

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

FORM 10-K

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

For the Fiscal Year Ended: December 31, 2008

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

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

Commission File Number 333-119366

**NOVELOS THERAPEUTICS, INC.**

(Exact name of Registrant as specified in its Charter)

**Delaware**

(State or other jurisdiction  
of incorporation or organization)

**04-3321804**

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

**One Gateway Center, Suite 504**

**Newton, Massachusetts 02458**

(Address of principal executive offices and zip code)

Issuer's telephone number: **(617) 244-1616**

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

**Title of Class**

None

**Name of each exchange on which registered**

Not Applicable

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

**None**

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

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

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

Yes  No

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

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

(Do not check if a smaller reporting company)

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

Yes  No

The aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold, or the average bid and asked price of such common equity, as of June 30, 2008 was \$18,351,337.

As of March 20, 2009 there were 43,975,656 shares of the issuer's common stock outstanding.

NOVELOS THERAPEUTICS, INC.

FORM 10-K

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

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

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## PART I

### Item 1. Business

#### Overview

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

We are a biopharmaceutical company commercializing oxidized glutathione-based compounds for the treatment of cancer and hepatitis. NOV-002, our lead compound, is currently in Phase 3 development for treatment of lung cancer under a Special Protocol Assessment and Fast Track. NOV-002 is also in Phase 2 development for treatment of early-stage breast cancer and chemotherapy-resistant ovarian cancer. In February 2009, Novelos entered into a collaboration with Mundipharma International Corporation Limited (“Mundipharma”) to develop, manufacture and commercialize NOV-002 in Europe and Japan. NOV-205, our second compound, is in Phase 1b development for the treatment of chronic hepatitis C in non-responders. Both compounds have been licensed to Lee’s Pharmaceutical (HK) Ltd. (“Lee’s Pharma”) for development, manufacturing and commercialization in China.

NOV-002, our lead compound, acts together with chemotherapy as a chemoprotectant and a chemopotentiator. Three separate Phase 2 trials demonstrated clinical activity and safety of NOV-002 in combination with chemotherapy in non-small cell lung cancer. In May 2006, we finalized a Special Protocol Assessment (SPA) with the U.S. Food and Drug Administration (FDA) for a single pivotal Phase 3 trial in non-small cell lung cancer and obtained Fast Track designation in August 2006. The primary endpoint of this trial is improvement in median overall survival. We commenced patient enrollment in November 2006 and reached our enrollment target of 840 patients in March 2008. We expect that the results of this trial will be available in late 2009.

NOV-002 is also being developed to treat early-stage breast cancer. In June 2007 we commenced enrollment in a U.S. Phase 2 neoadjuvant breast trial, which is ongoing at The University of Miami and The Medical University of South Carolina to evaluate the ability of NOV-002 to enhance the effectiveness of chemotherapy. As presented at the San Antonio Breast Cancer Symposium in December 2008, six pathologic complete responses occurred in the first 15 women (40%) who have completed chemotherapy and undergone surgery, which is much greater than the less than 20% historical expectation in HER-2 negative patients. Furthermore, patients experienced decreased hematologic toxicities.

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

Based on results to date, we intend to initiate several Phase 2 trials with NOV-002 in cancers as well as chemotherapy-induced anemia. Our ability to initiate these trials in 2009 will depend on available funding, principally from partnering arrangements or the issuance of debt or equity securities.

NOV-205, our second compound, acts as a hepatoprotective agent with immunomodulating and anti-inflammatory properties. Our Investigational New Drug Application for NOV-205 as monotherapy for chronic hepatitis C has been accepted by the FDA. A U.S. Phase 1b clinical trial in patients who previously failed treatment with pegylated interferon plus ribavirin was completed in December 2007. Based on favorable safety results of that trial, we plan to initiate a longer duration, proof-of-concept trial in the event we obtain the additional funding necessary for that purpose. However, there can be no assurance that such funding will be available.

Both compounds have completed clinical trials in humans and have been approved for use in Russia, where they were originally developed. We own all intellectual property rights worldwide (excluding Russia and other states of the former Soviet Union) related to compounds based on oxidized glutathione, including NOV-002 and NOV-205.

Our intellectual property portfolio of issued patents includes six U.S. patents, two European patents and one Japanese patent. Overall, we have filed more than thirty patent applications worldwide, with coverage including composition of matter, method of use and manufacturing. We believe that the breadth of our intellectual property will allow us to expand our product pipeline by claiming and commercializing additional compounds that are based on oxidized glutathione.

### **Business Strategy**

Our primary objective is to fully exploit our proprietary scientific and intellectual property portfolio in oxidized glutathione-based therapeutics. NOV-002, currently in Phase 3 development in the U.S. and Europe, has demonstrated an excellent safety and efficacy profile in Russia as a combination treatment with chemotherapy for many different cancers particularly in non-small cell lung cancer, an indication with large and growing unmet medical needs. For example, according to a 1996-1998 Russian non-small cell lung cancer trial, NOV-002 increased the one-year survival rate from 17% to 63% ( $p < 0.01$ ) when used in combination with chemotherapy. This result represented an 80% improvement over the U.S. survival rate of 35% that results from the current standard of care. Positive results in a controlled U.S.-based Phase 1/2 non-small cell lung cancer study completed in August 2005 were consistent with the positive results obtained in earlier Russian clinical studies.

We intend to obtain a U.S. marketing partner for NOV-002 after the non-small cell lung cancer Phase 3 clinical trial results are available (expected late-2009). In February 2009, we entered into a collaboration with Mundipharma under which we granted Mundipharma exclusive rights to develop, manufacture and commercialize NOV-002 in Europe and Japan. In December 2007 we entered into a collaboration agreement with Lee's Pharma (which is 30% owned by Sigma-Tau Group) under which we granted Lee's Pharma exclusive rights to develop, manufacture and commercialize NOV-002 for cancer and NOV-205 for hepatitis in China, Hong Kong, Macau and Taiwan.

In legacy Russian clinical studies, NOV-205 has demonstrated the ability to substantially decrease the serum viral load of patients with either hepatitis B or C as well as to restore normal liver function as evidenced by blood biochemical markers. In the U.S., both hepatitis B and C are relatively large markets, but hepatitis B is reasonably well served. Therefore, we intend to concentrate clinical development efforts on chronic hepatitis C, which we believe represents a more direct path to regulatory approval and has the potential to provide patients with an improved therapy regimen compared to those currently available. In December 2007, based on a favorable safety profile, we concluded a U.S. Phase 1b clinical trial for the treatment of chronic hepatitis C in non-responders. We plan to commence a proof-of-concept trial in the event we obtain the additional funding necessary for that purpose. However, there can be no assurance that such funding will be available. In the event that we are able to complete this trial successfully, we intend to explore licensing opportunities with third parties for the development, manufacture and commercialization of NOV-205.

### **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 NOV-205, and associated metabolic enzymes. It is considered within the medical research community 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.

Protein S-glutathionylation attendant to cellular redox changes at the cell surface and intracellularly are known to affect a variety of critical cell functions, including:

- Cell signaling pathways
- Cytoskeletal structure/function
- Protein folding/stability

- Calcium homeostasis
- Energy metabolism
- Redox homeostasis

In addition, changes in the ratio of reduced to oxidized forms of glutathione (GSH/GSSG) can modulate protein phosphorylation in signal pathways, further amplifying the impact of redox changes on cell function. Examples of redox-sensitive gene expression include regulation of gene transcription factors such as NFκB and AP-1, which have been shown to have pivotal roles in the regulation of many genes involved in immune and inflammatory responses, including cytokines and growth factors. The activities of other immune/inflammation regulatory proteins are also sensitive to GSH/GSSG (e.g., mitogen-activated protein kinases, or MAPKs) as are elements of the cytoskeleton (e.g., actin) that control interaction and communication between the cells and their surrounding environment (e.g., extracellular matrix) and cell surface proteins (e.g., protein disulfide isomerase, or PDI), which have been implicated in the modulation of tumor cell invasiveness and metastasis.

Importantly, it has been shown that oxidized glutathione itself is capable of causing protein glutathionylation, leading to changes in cell signaling pathway function. Thus, GSSG, or NOV-002, added to cells can result in a rapid, transient alteration of cell surface or intracellular redox state by shifting the equilibrium towards the formation of mixed disulfides with protein thiols. This is accompanied by glutathionylation of cellular proteins and alterations in phosphorylation of signaling proteins (e.g., MAPKs, AKT, JAK2, STAT5).

Findings with NOV-002 and NOV-205 in animals and humans are consistent with a variety of known effects of modulating cellular redox status (e.g., blood precursor cell proliferation (hematopoiesis)), modulation of cytokine and growth factor production (including those known to control production of blood cells), immune system modulation, and cytoskeletal alterations that may impact the migration and invasiveness of tumor cells. Identification of the precise molecular targets of the GSSG component of NOV-002 and NOV-205, which would account for their clinical effects, is the subject of ongoing study.

### **Products in Development**

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

#### NOV-002

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

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

In the U.S., NOV-002 is in Phase 3 development for treatment of non-small cell lung cancer under a Special Protocol Assessment with Fast Track designation. NOV-002 is approved in Russia for general medicinal usage as an immunostimulant in combination with chemotherapy and antimicrobial therapy, and specifically for indications such as tuberculosis and psoriasis. Efficacy and excellent safety have been demonstrated in trials with 390 patients in Russia across numerous types of cancer including non-small cell lung cancer, breast cancer, ovarian cancer, colorectal cancer and pancreatic cancer. Since the Russian Ministry of Health approval in 1998, it is estimated that NOV-002 has been administered to over 10,000 patients.

According to the American Cancer Society, about 1.44 million U.S. men and women were expected to be diagnosed with cancer in 2008. Over 566,000 U.S. cancer patients were expected to die in 2008, 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. According to the American Cancer Society, approximately 215,000 people were expected to be diagnosed with lung cancer in 2008 in the U.S., with approximately 162,000 deaths. According to the American Cancer Society, approximately 1,500,000 new cases of lung cancer were expected worldwide in 2007 and approximately 1,350,000 deaths were projected from lung cancer in 2007. According to a Rodman and Renshaw report dated December 2006, the pharmaceutical market for treating lung cancer was approximately \$800 million per year in the U.S. and \$1.8 billion worldwide, expected to grow to greater than \$8 billion worldwide by 2011. Non-small cell lung cancer accounts for more than 80% of lung cancer. Only about 15% of non-small cell lung cancer patients are diagnosed early enough to be eligible for surgery.

Platinum-based chemotherapy regimens are standard first-line treatment for advanced non-small cell lung cancer patients, since these patients are not eligible for surgery. Carboplatin and paclitaxel are the most common combination therapy in the U.S., while cisplatin and gemcitabine are more common in Europe. During treatment, patients continue to be subject to serious adverse effects. According to December 2003 Credit Suisse First Boston and UBS reports and Phase 3 clinical trials conducted as recently as 2005, the one-year survival rate for first-line therapy is typically only about 35%, median survival is approximately 8.5 months and the objective tumor response (defined as greater than 50% tumor shrinkage) rate is about 20%. Overall, fewer than 5% of advanced non-small cell lung cancer patients survive five years. Docetaxel is approved for use as second-line treatment of non-small cell lung cancer. New dosing regimens with existing cytotoxic drugs are likely to provide only incremental improvements in efficacy and/or safety, and are very expensive. Similarly, emerging targeted biologic therapies, such as Astra Zeneca's IRESSA®, OSI's TARCEVA®, Genentech's AVASTIN® and ImClone's ERBITUX®, may offer some benefit for certain patient subpopulations, but overall efficacy has remained low. Moreover, there are significant safety concerns and the costs to manufacture are very high. Thus, there is an unmet need for efficacious, and cost-effective, treatments for non-small cell lung cancer, particularly for late-stage patients.

NOV-002 can be distinguished from other drugs for non-small cell lung cancer on the market or in development because, based on available data, NOV-002 possesses the key attributes of safety, improved recovery from chemotherapy toxicity, potentiation of chemotherapy (increased survival rates and better anti-tumor effects) and low cost of manufacture. In a controlled randomized U.S. Phase 1/2 clinical trial, advanced non-small cell lung cancer patients treated with NOV-002 in combination with paclitaxel and carboplatin demonstrated improved objective tumor response (69% of the patients treated with NOV-002 plus chemotherapy had 50% or greater tumor shrinkage versus only 33% of the patients treated with chemotherapy alone,  $p < 0.05$ ) and higher tolerance of chemotherapy versus the control group ( $p < 0.01$ ). In a controlled randomized Russian trial, when used in combination with cisplatin-based chemotherapy, NOV-002 increased the one-year survival of advanced non-small cell lung cancer patients from 17% to 63%,  $p < 0.01$  (versus 35% typical in the U.S.). On the basis of U.S. and Russian data, we believe that NOV-002 may be used in combination with first-line chemotherapy treatments and may be complementary to second-line and recently emerging third-line products. Furthermore, we believe that NOV-002 may have utility in all stages of non-small cell lung cancer and in other solid tumor types as well.

The Russian non-clinical and clinical data set (which includes clinical safety and efficacy data, extensive animal toxicology studies and a comprehensive chemistry and manufacturing package) was accepted by the FDA as the basis of an 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 trial was to demonstrate safety, detect trends towards efficacy, compare routes of administration and support initiation of a Phase 3 trial. We finalized a Special Protocol Assessment with the FDA in May 2006 for a single pivotal Phase 3 trial in advanced non-small cell lung cancer in combination with first-line chemotherapy, and obtained Fast Track designation in August 2006. The primary endpoint of this trial is improvement in median overall survival, and we reached our enrollment target of 840 patients in March 2008. We expect the pivotal Phase 3 trial to conclude in late 2009.

