b>2,727,651</b>	<b>\$ 0.60</b>	<b>0</b>

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

At the close of business on March 21, 2006, there were issued and outstanding 39,130,272 shares of our common stock. The following table provides information regarding beneficial ownership of our common stock as of March 21, 2006 by:

- 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 21, 2006.

Name and Address of Beneficial Owner	Shares Beneficially Owned			
	Outstanding	Right to Acquire	Total	Percentage
Margie Chassman 445 West 23 <sup>rd</sup> Street, Apt. 16E New York, NY 10011	4,012,376	66,666	4,079,042	10.4%
Wood River Trust c/o Michael C. Doyle, co-trustee Stewart Management Company 1410 Nemours Building 1007 Orange Street Wilmington, DE 19801	3,850,000	0	3,850,000	9.8%
Harry S. Palmin	263,818	737,130	1,000,948	2.5%
Simyon Palmin	1,738,939	487,826	2,226,765	5.6%
Christopher J. Pazoles, Ph.D.	0	116,667	116,667	*
Mark Balazovsky	1,452,871	13,334	1,466,205	3.7%
Michael J. Doyle	0	25,000	25,000	*
David McWilliams	0	152,778	152,778	*
Sim Fass	0	100,000	100,000	*
Howard Schneider	0	100,000	100,000	*
All directors and officers as a group (8 persons)	3,455,628	1,732,735	5,188,363	12.7%

\* Less than one percent.

## Item 12. Certain Relationships and Related Transactions

In connection with our private placements of units on May 27, 2005, June 29, 2005, July 29, 2005 and August 9, 2005, we paid Margie Chassman, one of the beneficial owners of in excess of 5% of our common stock, an aggregate of \$52,000 as finders fees.

In connection with our private placement of Series A preferred stock and common stock purchase warrants on September 30, 2005 and October 3, 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.

In May 2005, we issued The Oxford Group 2,016,894 shares of our common stock in exchange for its forgiveness of our obligation to pay The Oxford Group an amount not to exceed \$20 million, limited to 10% of our earnings before interest and taxes. This obligation resulted from the assignment of the exclusive intellectual property and marketing rights to the oxidized glutathione drug development platform technology, worldwide, excluding Russia and other countries comprising the former Soviet Union in 2000. The shares were issued to two of our directors, Simyon Palmin and Mark Balazovsky, and to one of our shareholders. Simyon Palmin is the president of The Oxford Group.

We are obligated to pay The Oxford Group a royalty of 0.8% of our revenue derived from our oxidized glutathione products during the patent life of the products. All or a portion of these payments may be distributed to Simyon Palmin and Mark Balazovsky, two of our directors.

In August 2000, Simyon Palmin loaned us \$271,890 and Harry Palmin loaned us \$250,041. In May 2005, Simyon Palmin forgave this loan plus accrued interest of \$79,618 and Harry Palmin forgave this loan plus accrued interest of \$74,505.

From October 1996 to October 1998, Simyon Palmin loaned us \$99,000. In May 2005, he forgave the accrued interest of \$24,362 related to this loan.

We were indebted to Simyon Palmin in the principal amount of \$300,000 and Harry Palmin in the principal amount of \$100,000. In May 2005, Simyon Palmin converted this debt into 480,000 shares of

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our common stock and Harry Palmin converted this debt into 160,000 shares of our common stock. We also paid Messrs. Palmin an aggregate of \$23,976 and \$11,250 in accrued interest on the debt during 2005 and 2004, respectively.

We acquired our rights to the oxidized glutathione technology from ZAO Bam, a company controlled by one of our directors, Mark Balazovsky. We are required to pay ZAO Bam a 1.2% royalty on our revenue from the oxidized glutathione products during the patent life of the products and \$2 million for each of our products utilizing such technology approved by the FDA 18 months following such approval. Further, if we license any such products to third parties, we are required to pay ZAO Bam 3% of all licensing revenue and an additional 9% of such revenue to the extent it exceeds our developmental costs of the licensed products. However, we are not required to make this payment if we are paying the 1.2% royalty. ZAO Bam also granted us an exclusive right of first option and right of first refusal with respect to all future developments, discoveries or inventions of ZAO Bam.

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. Mr. Blech did not lend us any money. The two loans, 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:

<u>Investor</u>	<u>Number of Shares of Common stock</u>
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. These investors have agreed not to publicly sell their shares of common stock until November 2006 and if they sell their shares in a private transaction, the buyer must also agree not to sell their shares publicly until November 2006.

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.

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Furthermore, Mr. Blech was discharged in bankruptcy in the United States Bankruptcy Court for the Southern District of New York in March 2000.

In November and December 2004, Simyon Palmin loaned us \$19,000. In April and June 2005, we repaid the principal amount and Mr. Palmin forgave the interest of \$465.

In February 2004, we entered into a consulting agreement with David McWilliams, one of our directors, whereby he performed interim chief executive officer services for us. We mutually terminated this consulting agreement in December 2004. As compensation for his services and for joining our board of directors, we granted Mr. McWilliams an option to purchase 152,778 shares of our common stock in April 2004.

During various time periods in 2003 and 2004, payroll and associated payroll taxes were accrued for Simyon Palmin and Harry Palmin in the amounts of \$207,518 and \$152,839, respectively. In May 2005, Messrs. Palmin forgave these amounts.

**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

Exhibit No.	Description	Filed with this Form 10-KSB	Incorporated by Reference		Exhibit No.
			Form	Filing Date	
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	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
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, 2005 and December 31, 2004 were:

	2005	2004
Audit	\$ 80,775	\$ —
Audit Related	9,700	—
Tax	—	—
All Other	—	—
<b>Total</b>	<b>\$ 90,475</b>	<b>\$ —</b>

*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. Stowe & Degon was not engaged to audit the Company's 2004 financial statements until 2005. The Audit fees noted above for the year ended December 31, 2005 were for professional services rendered for the audits of the financial statements of the Company and statutory audits and reviews 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.

*All Other Fees:* All other fees includes assistance with miscellaneous reporting requirements and interpretation of technical issues.

The audit committee considered and determined that the provision of non-audit services provided by Stowe & Degon is compatible with maintaining the firm's independence. In 2005 and 2004, there were no non-audit services 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 & Degen 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 & Degen for 2005 was obtained in reliance on the waiver of the pre-approval requirement afforded in SEC regulations.

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**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 24, 2006

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 24, 2006

By: /s/ George R. Vaughn

George R. Vaughn

Title: Chief Financial Officer

Date: March 24, 2006

By: /s/ Simyon Palmin

Simyon Palmin

Title: Chairman of the Board of Directors

Date: March 24, 2006

By: /s/ Mark B. Balazovsky

Mark B. Balazovsky

Title: Director

Date: March 24, 2006

By: /s/ Michael J. Doyle

Michael J. Doyle

Title: Director

Date: March 24, 2006

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By: /s/ Sim Fass

Sim Fass

Title: Director

Date: March 24, 2006

By: /s/ David B. McWilliams

David B. McWilliams

Title: Director

Date: March 24, 2006

By: /s/ Howard M. Schneider  
Howard M. Schneider  
Title: Director

Date: March 24, 2006

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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 24, 2006

/s/ HARRY S. PALMIN  
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 24, 2006

/s/ GEORGE R. VAUGHN

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, 2005, 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  
Harry S. Palmin  
Chief Executive Officer and President

/s/ GEORGE R. VAUGHN  
George R. Vaughn  
Chief Financial Officer

Dated: March 24, 2006

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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