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

- Group A: NOV-002, administered intravenously and intramuscularly, in combination with cytotoxic chemotherapy (carboplatin with paclitaxel);
- Group B: NOV-002, administered intravenously and subcutaneously, in combination with cytotoxic chemotherapy; and

- 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 (i.e., complete or partial tumor shrinkage) showed the following:

- Six out of 13 (46%) patients in Group A demonstrated objective tumor response;
- 11 out of 16 (69%) patients in Group B demonstrated objective tumor response; and
- five out of 15 (33%) in Group C, the control group, demonstrated objective tumor response.

The difference in objective tumor response between Groups B and Group C (69% versus 33%) was statistically significant ( $p=0.044$ ).

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

In St. Petersburg, Russia, a multi-center, randomized, open-label study was conducted during 1996-1998 to evaluate the safety and efficacy of NOV-002 in patients with advanced non-small cell lung cancer. In this study, patients receiving NOV-002 in combination with chemotherapy had a significantly increased one-year survival rate over the control group (63% treated group vs. 17% control,  $p<0.01$ ). In addition, ability to conduct daily activities, quality of life, tolerance to chemotherapy, hematologic parameters and kidney/liver toxicity markers appeared to improve or normalize in patients receiving NOV-002 in comparison to those in the control group. As in the U.S. Phase 1/2 trial, patients receiving NOV-002 were able to receive significantly more cycles of chemotherapy ( $p<0.01$ ). Importantly, no NOV-002-associated adverse effects were observed. In addition, in an independent study in advanced non-small cell lung cancer study of similar design in Moscow in 2000, 52% of the patients treated with NOV-002 survived for at least one year.

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

We are also developing NOV-002 to treat early-stage breast cancer in combination with chemotherapy. These patients are often treated with chemotherapy to minimize surgical intervention. A U.S. Phase 2 trial to evaluate the ability of NOV-002 to enhance the effectiveness of such chemotherapy while diminishing side-effects commenced in June 2007 at the Medical University of South Carolina (MUSC) Hollings Cancer Center. MUSC is collaborating on the trial with the Braman Family Breast Cancer Institute at the Sylvester Comprehensive Care Center University of Miami Miller School of Medicine (Sylvester). Alberto Montero, MD, Assistant Professor of Medicine at Sylvester, is the Principal Investigator.

Breast cancer remains a serious public health concern throughout the world. According to the American Cancer Society, approximately 183,000 women in the US were expected to be diagnosed with breast cancer in 2008, and approximately 41,000 were expected to die from the disease. Neoadjuvant or preoperative systemic chemotherapy is commonly employed in patients with locally advanced stage III breast cancer and in some patients with stage II tumors. Administration of neoadjuvant chemotherapy reduces tumor size, thus enabling breast conservation surgery in patients who otherwise would require a mastectomy. Furthermore, several studies have shown that pathologic complete response (pCR) following neoadjuvant chemotherapy is associated with a significantly higher probability of long-term survival. However, only a minority of patients with HER-2/neu negative breast cancer achieve a pCR with standard chemotherapy.

The primary objective of this open-label, single-arm trial is to determine if preoperative administration of NOV-002 in combination with eight cycles of chemotherapy (four of doxorubicin and cyclophosphamide followed by four of docetaxel) results in an appreciably higher pCR rate than expected with this same chemotherapeutic regimen alone. According to the Simon two-stage trial design, if four or more pCRs were observed in the first stage of the trial (19 women), enrollment would continue into the second stage, for a total of 46 women.

As of December 2008, 19 women have been enrolled, with six pCRs already demonstrated in the first 15 women (40%) who have completed chemotherapy and undergone surgery, which is much greater than the less than 20% historical expectation in HER-2 negative patients. Furthermore, NOV-002 was associated with decreased hematologic toxicities and with decreased use of growth factors (Erythropoiesis-Stimulating Agents, which are potentially harmful) relative to historical experience. Detailed results were presented at the San Antonio Breast Cancer Symposium in December 2008. Having achieved an interim efficacy target even earlier than expected, the trial is moving into the second stage. Full enrollment of 46 patients is expected in the third quarter 2009, with trial conclusion anticipated in mid-2010.

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

According to the American Cancer Society, approximately 22,000 U.S. women were expected to be diagnosed with ovarian cancer in 2008 and 15,500 women are expected to die from it. According to a Rodman and Renshaw report dated December 2006, the pharmaceutical market for treating ovarian cancer was estimated to be \$300 million per year. There is a lack of effective treatment, particularly in the case of patients who are chemotherapy refractory (those who do not respond to chemotherapy) or resistant (those who relapse shortly after receiving chemotherapy).

First-line chemotherapy treatment is the same in ovarian cancer as in non-small cell lung cancer. Standard first-line treatment for ovarian cancer patients is carboplatin and paclitaxel chemotherapy in combination. Doxorubicin and topotecan alternate as second- and third-line chemotherapy treatments.

Refractory/resistant ovarian cancer patients have a very poor prognosis because they are faced with inadequate therapeutic options. According to a Lehman Brothers report dated September 2002, response rates from second-line treatments, such as doxorubicin and topotecan, are typically less than 12%. Once a woman's ovarian cancer is defined as platinum resistant, the chance of having a partial or complete response to further platinum therapy is typically less than 10%, according to an article by A. Berkenblit in the June 2005 issue of the *Journal of Reproductive Medicine*.

In Russia in 1998, twenty ovarian cancer case studies were analyzed. All of these patients were treated for three cycles with platinum-based chemotherapy but continued with progressive disease according to qualitative assessments and Cancer Antigen 125. The patients were then treated with NOV-002 for three to four weeks, followed by three more cycles of the same platinum-based chemotherapy (to which they previously failed to respond to) in conjunction with NOV-002. The observed 40% objective tumor response rate across these case studies is much higher than would ordinarily be expected in patients who had previously been non-responsive to platinum-based chemotherapy. 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 (i.e., no tumor growth).

In a U.S. Phase 2 chemotherapy-resistant ovarian cancer trial at Massachusetts General Hospital and Dana-Farber Cancer Institute from July 2006 through May 2008, NOV-002 (plus carboplatin) slowed progression of the disease in 60% of evaluable patients (9 out of 15 women). The median progression-free survival was 15.4 weeks, almost double the historical control of 8 weeks. These results were presented at the American Society of Clinical Oncology in May 2008. We plan to initiate a second Phase 2 trial in chemotherapy-resistant ovarian cancer patients in the event we obtain the additional funding necessary for that purpose. However, there can be no assurance that such funding will be available.

#### 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, a September 2006 publication of *Nature Reviews Drug Discovery* estimated the current global market to be in excess of \$3 billion per year, and estimated it would grow to more than \$8 billion by 2010. The Centers for Disease Control and Prevention (CDC), estimated that in 2003, 3.9 million persons in the U.S. were infected with hepatitis C, and 2.7 million persons in the U.S. had chronic infection. The CDC further estimated that there are approximately 30,000 new hepatitis C infections and 8,000-10,000 hepatitis C-related 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 had been treated in previous anecdotal studies. After relatively short treatment periods (one to two months), the drug was shown to eliminate the serum viral load in hepatitis B patients and to decrease viral load below detection in 40-60% of hepatitis C subjects. Importantly, these reductions were largely maintained during one to three months of post-treatment follow-up. In addition, NOV-205 was shown to improve 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 or anemia). Furthermore, these drugs are effective in only a fraction of the patient population and are very expensive. Other new products for hepatitis C, beyond variations of ribavirin and interferon (e.g., HCV protease inhibitors), are at early stages of development and could potentially be used in combination with NOV-205.

On the basis of the clinical and pre-clinical data package underlying Russian approval of NOV-205, in combination with U.S. chemistry and manufacturing information, we filed an Investigational New Drug Application with the FDA for NOV-205 as monotherapy in chronic hepatitis C in March 2006. The FDA accepted our Investigational New Drug Application in April 2006, and a U.S. Phase 1b trial in patients who previously failed treatment with pegylated interferon plus ribavirin commenced in September 2006 and was completed in December 2007. Based on the favorable safety data obtained from this trial, we plan to initiate a longer duration proof-of-concept trial in the event we obtain the additional funding necessary for that purpose. However, there can be no assurance that such funding will be available.

#### **Non-clinical Research Program**

Our non-clinical research program is aimed at gaining a better understanding of the mechanism(s) of action of our oxidized glutathione-based drug products and adding to the Russian non-clinical data 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 a funded research collaboration with the laboratory of Kenneth Tew, Ph.D., D.Sc., Chairman of the Department of Cell and Molecular Pharmacology and Experimental Therapeutics at The Medical University of South Carolina. Dr. Tew is also chairman of our Scientific Advisory Board and a stockholder. The general objectives of this research program are to add to the understanding of NOV-002 and NOV-205 as drug products, particularly with respect to their molecular and cellular mechanisms of action and to facilitate the design and execution of clinical studies and the interactions with the FDA and the scientific community. Funded research collaborations have been conducted or are underway at other academic/scientific institutions including Harvard/Massachusetts General Hospital, the Wistar Institute, the University of Massachusetts Medical Center and the University of Miami to further elaborate *in vitro* and *in vivo* mechanisms of drug action that may underlie the clinical therapeutic profiles of NOV-002 and NOV-205.

#### **Manufacturing**

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

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

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

### **Intellectual Property**

We own all intellectual property rights worldwide (excluding Russia and other states of the former Soviet Union) related to both clinical-stage compounds (i.e., NOV-002 and NOV-205) and other pre-clinical compounds based on oxidized glutathione. We have six issued patents in the U.S. We also have two issued patents in Europe and one in Japan. Overall, we have filed more than 30 patent applications worldwide. Novelos has entered into a collaboration with Mundipharma to develop, manufacture and commercialize NOV-002 in Europe and Japan. NOV-205, our second compound, is in Phase 1b development for the treatment of chronic hepatitis C in non-responders. Both compounds have been licensed to Lee's Pharma for development, manufacture and commercialization in China.

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

### **Employees**

As of March 1, 2009 we had eight full-time employees. We believe our relationships with our employees are good.

### **Regulation**

The manufacturing and marketing of NOV-002 and NOV-205 and our related research and development activities are subject to regulation for safety, efficacy and quality by numerous governmental authorities in the United States and other countries. We anticipate that these regulations will apply separately to each drug and compound in our drug therapy technology. We believe that complying with these regulations will involve a considerable level of time, expense and uncertainty.

In the United States, drugs are subject to rigorous federal regulation and, to a lesser extent, state regulation. The Federal Food, Drug and Cosmetic Act and other federal and state statutes and regulations govern, among other things, the testing, manufacture, safety, efficacy, labeling, storage, recordkeeping, approval, advertising and promotion of our drugs. Drug development and approval within this regulatory framework is difficult to predict and will take a number of years and involve the expenditure of substantial resources.

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

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

- FDA approval of the New Drug Application or Biologic Drug License Application prior to any commercial sale or shipment of the product.

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

Whether or not FDA approval has been obtained, approval of a product by regulatory authorities in foreign countries must be obtained prior to the commencement of commercial sales of the drug in such countries. The requirements governing the conduct of clinical trials and drug approvals vary widely from country to country, and the time required for approval may be longer or shorter than that required for FDA approval. Although there are some procedures for unified filings for certain European countries, in general, each country has its own procedures and requirements.

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

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

**The report from our independent registered public accounting firm included in this annual report on Form 10-K indicates that there is substantial doubt about whether we will be able to continue as a going concern.**

The report from our independent registered public accounting firm included with this annual report on Form 10-K indicates that factors exist that raise substantial doubt about our ability to continue as a going concern. We believe that our funds at December 31, 2008, together with the net proceeds of approximately \$9,200,000 from the sale of shares of our Series E preferred stock in February 2009 (see Note 10 to the financial statements), are adequate to continue operations at budgeted levels into late 2009. Our ability to execute our operating plan beyond late 2009 is dependent on our ability to obtain additional capital (including through the sale of equity and debt securities and by entering into collaborative arrangements for licensing rights in North America) to fund our development activities. We plan to pursue these alternatives during 2009, but there can be no assurance that we will obtain such additional capital. We anticipate that clinical results from our Phase 3 clinical trial in non-small cell lung cancer will be available in late 2009. The primary endpoint of the trial is increased median overall survival, to be measured following the occurrence of 725 events (deaths). The timing and content of those clinical results may affect our projected cash requirements and our ability to obtain capital. Furthermore, continuing adverse conditions in the capital markets globally may impair our ability to obtain funding in a timely manner. We are continuously evaluating measures to further reduce our costs to preserve existing capital. If we are unable to obtain sufficient additional funding, we will be required, beginning in late 2009, to scale back our administrative activities and clinical development programs, including the Phase 3 clinical development of our lead drug candidate, NOV-002, or we may have to cease our operations entirely.

##### **We may have difficulty raising additional capital for our future operations.**

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

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

- the number of potential products and technologies in development;
- continued progress and cost of our research and development programs;
- progress with pre-clinical studies and clinical trials, including the results of our Phase 3 clinical trial expected in late 2009;

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

We may consume available resources more rapidly than currently anticipated, resulting in the need for additional funding sooner than expected. We may seek to raise any necessary additional funds through the issuance of warrants, equity or debt financings or executing collaborative arrangements with corporate partners or other sources, which may be dilutive to existing stockholders or otherwise have a material effect on our current or future business prospects. In addition, in the event that additional funds are obtained through arrangements with collaborative partners or other sources, we may have to relinquish economic and/or proprietary rights to some of our technologies or products under development that we would otherwise seek to develop or commercialize by ourselves. If adequate funds are not available, we may be required to significantly reduce or refocus our development efforts with regard to our drug compounds. Currently, while we believe that we have available cash sufficient to meet our working capital requirements into late 2009, assuming our expense levels do not exceed our current plan and that we maintain a vendor payment cycle that is consistent with, or slightly longer than, our past practice. However, there can be no assurance that these assumptions are correct. Furthermore, if we do not generate revenues or raise additional capital, we will not be able to sustain our operations at existing levels once our current funds are exhausted.

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

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

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

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

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

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

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

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

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

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

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

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

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

In order to obtain regulatory approvals, we must demonstrate that each drug is safe and effective for use in humans and functions as a therapeutic against the effects of a disease or other physiological response. To date, studies conducted in Russia involving our NOV-002 and NOV-205 products have shown what we believe to be promising results. However, 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 in the United States. While we have experienced positive preliminary results in the earlier stage trials for certain indications in the U.S., there can be no assurance that we can demonstrate that these products are safe or effective in advanced clinical trials. We are also not able to give assurances that the results of the tests already conducted can be repeated or that further testing will support our applications for regulatory approval. As a result, our drug and technology research program may be curtailed, redirected or eliminated at any time. If this occurs, we may have to cease our operations entirely.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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



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

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

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

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

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

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

We are conducting a portion of our clinical trial activities in both Western and Eastern Europe. We anticipate that approximately 40% of the remaining Phase 3 clinical trial budget of approximately \$4 million will be incurred in Euros. Significant depreciation in the value of the U.S. Dollar against principally the Euro could adversely affect our ability to complete the trials, particularly if we are unable to redirect funding or raise additional funds. Since the timing and amount of foreign-denominated payments are uncertain and dependent on a number of factors, it is difficult to cost-effectively hedge the potential exposure. Therefore, to date, we have not entered into any foreign currency hedges to mitigate the potential exposure.

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

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

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

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

**If users of our products are unable to obtain adequate reimbursement from third-party payers, or if new restrictive legislation is adopted, market acceptance of our products may be limited, which could limit revenue we might otherwise generate from sales of our products.**

The continuing efforts of government and insurance companies, health maintenance organizations and other payers of healthcare costs to contain or reduce costs of health care may adversely affect our ability to generate future revenues and achieve profitability, including by limiting the future revenues and profitability of our potential customers, suppliers and collaborative partners. For example, in certain foreign markets, pricing or profitability of prescription pharmaceuticals is subject to government control. In the U.S., federal and state governments have focused and will likely continue to focus, on healthcare reform, including initiatives directed at lowering the total cost of health care and the cost of prescription pharmaceuticals, as well as other reforms 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 (HMOs). Third-party payers are increasingly challenging the prices charged for medical drugs and services. Also, the trend toward managed health care in the United States and the concurrent growth of organizations such as HMOs that could control or significantly influence the purchase of healthcare services and drugs, as well as legislative proposals to reform health care or reduce government insurance programs, may all result in lower prices for or rejection of our drugs. The cost containment measures that healthcare payers and providers are instituting and the effect of any healthcare reform could materially harm our ability to operate profitably.

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

Our success will depend to a significant degree on the continued services of 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 resources reasonably necessary to comply with evolving standards, which may result in increased general and administrative expense and a diversion of management time and attention from revenue-generating activities to compliance activities. In our annual report for the fiscal year ending December 31, 2009 we will be required to include an attestation report of our independent registered public accounting firm on internal control over financial reporting which may result in additional costs.

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

Our directors, officers and holders of our Series E preferred stock beneficially own, in the aggregate, approximately 56% of our outstanding voting shares, subject to certain blocking provisions that may be waived with 61 days notice. The interests of our current officers, directors and Series E investors may differ from the interests of other stockholders. Further, our current officers, directors and Series E investors may have the ability to significantly affect the outcome of all corporate actions requiring stockholder approval, including the following actions:

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

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

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

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

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

- selling or otherwise disposing of all or substantially all of our assets, (and in the case of licensing any material intellectual property) or entering into a merger or consolidation with another company unless we are the surviving corporation, the Series E Preferred Stock remains outstanding and there are no changes to the rights and preferences of the Series E Preferred Stock;
- redeeming or repurchasing any capital stock other than Series E Preferred Stock; or
- incurring any new debt for borrowed money in excess of \$500,000.

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

**We were unable to pay dividends to our preferred stockholders on June 30, 2008, September 30, 2008 and December 31, 2008, we do not expect to be able to pay dividends to preferred stockholders on March 31, 2009, and we may be unable to pay dividends to preferred stockholders when due in future periods.**

As a result of continuing losses during 2008, we did not have legally available funds for the payment of dividends under Delaware corporate law. Accordingly, we were unable to pay dividends totaling \$1,689,323 that were accrued in respect of the Series D and Series C preferred stock as of December 31, 2008. All outstanding shares of our Series D preferred stock (and rights associated therewith, including accrued but unpaid dividends) were exchanged for shares of Series E preferred stock on February 11, 2009. Our ability to pay cash dividends on stated future dividend payment dates will be dependent on a number of factors including the timing of future financings and the amount of net losses in future periods. We anticipate that future dividends on Series E preferred stock will be paid by issuing shares of common stock or additional shares of Series E preferred stock, which will result in additional dilution to existing shareholders. We anticipate that the accrued unpaid dividend on our Series C preferred stock will continue to accumulate.

**Item 2. Properties**

We lease our executive office in Newton, Massachusetts. Our office consists of approximately 3,000 square feet and is rented for approximately \$7,700 per month. This lease expires in August 2009 and we anticipate obtaining an extension on the lease. 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, 2008.

**PART II**

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

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

<b>Fiscal Year 2007</b>	<b>High</b>	<b>Low</b>
First quarter	\$ 1.24	\$ 0.85
Second quarter	1.40	0.82
Third quarter	0.90	0.45
Fourth quarter	0.67	0.43

<b>Fiscal Year 2008</b>		High	Low
First Quarter	\$	0.82	\$ 0.43
Second Quarter		0.64	0.44
Third Quarter		0.54	0.35
Fourth Quarter		0.49	0.19

On December 31, 2008 there were 101 holders of record of our common stock. This number does not include stockholders for whom shares were held in a “nominee” or “street” name.

We have not declared or paid any cash dividends on our common stock and do not anticipate declaring or paying any cash dividends in the foreseeable future. We are prohibited from paying any dividends on common stock as long as any shares of our Series E preferred stock are outstanding or as long as there are accumulated but unpaid dividends on our Series C preferred stock. We currently expect to retain future earnings, if any, for the development of our business.

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

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

#### **2009**

On February 11, 2009 we sold 200 shares of our Series E convertible preferred stock and warrants to purchase 9,230,769 shares of common stock, receiving gross proceeds of \$10,000,000 and paid approximately \$800,000 in fees and expenses. In addition, 413.5 shares of Series D convertible preferred stock and accumulated dividends thereon were exchanged for 445.442875 shares of Series E convertible preferred stock.

#### **2008**

On August 15, 2008, pursuant to a securities purchase agreement dated August 14, 2008, we sold 4,615,384 shares of our common stock to two related accredited investors at \$0.65 per share, receiving aggregate gross proceeds of approximately \$3,000,000.

On April 11, 2008, we issued 113.5 shares of our Series D convertible preferred stock and warrants to purchase 4,365,381 shares of our common stock to institutional investors. We received gross proceeds of \$5,675,000 and paid approximately \$200,000 in fees and expenses. In connection with this transaction, 300 shares of Series B convertible preferred stock were exchanged for 300 shares of Series D convertible preferred stock. Following the closing of the transaction we paid dividends of \$740,280 to preferred stockholders.

On January 16, 2008, we issued 100,000 shares of our common stock to Howard Schneider, one of our directors, upon the exercise of his stock option at a price of \$0.01 per share for total consideration of \$1,000, pursuant to an option granted in February 2005.

#### **2007**

On May 2, 2007, we issued 300 shares of our Series B convertible preferred stock and warrants to purchase 7,500,000 shares of our common stock to institutional investors. We received gross proceeds of \$15,000,000 and paid approximately \$1,300,000 in fees and expenses. We also issued warrants to purchase 900,000 shares of our common stock to Rodman & Renshaw LLC and VFT Special Ventures, Ltd. (an affiliate of Emerging Growth Equities) as partial consideration for their placement agent services in connection with the financing.

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

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

## Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

### Overview

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

NOV-002, our lead compound, is currently in Phase 3 development for non-small cell lung cancer. NOV-002 is intended for use in combination with chemotherapy to act as a chemoprotectant and an immunomodulator. Three separate Phase 2 trials demonstrated clinical activity and safety of NOV-002 in combination with chemotherapy in non-small cell lung cancer. In May 2006, we finalized a Special Protocol Assessment (SPA) with the FDA for a single pivotal Phase 3 trial in advanced non-small cell lung cancer in combination with first-line chemotherapy, and received Fast Track designation in August 2006. The primary endpoint of this trial is improvement in median overall survival. Patient enrollment commenced in November 2006 and targeted enrollment was reached in March 2008. We believe that results for this trial will be available in late 2009.

NOV-002 is also being developed to treat early-stage breast cancer. In June 2007 we commenced enrollment in a U.S. Phase 2 neoadjuvant breast trial, which is ongoing at The University of Miami and The Medical University of South Carolina to evaluate the ability of NOV-002 to enhance the effectiveness of chemotherapy. As presented at the San Antonio Breast Cancer Symposium (December 2008) six pathologic complete responses occurred in the first 15 women (40%) who have completed chemotherapy and undergone surgery, which is much greater than the less than 20% historical expectation in HER-2 negative patients. Furthermore, patients experienced decreased hematologic toxicities.

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

Based on results to-date, in 2009 we intend to initiate several Phase 2 trials with NOV-002 in cancers as well as chemotherapy-induced anemia. Our ability to initiate these trials, and the timing of such trials, will depend on available funding, principally from collaborative arrangements or the issuance of debt or equity securities.

NOV-205, our second compound, is intended for use as a hepatoprotective agent with immunomodulating and anti-inflammatory properties. Our Investigational New Drug Application for NOV-205 as monotherapy for chronic hepatitis C has been accepted by the FDA. A U.S. Phase 1b clinical trial in patients who previously failed treatment with pegylated interferon plus ribavirin was completed in December 2007. Based on favorable safety results of that trial, we plan to initiate a longer duration, proof-of-concept trial in the event we obtain the additional funding necessary for that purpose. However, there can be no assurance that such funding will be available.

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

### Results of Operations

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

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

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

**Years Ended December 31, 2008 and 2007**

**Revenue.** During the year ended December 31, 2008 we recognized \$33,000 in license fees in connection with our collaboration with Lee's Pharmaceutical (HK) Ltd. ("Lee's Pharma"), which commenced in December 2007. Under the terms of our agreement with Lee's Pharma, the Company received an upfront license fee of \$500,000 in March 2008 and is entitled to receive up to \$1,700,000 in future milestone payments upon the completion of development and marketing milestones by Lee's Pharma. The \$500,000 initial payment received is being amortized over the estimated term of the agreement, 15 years. During the year ended December 31, 2008, we also recognized \$93,000 in grant revenue related to a grant received from the U.S. Department of Health and Human Services. The related costs are included as a component of research and development expense.

**Research and Development.** Research and development expense for the year ended December 31, 2008 was \$14,527,000, compared to \$17,428,000 for the year ended December 31, 2007. The \$2,901,000, or 17%, decrease in research and development expense was due to a combination of factors. In March 2008, we reached the enrollment target for our Phase 3 clinical trial of NOV-002, and an increasing number of patients completed their treatment regimen throughout 2008. As a result, certain clinical costs have leveled out or declined. The cost of the chemotherapy drug to be provided to patients at clinical sites in Europe decreased by \$1,669,000. Clinical investigator expenses, which are affected by the number of patients that remain on treatment, decreased by \$952,000. Drug manufacturing and distribution costs (including storing and shipping chemotherapy drug) decreased by \$777,000. Salaries and related costs increased \$385,000, principally from the hiring of additional personnel in late 2007 and early 2008 as well as salary increases that were effective at the beginning of 2008. Overhead costs such as travel and postage increased by \$130,000.

**General and Administrative.** General and administrative expense for the year ended December 31, 2008 was \$2,190,000, compared to \$2,866,000 for the year ended December 31, 2007. The \$676,000, or 24%, decrease in general and administrative expense was due principally to a \$799,000 decrease in accrued expense for potential liquidated damages associated with registration rights agreements. We had accrued an estimate for such damages in 2007 and those damages were then waived in connection with the sale of Series D Preferred Stock during 2008 (see Note 4). Stock-based compensation also decreased by \$53,000 in the year ended December 31, 2008 compared to the prior year. These decreases were partially offset by a \$144,000 increase in professional fees, principally those related to partnering and investor activities and a \$32,000 increase in salary, directors fees and overhead.

**Interest Income.** Interest income for the year ended December 31, 2008 was \$131,000 compared to \$730,000 for the same period in 2007. This decrease is a result of lower cash balances as well as a decline in prevailing interest rates.

**Preferred Stock Dividends.** During the year ended December 31, 2008 we paid cash dividends to Series B and C preferred stockholders of \$740,000 and accrued \$1,689,000 of dividends due to our Series C and D preferred stockholders. The accrued dividends were not paid because we did not have legally available funds for the payment of dividends under Delaware corporate law. In February 2009, all outstanding shares of Series D preferred stock and associated rights, including accrued dividends totaling \$1,597,000 (\$1,396,000 of which had accrued at December 31, 2008) were exchanged for 445.442875 shares of Series E preferred stock. During the year ended December 31, 2008 we also recorded deemed dividends to preferred stockholders totaling \$4,417,000. This amount represents the value attributed to the reduction in exercise and conversion prices of the warrants and preferred stock issued in May 2007 in connection with the financing that occurred in April 2008, as described in Note 4 to the financial statements.

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

During the year ended December 31, 2007 we paid cash dividends to Series A and C preferred stockholders of \$261,000 and dividends of \$563,000 to Series B preferred stockholders. An additional \$337,000 of dividends were declared and accrued but not paid to Series B preferred stockholders. During the year ended December 31, 2007 we also recorded deemed dividends to preferred stockholders totaling \$9,003,000 (including a payment of \$40,000 made upon the exchange of Series A for Series C preferred shares). This amount represents the value attributed to the beneficial conversion feature of the Series B convertible preferred stock of \$7,824,000 and the fair value of warrants and cash of \$1,179,000 transferred to the former Series A preferred stockholders in connection with the exchange of their shares for shares of Series C preferred stock that were subordinated to the Series B shares. The deemed dividends and cash dividends have been included in the calculation of net loss attributable to common stockholders of \$29,721,000, or \$0.76 per share, for the year ended December 31, 2007. The deemed dividends and cash dividends are excluded from our net loss (from operating activities) of \$19,557,000 or \$0.50 per share, for the year ended December 31, 2007.

### **Liquidity and Capital Resources**

We have financed our operations since inception through the sale of securities and the issuance of debt (which was subsequently paid off or converted into equity). As of December 31, 2008, we had \$1,262,000 in cash and equivalents.

During the year ended December 31, 2008, approximately \$17,332,000 in cash was used in operations, primarily due to a net loss of \$16,451,000, a net decrease of \$1,827,000 in accounts payable and accrued liabilities and a \$3,000 increase in other current assets. Deferred revenue increased by \$467,000 as a result of a payment received in connection with a licensing arrangement (net of revenue recognized under the arrangement during the year). The cash impact of the loss was offset by non-cash stock-based compensation expense of \$453,000 and depreciation, amortization and loss on disposal of fixed assets totaling \$23,000. During the year ended December 31, 2008, cash of approximately \$1,136,000 was provided by investing activities resulting from the release of restrictions on \$1,185,000 of cash that had been previously restricted in connection with a standby letter of credit, offset by payments of \$49,000 to purchase fixed assets.

During the year ended December 31, 2008, we received net proceeds of \$5,470,000 from the sale of our Series D Preferred stock (see Note 4 to the financial statements), net proceeds of \$2,987,000 from the sale of common stock and proceeds of \$1,000 from the exercise of stock options. We paid dividends totaling \$740,000 to our Series B and Series C preferred stockholders.

We believe that we have adequate funds at December 31, 2008, including the proceeds from the sale of Series E preferred stock in February 2009 (see Note 10 to the financial statements), to continue operations at budgeted levels into late 2009. Our ability to execute our operating plan beyond late 2009 is dependent on our ability to obtain additional capital (including through the sale of equity and debt securities and by entering into collaborative arrangements for licensing rights in North America) to fund our development activities. We plan to pursue these alternatives during 2009, but there can be no assurance that we will obtain the additional capital necessary to fund our business beyond late 2009. We anticipate that clinical results from our Phase 3 clinical trial in non-small cell lung cancer will be available in late 2009. The primary endpoint of the trial is increased median overall survival, to be measured following the occurrence of 725 events (deaths). The timing and content of those clinical results may impact our projected cash requirements and our ability to obtain capital. Furthermore, continuing adverse conditions in the capital markets globally may affect our ability to obtain funding in a timely manner. We are continuously evaluating measures to further reduce our costs to preserve existing capital. If we are unable to obtain sufficient additional funding, we will be required, beginning in late 2009, to scale back our administrative activities and clinical development programs, including the Phase 3 clinical development of our lead drug candidate, NOV-002, or we may be required to cease operations entirely.



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

*Stock-based Compensation.* We account for stock-based compensation in accordance with Statement of Financial Accounting Standards (SFAS) 123R, *Share-Based Payment*, or SFAS 123R. SFAS 123R requires measurement of the cost of employee services received in exchange for an award of equity instruments based on the grant-date fair value of the award. That cost is recognized over the period during which an employee is required to provide service in exchange for the award, the requisite service period (usually the vesting period). We account for transactions in which services are received from non-employees in exchange for equity instruments based on the fair value of such services received or of the equity instruments issued, whichever is more reliably measured, in accordance with SFAS 123 and the Emerging Issues Task Force (EITF) Issue 96-18, *Accounting for Equity Instruments That Are Issued to Other than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*, or EITF 96-18.

Accounting for equity instruments granted or sold by us under SFAS 123R and EITF 96-18 requires fair-value estimates of the equity instrument granted or sold. If our estimates of the fair value of these equity instruments are too high or too low, our expenses may be over- or understated. For equity instruments granted or sold in exchange for the receipt of goods or services, we estimate the fair value of the equity instruments based on consideration of factors that we deem to be relevant at that time.

**ITEM 8. 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, 2008 and 2007 and the related statements of operations, redeemable preferred stock and stockholders' deficiency, and cash flows for the years then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Novelos Therapeutics, Inc. as of December 31, 2008 and 2007 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.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has incurred continuing losses in the development of its products and has a stockholders' deficiency at December 31, 2008. These factors raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in this regard are described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ Stowe & Degon LLC

Westborough, Massachusetts  
March 17, 2009

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

	<b>December 31, 2008</b>	<b>December 31, 2007</b>
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and equivalents	\$ 1,262,452	\$ 9,741,518
Restricted cash	—	1,184,702
Prepaid expenses and other current assets	129,785	133,281
Total current assets	1,392,237	11,059,501
<b>FIXED ASSETS, NET</b>	58,451	32,809
<b>DEPOSITS</b>	15,350	15,350
<b>TOTAL ASSETS</b>	<b>\$ 1,466,038</b>	<b>\$ 11,107,660</b>
<b>LIABILITIES, REDEEMABLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIENCY</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable and accrued liabilities	\$ 4,653,912	\$ 6,372,478
Accrued compensation	240,639	349,412
Accrued dividends	1,689,322	337,500
Deferred revenue – current	33,333	—
Total current liabilities	6,617,206	7,059,390
<b>DEFERRED REVENUE – NONCURRENT</b>	433,333	—
<b>COMMITMENTS AND CONTINGENCIES</b>		
<b>REDEEMABLE PREFERRED STOCK:</b>		
Series D convertible preferred stock, \$0.00001 par value; 420 shares designated; 413.5 shares issued and outstanding at December 31, 2008 (liquidation preference \$22,070,562) (Note 4)	13,904,100	—
Series B convertible preferred stock, \$0.00001 par value; 400 shares designated; 300 shares issued and outstanding at December 31, 2007 (Note 4)	—	9,918,666
	13,904,100	9,918,666
<b>STOCKHOLDERS' DEFICIENCY:</b>		
Preferred stock, \$0.00001 par value; Series C 8% cumulative convertible preferred stock; 272 shares issued and outstanding at December 31, 2008 and 2007 (liquidation preference \$3,557,760 and \$3,264,000 at December 31, 2008 and 2007, respectively) (Note 4)	—	—
Common stock, \$0.00001 par value; 150,000,000 shares authorized; 43,975,656 shares issued and outstanding at December 31, 2008; 39,260,272 shares issued and outstanding at December 31, 2007	440	392
Additional paid-in capital	40,204,112	37,370,959
Accumulated deficit	(59,693,153)	(43,241,747)
Total stockholders' deficiency	(19,488,601)	(5,870,396)
<b>TOTAL LIABILITIES, REDEEMABLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIENCY</b>	<b>\$ 1,466,038</b>	<b>\$ 11,107,660</b>

*See notes to financial statements.*

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

	<b>Year Ended December 31,</b>	
	<b>2008</b>	<b>2007</b>
REVENUE	\$ 125,968	\$ —
<b>COSTS AND EXPENSES:</b>		
Research and development	14,526,619	17,427,804
General and administrative	2,190,366	2,866,383
Total costs and expenses	16,716,985	20,294,187
LOSS FROM OPERATIONS	(16,591,017)	(20,294,187)
<b>OTHER INCOME:</b>		
Interest income	130,611	729,922
Miscellaneous	9,000	7,130
Total other income	139,611	737,052
NET LOSS	(16,451,406)	(19,557,135)
PREFERRED STOCK DIVIDENDS	(2,092,102)	(1,161,120)
PREFERRED STOCK DEEMED DIVIDENDS	(4,417,315)	(9,003,083)
NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS	\$(22,960,823)	\$(29,721,338)
<b>BASIC AND DILUTED NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS PER COMMON SHARE</b>	<b>\$ (0.56)</b>	<b>\$ (0.76)</b>
WEIGHTED AVERAGE SHARES USED IN COMPUTING BASIC AND DILUTED NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS PER COMMON SHARE	41,100,883	39,247,532

*See notes to financial statements.*

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

	REDEEMABLE PREFERRED STOCK		Common Stock		Series A Cumulative Convertible Preferred Stock		Series C Cumulative Convertible Preferred Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity (Deficiency)
	Series B and D Convertible Preferred Stock		Shares	Amount	Shares	Amount	Shares	Amount			
	Shares	Amount									
BALANCE AT JANUARY 1, 2007	—	\$ —	39,235,272	\$ 392	3,264	\$ —	—	\$ —	\$ 34,294,154	\$ (23,684,612)	\$ 10,609,934
Exercise of stock options	—	—	25,000	—	—	—	—	—	250	—	250
Compensation expense associated with options issued to employees	—	—	—	—	—	—	—	—	343,233	—	343,233
Compensation expense associated with options issued to non-employees	—	—	—	—	—	—	—	—	160,057	—	160,057
Issuance of Series B redeemable convertible preferred stock and warrants, net of issuance costs of \$1,306,949	300	17,743,051	—	—	—	—	—	—	3,774,385	—	3,774,385
Beneficial conversion feature on Series B redeemable convertible preferred stock	—	(7,824,385)	—	—	—	—	—	—	7,824,385	—	7,824,385
Deemed dividend related to the accretion of beneficial conversion feature on Series B redeemable convertible preferred stock	—	—	—	—	—	—	—	—	(7,824,385)	—	(7,824,385)
Retirement of Series A preferred stock and issuance of Series C preferred stock	—	—	—	—	(3,264)	—	272	—	—	—	—
Issuance of common stock purchase warrants in connection with exchange of preferred stock	—	—	—	—	—	—	—	—	1,138,698	—	1,138,698
Deemed dividend recorded in connection with exchange of Series A for Series C convertible preferred stock	—	—	—	—	—	—	—	—	(1,178,698)	—	(1,178,698)
Dividends paid on preferred stock	—	—	—	—	—	—	—	—	(823,620)	—	(823,620)
Dividends accrued on preferred stock	—	—	—	—	—	—	—	—	(337,500)	—	(337,500)
Net loss	—	—	—	—	—	—	—	—	—	(19,557,135)	(19,557,135)
<b>BALANCE AT DECEMBER 31, 2007</b>	<b>300</b>	<b>9,918,666</b>	<b>39,260,272</b>	<b>392</b>	<b>—</b>	<b>—</b>	<b>272</b>	<b>—</b>	<b>37,370,959</b>	<b>(43,241,747)</b>	<b>(5,870,396)</b>
Exercise of stock options	—	—	100,000	1	—	—	—	—	999	—	1,000
Compensation expense associated with options issued to employees	—	—	—	—	—	—	—	—	395,194	—	395,194
Compensation expense associated with options issued to non-employees	—	—	—	—	—	—	—	—	58,133	—	58,133
Issuance of common stock in a private placement	—	—	4,615,384	47	—	—	—	—	2,986,691	—	2,986,738
Issuance of Series D redeemable convertible preferred stock and warrants, net of issuance costs of \$205,328	113.5	4,167,080	—	—	—	—	—	—	1,302,592	—	1,302,592
Adjustment to record the carrying value of Series D redeemable convertible preferred stock at market value on the date of sale	—	(181,646)	—	—	—	—	—	—	181,646	—	181,646
Fair value of reduction in conversion and exercise price of Series B redeemable convertible preferred stock and warrants	—	3,876,912	—	—	—	—	—	—	722,049	—	722,049
Accretion of deemed dividend associated with the reduction of conversion and exercise prices on Series B redeemable convertible preferred stock and warrants	—	(3,876,912)	—	—	—	—	—	—	(722,049)	—	(722,049)
Dividends paid on preferred stock	—	—	—	—	—	—	—	—	(402,780)	—	(402,780)
Dividends accrued on preferred stock	—	—	—	—	—	—	—	—	(1,689,322)	—	(1,689,322)
Net loss	—	—	—	—	—	—	—	—	—	(16,451,406)	(16,451,406)
<b>BALANCE AT DECEMBER 31, 2008</b>	<b>413.5</b>	<b>\$ 13,904,100</b>	<b>43,975,656</b>	<b>\$ 440</b>	<b>—</b>	<b>\$ —</b>	<b>272</b>	<b>\$ —</b>	<b>\$ 40,204,112</b>	<b>\$ (59,693,153)</b>	<b>\$ (19,488,601)</b>

See notes to financial statements.

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

	<b>Year Ended December 31,</b>	
	<b>2008</b>	<b>2007</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$(16,451,406)	\$(19,557,135)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	16,889	15,367
Loss on disposal of fixed assets	6,472	—
Stock-based compensation	453,327	503,290
Change in:		
Prepaid expenses and other current assets	3,496	161,714
Accounts payable and accrued liabilities	(1,718,566)	5,284,437
Accrued compensation	(108,773)	124,028
Deferred revenue	466,666	—
Cash used in operating activities	<u>(17,331,895)</u>	<u>(13,468,299)</u>
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Purchases of fixed assets	(49,003)	(24,366)
Change in restricted cash	1,184,702	470,549
Deposits	—	(4,475)
Cash provided by investing activities	<u>1,135,699</u>	<u>441,708</u>
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from issuance of common stock, net	2,986,738	—
Proceeds from issuance of Series B convertible preferred stock, net	—	13,693,051
Proceeds from issuance of Series D convertible preferred stock, net	5,469,672	—
Dividends paid to preferred stockholders	(740,280)	(823,620)
Payment to preferred stockholders in connection with exchange of shares (1)	—	(40,000)
Proceeds from exercise of stock option	1,000	250
Cash provided by financing activities	<u>7,717,130</u>	<u>12,829,681</u>
DECREASE IN CASH AND EQUIVALENTS	(8,479,066)	(196,910)
CASH AND EQUIVALENTS AT BEGINNING OF YEAR	9,741,518	9,938,428
CASH AND EQUIVALENTS AT END OF YEAR	<u>\$ 1,262,452</u>	<u>\$ 9,741,518</u>
<b>SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING AND FINANCING ACTIVITIES</b>		
Deemed dividends on preferred stock	<u>\$ 4,417,315</u>	<u>\$ 8,963,083</u>
Dividends accrued but not paid to preferred stockholders	<u>\$ 1,689,322</u>	<u>\$ 337,500</u>
Issuance of warrants to preferred stockholders	<u>\$ 1,302,592</u>	<u>\$ 3,774,385</u>
Issuance of warrants to placement agents	<u>\$ —</u>	<u>\$ 768,621</u>
Exchange of Series B for Series D preferred stock	<u>\$ 9,918,666</u>	<u>\$ —</u>

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

*See notes to financial statements.*

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

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

Novelos Therapeutics, Inc. (“Novelos” or the “Company”) is a drug development company focused on the development of therapeutics for the treatment of cancer and hepatitis. Novelos owns exclusive worldwide intellectual property rights (excluding Russia and other states of the former Soviet Union) related to certain clinical compounds and other pre-clinical compounds based on oxidized glutathione.

The Company 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.

These financial statements have been prepared on the basis that the Company will continue as a going concern. The Company is devoting substantially all of its efforts toward the research and development of its products and has incurred operating losses since inception. The process of developing products will continue to require significant research and development, non-clinical testing, clinical trials and regulatory approval. The Company expects that these activities, together with general and administrative costs, will result in continuing operating losses for the foreseeable future. The Company believes that it has adequate funds, including the proceeds from the sale of preferred stock in February 2009, to continue operations into late 2009. The Company’s ability to execute its operating plan beyond late 2009 is dependent on its ability to obtain additional capital (including through the sale of equity and debt securities and by entering into collaborative arrangements for licensing rights in North America) to fund its development activities. The Company plans to actively pursue these alternatives during 2009, but there can be no assurance that it will obtain the additional capital necessary to fund its business beyond the end of 2009. The Company anticipates that the results from its Phase 3 clinical trial in non-small cell lung cancer will be available in late 2009. The primary endpoint of the trial is increased median overall survival, to be measured following the occurrence of 725 events (deaths). The timing and content of those clinical results may impact the Company’s projected cash requirements and its ability to obtain capital. Furthermore, continuing difficult conditions in the capital markets globally may adversely affect the ability of the Company to obtain funding in a timely manner. The Company is continuously evaluating measures to further reduce costs to preserve existing capital. If the Company is unable to obtain sufficient additional funding, it will be required, beginning in late 2009, to scale back its administrative activities and clinical development programs including the Phase 3 clinical development of its lead drug candidate, NOV-002.

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

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

**Use of Estimates** — The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue and expenses and disclosure of contingent assets and liabilities. Management’s estimates are based primarily on relevant historical experience and other assumptions that management believes to be reasonable. Estimates include those for unbilled contract service fees such as amounts due to clinical research organizations, clinical investigators and contract manufacturers. Actual results could differ from those estimates.

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

**Restricted Cash** — Restricted cash at December 31, 2007 consisted of cash pledged as security on a letter of credit agreement with a bank. The letter of credit expired in 2008.



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

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

**Stock-based Compensation** — The Company applies the fair-value recognition provisions of Statement of Financial Accounting Standards (SFAS) No. 123(R), *Share-Based Payment* (SFAS 123R) in accounting for stock-based compensation. The Company accounts for share-based payments granted to non-employees in accordance with Emerging Issues Task Force (EITF) No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*. See Note 6 for a further description of the Company's accounting policies related to stock-based compensation.

**Revenue Recognition** — Revenue is recognized when persuasive evidence of an arrangement exists, the price is fixed and determinable, delivery has occurred, and there is reasonable assurance of collection. Upfront payments received in connection with technology license or collaboration agreements are recognized over the estimated term of the related agreement. Milestone payments received in connection with license or collaboration agreements are recognized upon completion of the applicable milestones, provided that there are no further delivery obligations associated with the milestone. Royalty revenue will be recognized upon the receipt of royalty reports from third parties.

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

**Income Taxes** — The Company uses the liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on temporary differences between financial statement and tax basis of assets and liabilities and net operating loss and credit carryforwards using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. Valuation allowances are established when it is more likely than not that some portion of the deferred tax assets will not be realized.

The Company adopted FIN 48, "*Accounting for Uncertainty in Income Taxes – an Interpretation of FASB Statement No. 109*", on the first day of its 2007 fiscal year. The implementation had no effect on the Company's reported financial position or results of operations in the year ended December 31, 2008.

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

**Fair Value of Financial Instruments** — SFAS No. 107, *Disclosures About Fair Value of Financial Instruments*, requires disclosure of the fair value of certain financial instruments. The Company's financial instruments consist of cash equivalents, accounts payable, accrued expenses and redeemable preferred stock. The estimated fair value of the redeemable preferred stock, determined on an as-converted basis, was \$14,950,000 and \$8,850,000 at December 31, 2008 and 2007, respectively. The estimated fair value of the remaining financial instruments approximates their carrying value due to their short-term nature.

**Concentration of Credit Risk** — Financial instruments that subject the Company to credit risk consist of cash and equivalents on deposit with financial institutions. The Company's excess cash is invested on an overnight basis in securities that are fully collateralized. When funds are not invested overnight, cash is on deposit in a non-interest-bearing transaction account that is fully covered by FDIC deposit insurance until December 31, 2009.

**New Accounting Pronouncements** — In June 2008 the Emerging Issues Task Force reached a consensus on Issue No. 07-5 *Determining Whether an Instrument (or Embedded Feature) is Indexed to an Entity's Own Stock* (EITF 07-5). EITF 07-5 establishes a framework for determining whether certain freestanding and embedded instruments are indexed to a company's own stock for purposes of evaluation of the accounting for such instruments under existing accounting literature. EITF 07-5 is effective for fiscal years beginning after December 15, 2008. The Company is currently evaluating the impact of this standard on its financial statements and anticipates that effective January 1, 2009, the fair value of certain outstanding warrants containing anti-dilution provisions, issued in 2005 and 2006, will be required to be reclassified from equity to a liability and revalued on a quarterly basis, with changes in fair value recognized as a component of earnings or loss.

In December 2007 the Emerging Issues Task Force reached a consensus on Issue No. 07-1 *Accounting for Collaborative Arrangements* (EITF 07-1). EITF 07-1 defines collaborative arrangements and establishes reporting requirements for transactions between participants in a collaborative arrangement and between participants in the arrangement and third parties. EITF 07-1 is effective for fiscal years beginning after December 15, 2008. The Company is currently evaluating the impact of this standard on its financial statements and related disclosures.

In June 2007, the Emerging Issues Task Force reached a consensus on Issue No. 07-3 *Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities* (EITF 07-3). EITF 07-3 requires that nonrefundable advance payments for goods or services used or rendered for future research and development activities be deferred and capitalized and subsequently recognized as an expense as the goods are delivered or the related services are performed. EITF 07-3 is effective for fiscal years beginning after December 15, 2007 and interim periods within those fiscal years with no earlier application permitted. This standard had no effect on the Company's reported financial position or results of operations in the year ended December 31, 2008.

In February 2007, the Financial Accounting Standards Board (FASB) issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities – Including an Amendment to FASB Statement No. 115* (SFAS 159). SFAS 159 permits entities to choose to measure many financial instruments and certain other items at fair value. SFAS 159 is effective for financial statements issued for fiscal years beginning after November 15, 2007. This standard had no effect on the Company's reported financial position or results of operations in the year ended December 31, 2008.

### 3. FIXED ASSETS

Fixed assets consisted of the following at December 31:

	<u>2008</u>	<u>2007</u>
Office and computer equipment	\$ 73,261	\$ 51,652
Computer software	25,896	7,896
Leasehold improvements	4,095	4,095
Total fixed assets	103,252	63,643
Less accumulated depreciation and amortization	(44,801)	(30,834)
Fixed assets, net	<u>\$ 58,451</u>	<u>\$ 32,809</u>

### 4. STOCKHOLDERS' EQUITY (DEFICIENCY)

#### *2005 Issuance of Common Stock –*

From May 27, 2005 through August 9, 2005, the Company completed a private offering of securities, exempt from registration under the Securities Act of 1933, in which it sold to accredited investors 4,000,000 shares of common stock and issued 2,000,000 common stock warrants (initially exercisable at \$2.25 per share) for net cash proceeds of approximately \$3,715,000 (net of cash issuance costs of approximately \$735,000) and conversion of debt and accrued interest of \$550,000. In connection with the private placement, the Company also issued 125,000 shares of common stock to placement agents with a value of approximately \$156,000 and issued 340,000 common stock warrants to placement agents and finders at an initial exercise price of \$2.00 per share. Pursuant to anti-dilution provisions, the number of warrants issued to investors, placement agents and finders as well as the exercise price of the warrants have changed. On August 11, 2008, warrants to purchase 6,923,028 shares of preferred stock at an exercise price of \$.65 per share expired unexercised. These warrants were issued in 2005 to the purchasers of shares of common stock. At December 31, 2008, warrants to purchase 1,046,143 shares of common stock at an exercise price of \$0.65 per share held by placement agents remain outstanding.

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

On September 30, 2005 and October 3, 2005, the Company sold, in a private placement, a total of 3,200 shares of its Series A 8% Cumulative Convertible Preferred Stock (“Series A Preferred Stock”) with a stated value of \$1,000 per share and 969,696 common stock warrants for net proceeds of \$2,864,000, net of issuance costs of \$336,000. See “Issuance of Series C Preferred Stock” below for a description of the exchange of Series A Preferred Stock that occurred in May 2007. The warrants issued in connection with the sale of Series A Preferred Stock had anti-dilution provisions that provided for adjustments to the exercise price upon the occurrence of certain events. Pursuant to these anti-dilution provisions the exercise price of the warrants was subsequently adjusted and as of December 31, 2008, the warrants are exercisable at \$0.65 per share.

### *2006 Issuance of Common Stock –*

On March 7, 2006, the Company completed a private offering of securities, exempt from registration under the Securities Act of 1933, in which it sold to accredited investors 11,154,073 shares of common stock at \$1.35 per share and warrants to purchase 8,365,542 shares of its common stock exercisable at \$2.50 per share for net cash proceeds of approximately \$13,847,000 (net of issuance costs of approximately \$1,211,000, including placement agent fees of approximately \$1,054,000). In connection with the private placement, the Company issued 669,244 common stock warrants (exercisable at \$2.50 per share) to the placement agents. Pursuant to anti-dilution provisions, as a result of subsequent financings, as of December 31, 2008, the number of shares of common stock issuable upon exercise of the warrants issued to investors and placement agents was 11,267,480 and the exercise price was \$2.00 per share. On February 11, 2009, the number and exercise price of the warrants was adjusted further. See Note 10.

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

On May 2, 2007, pursuant to a securities purchase agreement with accredited investors dated April 12, 2007 (the “Purchase Agreement”), as amended May 2, 2007, the Company sold 300 shares of a newly created series of preferred stock, designated “Series B Convertible Preferred Stock”, with a stated value of \$50,000 per share (the “Series B Preferred Stock”), and issued warrants (the “Series B Warrants”) to purchase 7,500,000 shares of common stock for an aggregate purchase price of \$15,000,000. The Series B Preferred Stock was initially convertible into 15,000,000 shares of common stock at \$1.00 per share. During 2008, the Company declared and paid \$675,000 in dividends to Series B stockholders (\$2,250 per share). During 2007, the Company declared dividends totaling \$900,000 (\$3,000 per share) to Series B preferred stockholders; \$562,500 (\$1,875 per share) of that amount was paid in cash during 2007. See “Issuance of Series D Preferred Stock” below for a description of the exchange of Series B Preferred Stock that occurred on April 11, 2008.

The common stock purchase warrants issued to these purchasers are exercisable for an aggregate of 7,500,000 shares of the Company’s common stock at an initial exercise price of \$1.25 per share and had an initial expiration date of May 2012. The warrant exercise price and/or number of warrants is subject to adjustment only for stock dividends, stock splits or similar capital reorganizations so that the rights of the warrant holders after such event will be equivalent to the rights of warrant holders prior to such event. If there is an effective registration statement covering the shares underlying the warrants and the volume weighted average price (“VWAP”), as defined in the warrant, of the Company’s common stock exceeds \$2.50 for 20 consecutive trading days, then on the 31<sup>st</sup> day following the end of such period any remaining warrants for which a notice of exercise was not delivered will no longer be exercisable and will be converted into a right to receive \$.01 per share. See “Issuance of Series D Preferred Stock” and Note 10 below for descriptions of amendments to the Series B Warrants that were executed on April 11, 2008 and February 11, 2009.

The Company and these purchasers entered into a registration rights agreement in connection with the closing of the sale of the Series B Preferred Stock. The registration rights agreement was subsequently amended on April 11, 2008 and on February 11, 2009. The agreement, as amended, requires the Company to use its best efforts to keep a registration statement covering 12,000,000 shares of common stock continuously effective under the Securities Act until the earlier of the date when all securities covered by the registration statement have been sold or the second anniversary of the closing. In the event the Company does not fulfill the requirements of the registration rights agreement, the Company is required to pay to the investors liquidated damages equal to 1.5% per month of the aggregate purchase price of the preferred stock and warrants until the requirements have been met. The 12,000,000 shares of common stock were included on a registration statement that became effective on April 28, 2008.

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

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

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

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

The Series C Preferred Stock had an annual dividend rate of 8% until October 1, 2008 and thereafter has an annual dividend rate of 20%. The dividends are payable quarterly. Such dividends shall be paid only after all outstanding dividends on the Series D Preferred Stock (with respect to the current fiscal year and all prior fiscal years) shall have been paid to the holders of the Series D Preferred Stock. During 2008, the Company paid \$65,280 in dividends on Series C Preferred Stock (\$240 per share). During 2007, the Company declared and paid dividends totaling \$173,355 (\$637 per share) to Series C preferred stockholders. As of December 31, 2008, there were accumulated unpaid dividends of \$294,000 (\$1,080 per share) on Series C Preferred Stock. The conversion price is subject to adjustment for stock dividends, stock splits or similar capital reorganizations. The Series C Preferred Stock does not have voting rights and is redeemable only at the option of the Company upon 30 days’ notice at a 20% premium plus any accrued but unpaid dividends. In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company’s affairs, the Series C Preferred stock will be treated as senior to Novelos common stock. After all required payments are made to holders of Series D Preferred Stock, the Series C Preferred stockholders will be entitled to receive first, \$12,000 per share and all accrued and unpaid dividends. If, upon any winding up of the Company’s affairs, the Company’s remaining assets available to pay the holders of Series C preferred stock are not sufficient to permit the payment in full, then all of the Company’s assets will be distributed to the holders of Series C preferred stock (and any remaining holders of Series D preferred stock as may be required) on a pro rata basis.

***Adjustment of Series C Preferred Stock Conversion Price***

In connection with the sale of Series D Preferred Stock described below, the conversion price of the Series C Preferred Stock was reduced to \$0.65 and became convertible into 5,021,537 shares of common stock.

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

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

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

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

### *Terms of Series D Preferred Stock*

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

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

The Series D Preferred Stock has an annual dividend rate of 9%, payable semi-annually on June 30 and December 31. Such dividends may be paid in cash or in registered shares of the Company's common stock at the Company's option, subject to certain conditions.

The Series D Preferred Stock ranks senior to all other outstanding series of preferred stock and common stock as to the payment of dividends and the distribution of assets upon voluntary or involuntary liquidation, dissolution or winding up of the Company's affairs. The Series D preferred stockholders will be entitled to receive first, \$50,000 per share and all accrued and unpaid dividends. Subject to any distributions that are required for any other series of preferred stock, the Series D preferred stockholders are then entitled to participate with the holders of the common stock in the distribution of remaining assets on a pro rata basis. If, upon any winding up of the Company's affairs, assets available to pay the holders of Series D Preferred Stock are not sufficient to permit the payment in full, then all assets will be distributed to the holders of Series D Preferred Stock on a pro rata basis. If the Company sells, leases or otherwise transfers substantially all of its assets, consummates a business combination in which it is not the surviving corporation or, if it is the surviving corporation, if the holders of a majority of the common stock immediately before the transaction do not hold a majority of common stock immediately after the transaction, in one or a series of events, change the majority of the members of the board of directors, or if any person or entity (other than the holders of Series D Preferred Stock) acquires more than 50% of the Company's outstanding stock, then the holders of Series D Preferred Stock are entitled to receive the same liquidation preference as described above, except that after receiving \$50,000 per preferred share and any accrued but unpaid dividends, they are not entitled to participate with the holders of any other series of preferred or common stock in a distribution of the remaining assets.

For as long as any shares of Series D Preferred Stock remain outstanding, the Company is prohibited from (i) paying dividends to its common stockholders, (ii) amending its certificate of incorporation, (iii) issuing any equity security or any security convertible into or exercisable for any equity security at a price of \$0.65 or less or with rights senior to the Series D Preferred Stock (except for certain exempted issuances), (iv) increasing the number of shares of Series D Preferred Stock or issuing any additional shares of Series D Preferred Stock, (v) selling or otherwise disposing of all or substantially all of its assets or intellectual property or entering into a merger or consolidation with another company unless the Company is the surviving corporation, the Series D Preferred Stock remains outstanding and there are no changes to the rights and preferences of the Series D Preferred Stock, (vi) redeeming or repurchasing any capital stock other than Series D Preferred Stock, (vii) incurring any new debt for borrowed money in excess of \$500,000 and (viii) changing the number of directors. The Company is required to reserve, out of authorized shares of common stock, 100% of the number of shares of common stock into which Series D Preferred Stock is convertible.

#### *Board and Observer Rights*

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

#### *Common Stock Purchase Warrants*

The Series D Warrants are exercisable for an aggregate of 4,365,381 shares of the Company's common stock at an exercise price of \$0.65 per share and expire in April 2013. If after the six-month anniversary of the date of issuance of the warrants there is no effective registration statement registering, or no current prospectus available for, the resale of the shares issuable upon the exercise of the warrants, the holder may conduct a cashless exercise whereby the holder may elect to pay the exercise price by having the Company withhold, upon exercise, shares having a fair market value equal to the applicable aggregate exercise price. In the event of such a cashless exercise, the Company would receive no proceeds from the sale of common stock in connection with such exercise.

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

If there is an effective registration statement covering the shares underlying the warrants and the VWAP, as defined in the warrant, of the Company's common stock exceeds \$2.50 for 20 consecutive trading days, then on the 31<sup>st</sup> day following the end of such period any remaining warrants for which a notice of exercise was not delivered shall no longer be exercisable and shall be converted into a right to receive \$.01 per share.

See Note 10 for a description of an amendment to Series D Warrants that was executed on February 11, 2009.

### *Registration Rights Agreement*

The Company entered into a registration rights agreement with these purchasers that requires the Company to file with the Securities and Exchange Commission no later than 5 business days following the six-month anniversary of the closing of the Series D Financing, a registration statement covering the resale of (i) a number of shares of common stock equal to 100% of the shares issuable upon conversion of the Series D Preferred Stock (excluding 12,000,000 shares of common stock issuable upon conversion of the Series D Preferred Stock that were included on a prior registration statement), (ii) a number of shares of common stock equal to 100% of the shares issuable upon exercise of the warrants issued in the Series D Financing and (iii) 7,500,000 shares of common stock issuable upon exercise of warrants dated May 2, 2007 held by the investors. The Company is required to use its best efforts to have the registration statement declared effective and 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 the Company fails to file the registration statement within the timeframe specified by the Registration Rights Agreement, the investors are entitled to receive liquidated damages equal to 1.5% per month (pro-rated on a daily basis for any period of less than a full month) of the aggregate purchase price of the Series D Preferred Stock and warrants until the Company files the delinquent registration statement. The Company is allowed to suspend the use of the registration statement for not more than 15 consecutive days or for a total of not more than 30 days in any 12-month period. The registration statement was required to be filed by October 18, 2008. As of December 31, 2008, the registration statement had not been filed. However, the Company had not concluded that it was probable that damages would become due. Therefore, no accrual for damages has been recorded. In connection with a financing that was completed on February 11, 2009, the damages from October 18, 2008 through February 11, 2009 under the Registration Rights Agreement were waived and the Registration Rights Agreement was replaced with an agreement requiring that a registration statement be filed in August 2009. See Note 10.

### *Placement Agent Fee and Other Costs*

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

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

At the closing, the Company entered into an amendment to the registration rights agreement dated May 2, 2007 with the holders of its Series B Preferred Stock to revise the definition of registrable securities under the agreement to include only the 12,000,000 shares of common stock that were included on a prior registration statement and to extend the registration obligations under the agreement by one year. On April 28, 2008, the amended registration statement covering the 12,000,000 shares of common stock required to be registered was declared effective. Accordingly, the Company has not accrued any liquidated damages at December 31, 2008 in connection with its registration obligation under the agreement. If the Company is unable to maintain the effectiveness of that registration statement through April 11, 2010, the Company may become liable for liquidated damages in future periods.

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

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

On February 11, 2009 all outstanding shares of Series D Preferred Stock and accumulated dividends thereon were exchanged for shares of Series E preferred stock. See Note 10.

### *Accounting Treatment of Series B and Series D Preferred Stock*

The terms of the Series B Preferred Stock contained provisions that allow the holders to elect to receive a liquidation payment in circumstances that are beyond the Company's control. Therefore the shares have been recorded as redeemable preferred stock outside of permanent equity in the balance sheet. The shares were initially recorded at their estimated as-converted fair value of \$19,050,000, net of cash issuance costs of \$1,306,949. That value was further reduced by the intrinsic value of the beneficial conversion feature of \$7,824,385. As a result of the effective adjustment to the conversion price of preferred stock and the adjustment to the exercise price of warrants that occurred in connection with the exchange of all outstanding shares of Series B Preferred Stock for shares of Series D Preferred Stock, in the quarter ended June 30, 2008, a deemed dividend of \$4,598,961 was recorded. This amount represents the incremental fair value on the date of the exchange resulting from the adjustment to the conversion price of the Series B Preferred Stock from \$1.00 to \$0.65 (\$3,876,912) and the exercise price of the warrants from \$1.25 to \$0.65 (\$722,049). These amounts were recorded as both debits and credits to temporary and permanent equity, respectively, in the year ended December 31, 2008. The incremental fair value of the adjustment to the conversion price of the Series B Preferred Stock was determined based on the market value of the additional 8,076,900 shares of common stock that became issuable following the exchange. The incremental fair value of the modification to the warrants was the difference between the fair value of the warrants immediately before and after modification using the Black-Scholes option pricing model. The fair value of the warrants prior to modification was calculated based on an estimated volatility of 80%, a discount rate of 2.34% and a term of 4.08 years. The fair value of the warrants after the modification was calculated based on an estimated volatility of 80%, a discount rate of 2.57% and a term of 5 years.

Since the terms of the Series D Preferred Stock also contain provisions that may require redemption in circumstances that are beyond the Company's control, the shares have been recorded as redeemable preferred stock outside of permanent equity in the balance sheet as of December 31, 2008. The gross proceeds of \$5,675,000 received in conjunction with the Series D Financing were allocated on a relative fair-value basis between the Series D Preferred Stock and the warrants. The relative fair-value of the Series D Warrants of \$1,302,592 was recorded as additional paid-in capital while the relative fair value of the Series D Preferred Stock of \$4,372,408 was recorded as temporary equity. The carrying value of the Series D Preferred Stock was immediately adjusted to its fair value of \$4,190,762 based on the fair value of the as-converted common stock. The difference of \$181,646 was recorded as a reduction to the deemed dividend described above. Issuance costs related to the Series D Financing of \$205,328 were netted against temporary equity. The total carrying value of temporary equity at December 31, 2008 of \$13,904,100 consists of the \$9,918,666 carrying value of the Series B Preferred Stock on the date of exchange plus the \$3,985,434 carrying value of the Series D Preferred Stock issued in the Series D Financing. The fair value of the Series D warrants was calculated using the Black-Scholes pricing model with a volatility of 80%, a discount rate of 2.57% and a term of 5 years.

Since the Company has concluded it is not probable that an event will occur which would allow the holders of Series D Preferred Stock to elect to receive a liquidation payment, the carrying value will not be adjusted until the time that such event becomes probable. The liquidation preference (redemption value) is \$22,070,562 at December 31, 2008.

#### ***2008 Issuance of Common Stock –***

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

The Common Stock Purchase Agreement provides that on and after six months following the closing, if there is not an available exemption from Rule 144 under the Securities Act to permit the sale of the common stock by the purchasers, then the Company will use its best efforts to file a registration statement (the "Registration Statement") under the Securities Act with the SEC covering the resale of the common stock. It further provides that the Company will use its best efforts to maintain the effectiveness of the Registration Statement until one year from closing or until all the common stock has been sold or transferred, whichever occurs first.

This purchase agreement also provides that if, prior to the public announcement of the conclusion of the Company's NOV-002 Phase 3 clinical trial in non-small cell lung cancer, the Company completes a Subsequent Equity Financing (as defined therein) and the holders of shares of Series D Preferred Stock receive, as consideration for their consent to such a financing, a reduction in the effective conversion price or exercise price, as applicable, of the shares of Series D Preferred Stock or common stock purchase warrants issued in connection therewith, or additional shares of common stock, then the purchasers will be entitled to receive additional shares of common stock based on the formula detailed in the purchase agreement.

**Common Stock Warrants** — The following table summarizes information with regard to outstanding warrants issued in connection with equity and debt financings as of December 31, 2008.



<b>Offering</b>	<b>Outstanding (as adjusted)</b>	<b>Exercise Price (as adjusted)</b>	<b>Expiration Date</b>
2005 Bridge Loans	720,000	\$ 0.625	April 1, 2010
2005 Issuance of Common Stock - Placement agents and finders	1,046,143	\$ 0.65	August 9, 2010
<b>Series A Preferred Stock (1):</b>			
Purchasers – September 30, 2005 closing	909,090	\$ 0.65	September 30, 2010
Purchasers – October 3, 2005 closing	60,606	\$ 0.65	October 3, 2010
2006 Issuance of Common Stock – Purchasers and placement agents (2)	11,267,480	\$ 2.00	March 7, 2011
<b>Series B Preferred Stock:</b>			
Purchasers	7,500,000	\$ 0.65	April 11, 2013
Placement agents	900,000	\$ 1.25	May 2, 2012
Series C Exchange	1,333,333	\$ 1.25	May 2, 2012
Series D Preferred Stock	4,365,381	\$ 0.65	April 11, 2013
<b>Total</b>	<b><u>28,102,033</u></b>		

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

(2) In connection with the financing described in Note 10 as a subsequent event, the number of shares of common stock underlying warrants issued in connection with the 2006 Issuance of Common Stock was increased to 12,379,848 and the exercise price was decreased to \$1.82.

No warrants have been exercised as of December 31, 2008. On August 11, 2008, warrants to purchase 6,923,028 shares of common stock expired unexercised.

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

	<b>December 31,</b>	
	<b><u>2008</u></b>	<b><u>2007</u></b>
2000 Stock Option Plan	56,047	73,873
2006 Stock Incentive Plan	4,770,000	2,220,000
Options issued outside of formalized plans	2,453,778	2,553,778
Warrants	28,102,033	28,973,047(1)
Preferred stock	36,829,192	22,014,000(1)
<b>Total shares reserved for future issuance</b>	<b><u>72,211,050</u></b>	<b><u>55,834,698</u></b>

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

**Authorized Shares** — There is a total of 150,000,000 shares of common stock authorized for issuance.

## 5. 2007 COLLABORATION AGREEMENT

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

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

## **6. STOCK-BASED COMPENSATION**

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

*2000 Stock Option Plan.* The Company's stock option plan established in August 2000 (the "2000 Plan") provides for grants of options to purchase up to 73,873 shares of common stock. Grants may be in the form of incentive stock options or nonqualified options. The board of directors determines exercise prices and vesting periods on the date of grant. Options generally vest annually over three years and expire on the tenth anniversary of the grant date. No options were granted or exercised under the 2000 Plan during 2007 or 2008. During 2008, options to purchase 17,826 shares of common stock were canceled.

*2006 Stock Incentive Plan.* On May 1, 2006, the Company's board of directors adopted, and on July 21, 2006 the Company's stockholders approved, the 2006 Stock Incentive Plan (the "2006 Plan"). A total of 5,000,000 shares of common stock are reserved for issuance under the 2006 Plan for grants of incentive or nonqualified stock options, rights to purchase restricted and unrestricted shares of common stock, stock appreciation rights and performance share grants. A committee of the board of directors determines exercise prices, vesting periods and any performance requirements on the date of grant, subject to the provisions of the 2006 Plan. Options are granted at or above the fair market value of the common stock at the grant date and expire on the tenth anniversary of the grant date. Vesting periods are generally two to three years. In the years ended December 31, 2008 and 2007, stock options for the purchase of 2,560,000 and 1,380,000 shares of common stock, respectively, were granted under the 2006 Plan. During 2008, options to purchase 10,000 shares of common stock were canceled. There have been no exercises under the 2006 Plan. As of December 31, 2008, 230,000 remain available for grant under the 2006 Plan. Options granted pursuant to the 2006 Stock Incentive Plan generally will become fully vested upon a termination event occurring within one year following a change in control, as defined. A termination event is defined as either termination of employment or services other than for cause or constructive termination of employees or consultants resulting from a significant reduction in either the nature or scope of duties and responsibilities, a reduction in compensation or a required relocation.

*Other Stock Option Activity.* During 2005 and 2004, the Company issued a total of 2,653,778 stock options to employees, directors and consultants outside of any formalized plan. These options are exercisable within a ten-year period from the date of grant, and vest at various intervals with all options being fully vested within two to three years of the grant date. The options are not transferable except by will or domestic relations order. The option price per share is not less than the fair market value of the shares on the date of the grant. During the years ended December 31, 2008 and 2007, options to purchase 100,000 and 25,000 shares, respectively, were exercised.

### **Accounting for Stock-Based Compensation**

The Company accounts for employee stock-based compensation in accordance with SFAS 123R. SFAS 123R requires all share-based payments to employees, including grants of employee stock options, to be recognized in the financial statements based on their fair values. The Company accounts for non-employee stock-based compensation in accordance with Emerging Issues Task Force (EITF) No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*. EITF 96-18 requires that companies recognize compensation expense based on the estimated fair value of options granted to non-employees over their vesting period, which is generally the period during which services are rendered by such non-employees.

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

	<b>Year Ended</b>	
	<b>December 31,</b>	
	<b>2008</b>	<b>2007</b>
<b>Employee and director stock option grants:</b>		
Research and development	\$ 159,519	\$ 163,558
General and administrative	<u>235,675</u>	<u>179,675</u>
	<u>395,194</u>	<u>343,233</u>
<b>Non-employee consultants stock option grants and restricted stock awards:</b>		
Research and development	24,131	17,233
General and administrative	<u>34,002</u>	<u>142,824</u>
	<u>58,133</u>	<u>160,057</u>
<b>Total stock-based compensation</b>	<b><u>\$ 453,327</u></b>	<b><u>\$ 503,290</u></b>

On May 13, 2008, the Company entered into a separation agreement with M. Taylor Burtis, a former officer of the Company, that provided, among other terms that all 166,667 unvested options held by Ms. Burtis as of May 13, 2008 were immediately vested and that she will have until December 31, 2009 to exercise the total 350,000 options held by her, at which time any unexercised options will expire. The 2008 stock-based compensation for research and development employees included in the table above includes incremental stock-based compensation expense of \$23,700 that was recorded in connection with the modification of the option terms.

#### **Determining Fair Value**

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

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

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

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

*Forfeitures.* As required by SFAS 123R, the Company records stock-based compensation expense only for those awards that are expected to vest. SFAS 123R requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. The term "forfeitures" is distinct from "cancellations" or "expirations" and represents only the unvested portion of the surrendered option. The Company has applied an annual forfeiture rate of 0% to all unvested options as of December 31, 2008 as the Company has experienced very few forfeitures to date and believes that there is insufficient history to develop an accurate estimate of future forfeitures. This analysis will be re-evaluated semi-annually and the forfeiture rate will be adjusted as necessary. Ultimately, the actual expense recognized over the vesting period will be for only those shares that vest.

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

	<b>Year Ended</b>	
	<b>December 31,</b>	
	<b>2008</b>	<b>2007</b>
Volatility	80%	80%
Weighted-average volatility	80%	80%
Risk-free interest rate	1.50%-3.28%	3.57%-4.66%
Expected life (years)	5	5
Dividend	0	0
Weighted-average exercise price	\$ 0.46	\$ 0.57
Weighted-average grant-date fair value	\$ 0.30	\$ 0.38

### Stock Option Activity

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

	<b>Options</b>	<b>Weighted</b>	<b>Weighted</b>	<b>Aggregate</b>
	<b>Outstanding</b>	<b>Average</b>	<b>Remaining</b>	<b>Intrinsic</b>
		<b>Exercise Price</b>	<b>Contracted</b>	<b>Value</b>
			<b>Term in</b>	
			<b>Years</b>	
Outstanding at January 1, 2007	3,492,651	\$ 0.70	8.4	\$ 1,773,777
Options granted	1,380,000	\$ 0.57		
Options exercised	(25,000)	\$ 0.01		
Outstanding at December 31, 2007	4,847,651	\$ 0.67	8.1	\$ 1,308,961
Options granted	2,560,000	\$ 0.46		
Options exercised	(100,000)	\$ 0.01		
Options canceled	(27,826)	\$ 2.23		
Outstanding at December 31, 2008	7,279,825	\$ 0.60	7.9	\$ 989,718
Exercisable at December 31, 2008	4,193,147	\$ 0.68	6.6	\$ 894,331

The aggregate intrinsic value of options outstanding is calculated based on the positive difference between the closing market price of the Company's common stock at the end of the respective period and the exercise price of the underlying options. During the year ended December 31, 2008 and 2007, the total intrinsic value of options exercised was \$74,000 and \$18,750, respectively and the total amount of cash received from exercise of these options was \$1,000 and \$250, respectively.

As of December 31, 2008 there was approximately \$886,000 of total unrecognized compensation cost related to unvested share-based compensation arrangements. Of this total amount, 53%, 31% and 16% is expected to be recognized during 2009, 2010 and 2011, respectively. The Company expects 3,086,678 in unvested options to vest in the future. The weighted average grant-date fair value of vested and unvested options outstanding at December 31, 2008 was \$0.41 and \$0.31, respectively. The weighted average grant-date fair value of vested and unvested options outstanding at December 31, 2007 was \$0.39 and \$0.41, respectively. The fair value of options that vested during the years ended December 31, 2008 and 2007 was approximately \$500,000 and \$701,000, respectively.

### 7. INCOME TAXES

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

	<u>2008</u>	<u>2007</u>
Net operating loss carryforwards	\$ 7,128,000	\$ 4,547,000
Research and development expenses	13,681,000	9,718,000
Tax credits	1,311,000	941,000
Capital loss carryforward	340,000	403,000
Stock-based compensation	449,000	375,000
Gross deferred tax asset	22,909,000	15,984,000
Valuation allowance	(22,909,000)	(15,984,000)
Net deferred tax asset	<u>\$ —</u>	<u>\$ —</u>

As of December 31, 2008, the Company had federal and state net operating loss carryforwards of approximately \$19,018,000 and \$12,367,000 respectively, which expire through 2028. In addition, the Company has federal and state research and development and investment tax credits of approximately \$1,077,000 and \$356,000, respectively which expire through 2028. The amount of net operating loss carryforwards which may be utilized annually in future periods may be limited pursuant to Section 382 of the Internal Revenue Code as a result of substantial changes in the Company's ownership that have occurred or that may occur in the future.

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

Because of the Company's limited operating history, continuing losses and uncertainty associated with the utilization of the net operating loss carryforwards in the future, management has provided a 100% allowance against the Company's gross deferred tax asset. In both 2008 and 2007, the increase in the valuation allowance represents the principal difference between the Company's total statutory tax rate of approximately 40% and its effective rate of 0%.

In June 2006, the Financial Accounting Standards Board ("FASB") issued FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes—an Interpretation of FASB Statement No. 109* (FIN No. 48), which clarifies the accounting for uncertainty in income tax positions. This interpretation requires that the Company recognize in its financial statements the impact of a tax position if that position is more likely than not of being sustained on audit, based on the technical merits of the position. The provisions of FIN No. 48 are effective for financial statements for fiscal years beginning after December 15, 2006. The cumulative effect of applying the provisions of FIN No. 48, if any, are required to be recorded as an adjustment to accumulated deficit. The Company adopted FIN No. 48 effective January 1, 2007. Upon adoption, there was no adjustment to accumulated deficit as the Company had no unrecognized tax benefits, and there were no accrued interest amounts or penalties related to tax contingencies.

The Company did not have any unrecognized tax benefits or accrued interest and penalties at any time during the years ended December 31, 2008 and 2007, and does not anticipate having any unrecognized tax benefits over the next twelve months. The Company is subject to audit by the IRS for tax periods commencing January 1, 2005.

## 8. NET LOSS PER SHARE

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

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

	<b>Year Ended</b>	
	<b>December 31,</b>	
	<u>2008</u>	<u>2007</u>
Stock options	<u>7,279,825</u>	<u>4,847,651</u>
Warrants	<u>28,102,033</u>	<u>26,873,047</u>
Conversion of preferred stock	<u>36,829,192</u>	<u>18,264,000</u>

## 9. COMMITMENTS

On May 25, 2007, the Company entered into a twenty-six-month lease for office space, commencing July 1, 2007. Monthly rent is \$7,175 per month for the first two months and \$7,675 per month for the remaining 24 months. Rent expense was \$92,100 and \$81,450 for the years ended December 31, 2008 and 2007, respectively. Future minimum lease payments under this non-cancelable lease are \$61,400 in 2009.

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

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

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

On July 15, 2005, the Company entered into an employment agreement with Christopher J. Pazoles, whereby he agreed to serve as the Company's vice president of research and development for an initial term of two years. The agreement is automatically renewed for successive one-year terms unless notice of termination is provided by either party at least 60 days prior to the end of any such term. The agreement was renewed for an additional one-year term on July 15, 2008 in accordance with its terms. The agreement provides for a minimum salary of \$195,000 during the current and any future terms as well as participation in standard benefit programs. The agreement further provides that upon resignation for good reason or termination without cause, both as defined, Dr. Pazoles will receive his base salary for the remainder of the contract term. In addition, his benefits will be paid for the twelve months following termination.

The Company entered into an employment agreement with Harry Palmin effective January 1, 2006, whereby he agreed to serve as the Company's president and chief executive officer for an initial term of two years. The agreement is automatically renewed for successive one-year terms unless notice of termination is provided by either party at least 90 days prior to the end of such term. The agreement was renewed for an additional one-year term on January 1, 2009 in accordance with its terms. The agreement provides for an initial salary of \$225,000, participation in standard benefit programs and an annual cash bonus at the discretion of the compensation committee. The agreement further provides that upon resignation for good reason or termination without cause, both as defined, Mr. Palmin will receive his pro rata share of the average of his annual bonus paid during the two fiscal years preceding his termination; his base salary and benefits for 11 months after the date of termination and fifty percent of his unvested stock options will vest. The agreement also contains a non-compete provision, which prohibits Mr. Palmin from competing with the Company for one year after termination of his employment with the Company.

## 10. SUBSEQUENT EVENTS

### 2009 Collaboration Agreement

On February 11, 2009 Novelos entered into a collaboration agreement (the “Collaboration Agreement”) with Mundipharma International Corporation Limited (“Mundipharma”) to develop manufacture and commercialize Licensed Products (as defined in the Collaboration Agreement), which includes the Company’s lead compound, NOV-002, in Europe and Asia/Pacific (excluding China) (the “Territory”). Mundipharma is an independent associated company of Purdue Pharma. L.P. (“Purdue”).

Under the Collaboration Agreement, Mundipharma received an exclusive license to develop, manufacture, market, sell or otherwise distribute the Licensed Products and improvements thereon in the Territory. Mundipharma will pay Novelos \$2.5 million upon the launch of NOV-002 in each country, up to a maximum of \$25 million. In addition, Mundipharma will make fixed sales-based payments up to an aggregate of \$60 million upon the achievement of certain annual sales levels payable once the annual net sales exceed the specified thresholds.

Mundipharma will also pay as royalties to Novelos, during the term of the Collaboration Agreement, a double-digit percentage on net sales of Licensed Products in countries within the Territory where, as of the effective date thereof, Novelos holds patents on the licensed technology based upon a four-tier royalty schedule. Royalties in countries in the Territory where Novelos does not hold patents as of the effective date will be paid at 50% of the royalty rates in countries where patents are held. The royalties will be calculated based on the incremental net sales in the respective royalty tiers and shall be due on net sales in each country in the Territory where patents are held until the last patent expires in the respective country. In countries in the Territory where Novelos does not hold patents as of the effective date of the Collaboration Agreement, royalties will be due until the earlier of 15 years from the date of Agreement or the introduction of a generic in the respective country resulting in a 20% drop in Mundipharma’s market share in such country.

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

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

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

## **Issuance of Series E Preferred Stock**

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

Concurrently with the execution of the Collaboration Agreement, Novelos sold to Purdue, an independent associated company of Mundipharma, 200 shares of a newly created series of the Company's preferred stock, designated "Series E Convertible Preferred Stock", par value \$0.00001 per share (the "Series E Preferred Stock") and a warrant (the "Series E Warrant") to purchase 9,230,769 shares of Novelos common stock for an aggregate purchase price of \$10,000,000 (the "Series E Financing"). Pursuant to the related securities purchase agreement with Purdue (the "Purchase Agreement"), Purdue has the right to designate one observer to attend all meetings of the Company's Board of Directors, committees thereof and access to all information made available to members of the Board. This right shall last until such time as Purdue no longer holds at least one-half of the Series E Preferred Stock issued to them at closing. Purdue has the right to participate in future equity financings with proceeds to the Company of at least \$20 million.

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

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

The Company also entered into an exchange agreement with the holders of Series D Preferred Stock under which all 413.5 outstanding shares of Series D Preferred Stock and accumulated but unpaid dividends thereon were exchanged for 445.442875 shares of Series E Preferred Stock. The rights and preferences of the Series E Preferred Stock are substantially the same as the Series D Preferred Stock. In addition, the holders of Series D Preferred Stock waived liquidated damages through the date of the exchange as a result of the Company's failure to file a registration statement covering the shares of common stock underlying the Series D Preferred Stock and warrants not otherwise registered. In connection with the execution of this exchange agreement, the Series B Warrants and the Series D Warrants were amended to extend the expiration of the warrants to December 31, 2015 and to remove the forced exercise provision. Also, the registration rights agreement dated May 2, 2007 with the holders of Series D Preferred Stock was amended to revise the definition of registrable securities under the agreement to refer to Series E Preferred Stock.

### *Terms of Series E Preferred Stock*

The shares of Series E Preferred Stock have a stated value of \$50,000 per share and are convertible into shares of common stock any time after issuance at the option of the holder at \$0.65 per share of common stock for an aggregate of 49,649,446 shares of common stock. If there is an effective registration statement covering the shares of common stock underlying the Series E Preferred Stock and the VWAP, as defined in the Series E Certificate of Designations, of Novelos common stock exceeds \$2.00 for 20 consecutive trading days, then the outstanding Series E Preferred Stock will automatically convert into common stock at the conversion price then in effect. The conversion price will be subject to adjustment for stock dividends, stock splits or similar capital reorganizations.

The Series E Preferred Stock has an annual dividend rate of 9%, payable semi-annually on June 30 and December 31. Such dividends may be paid in cash, in shares of Series E Preferred Stock or in registered shares of Novelos common stock at the Company's option, subject to certain conditions.



For as long as any shares of Series E Preferred Stock remain outstanding, Novelos will be prohibited from (i) paying dividends to its common stockholders, (ii) amending its certificate of incorporation, (iii) issuing any equity security or any security convertible into or exercisable for any equity security at a price of \$0.65 or less or with rights senior to the Series E Preferred Stock (except for certain exempted issuances), (iv) increasing the number of shares of Series E Preferred Stock or issuing any additional shares of Series E Preferred Stock, (v) selling or otherwise disposing of all or substantially all of its assets (or in the case of licensing, any material intellectual property) or entering into a merger or consolidation with another company unless Novelos is the surviving corporation, the Series E Preferred Stock remains outstanding and there are no changes to the rights and preferences of the Series E Preferred Stock, (vi) redeeming or repurchasing any capital stock other than the Series E Preferred Stock, (vii) incurring any new debt for borrowed money in excess of \$500,000 and (viii) changing the number of the Company's directors.

#### *Registration Rights Agreement*

Simultaneous with the execution of the Purchase Agreement, the Company entered into a registration rights agreement (the "Registration Rights Agreement") with Purdue and the holders (the "Series D Investors") of Novelos Series D Preferred Stock. The Registration Rights Agreement requires Novelos to file with the Securities and Exchange Commission no later than 5 business days following the six-month anniversary of the execution of the Securities Purchase Agreement, a registration statement covering the resale of (i) a number of shares of common stock equal to 100% of the shares issuable upon conversion of the Series E Preferred Stock (excluding 12,000,000 shares of common stock issuable upon conversion of the Series E Preferred Stock issued in exchange for shares of outstanding Series D Preferred Stock as described below that were included on a prior registration statement), (ii) 9,230,769 shares of common stock issuable upon exercise of the warrants issued to Purdue and (iii) 11,865,381 shares of common stock issuable upon exercise of warrants held by the Series D Investors. Novelos will be required to use its best efforts to have the registration statement declared effective and to keep the registration statement continuously effective under the Securities Act until the earlier of the date when all the registrable securities covered by the registration statement have been sold or the second anniversary of the closing. In the event Novelos fails to file the registration statement within the timeframe specified by the Registration Rights Agreement, it will be required to pay to Purdue and the Series D Investors liquidated damages equal to 1.5% per month (pro-rated on a daily basis for any period of less than a full month) of the aggregate purchase price of the Series E Preferred Stock and warrants until the delinquent registration statement is filed. Novelos will be allowed to suspend the use of the registration statement for not more than 15 consecutive days or for a total of not more than 30 days in any 12 month period. The Registration Rights Agreement replaces a prior agreement dated April 11, 2008 between Novelos and the Series D Investors.

#### *Advisor Fees*

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

#### *Accounting Treatment*

The Company is currently evaluating the accounting treatment for the Series E Financing and Collaboration Agreement. It is anticipated that the Series E Preferred Stock will be classified outside of permanent equity.

#### **ITEM 9. CHANGES AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE**

None.

## **ITEM 9A. CONTROLS AND PROCEDURES**

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

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on criteria established in the *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Management's evaluation included such elements as the design and operating effectiveness of key financial reporting controls, process documentation, accounting policies, and our overall control environment. Based on this evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, 2008. This annual report does not include an attestation report of the Company's independent registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by the Company's independent registered public accounting firm pursuant to temporary rules of the Securities and Exchange Commission that permit the Company to provide only management's report in this annual report.

*Evaluation of disclosure controls and procedures.* Based on our management's evaluation (with the participation of our principal executive officer and principal financial officer), as of the end of the period covered by this report, our principal executive officer and principal financial officer have concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, (the "Exchange Act")) are effective to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms.

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

*Changes in internal control over financial reporting.* Our management, in connection with its evaluation of internal controls (with the participation of our principal executive officer and principal financial officer), did not identify any change in internal control over the financial reporting process that occurred during our fourth fiscal quarter of 2008 that would have materially affected, or would have been reasonably likely to materially affect, our internal control over financial reporting.

## **ITEM 9B. OTHER INFORMATION**

None.

### PART III

#### ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.

Our current directors and executive officers are:

<u>Name</u>	<u>Age</u>	<u>Position</u>
Stephen A. Hill, B.M. B.Ch., M.A., F.R.C.S.	50	Chairman of the Board
Harry S. Palmin	39	President, Chief Executive Officer, Director
Elias B. Nyberg, DVM, BVSc, MACVS, MRCVS, MBA	55	Vice President of Regulatory, Quality and Compliance
Christopher J. Pazoles, Ph.D.	58	Vice President of Research and Development
Joanne M. Protano	40	Vice President, Chief Financial Officer and Treasurer
Kristin C. Schuhwerk	38	Vice President of Clinical Development and Operations
Michael J. Doyle (1) (2) (3)	50	Director
Sim Fass, Ph.D. (1) (2) (3)	67	Director
James S. Manuso, Ph.D.	60	Director
David B. McWilliams (2) (3)	65	Director
Howard M. Schneider (1) (3)	65	Director

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

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

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

**Harry S. Palmin.** Mr. Palmin has served as our president and a director since 1998 and our chief executive officer since January 2005. From 1998 to September 2005, he served as our acting chief financial officer. From 1996 to 1998, he was a vice president at Lehman Brothers and from 1993 to 1996, he was an associate at Morgan Stanley & Co. Mr. Palmin earned a B.A. in economics and business and a M.A. in international economics and finance from the International Business School at Brandeis University. He has also studied at the London School of Economics and the Copenhagen Business School.

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

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

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

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

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

**Sim Fass.** Dr. Fass has served as one of our directors since February 2005. Dr. Fass, now retired, served as chief executive officer and chairman of Savient Pharmaceuticals from 1997 to 2004, its president and chief executive officer from 1984 to 1997, and its chief operating officer from 1983 to 1984. From 1980 to 1983, Dr. Fass served as vice president and general manager of Wampole Laboratories. From 1969 to 1980, he held a number of marketing, sales and senior management positions at Pfizer, Inc in both pharmaceuticals and diagnostics. 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.

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

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

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

#### **Code of Ethics**

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

#### **ITEM 11. EXECUTIVE COMPENSATION**

##### **Executive Officer Compensation**

*Summary Compensation:* The following table sets forth certain information about the compensation we paid or accrued with respect to our principal executive officer and our two most highly compensated executive officers (other than our chief executive officer) who served as executive officers during the year ended December 31, 2008 and whose annual compensation exceeded \$100,000 for that year.

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

### Summary Compensation Table

Name and Principal Position	Year	Salary (\$)	Bonus (\$ (3))	Option Awards (\$ (4))	All other compensation (\$)	Total (\$)
Harry S. Palmin (1) President, Chief Executive Officer	2008	\$ 270,000	\$ 40,500	\$ 110,560	\$ 0	\$ 421,060
	2007	245,000	75,000	59,660	0	379,660
Christopher J. Pazoles (1) Vice President of Research and Development	2008	\$ 235,000	\$ 35,250	\$ 55,280	\$ 0	\$ 325,530
	2007	216,720	60,000	37,288	0	314,008
Kristin C. Schuhwerk (1) (2) Vice President of Clinical Development and Operations	2008	\$ 200,000	\$ 30,000	\$ 55,280	\$ 0	\$ 285,280
	2007	169,904	50,000	37,288	0	257,192

(1) There has been no increase to executive base salaries for 2009.

(2) Ms. Schuhwerk was appointed as an officer in December 2007. The compensation listed for 2007 was paid to her in her capacity as senior director of operations.

(3) Bonus amounts for 2008 were paid in 2009. Bonus amounts for 2007 were paid in 2008.

(4) The fair value of each stock award was estimated on the grant date using the Black-Scholes option-pricing model.

#### Employment Agreements

On January 31, 2006, we entered into an employment agreement with Harry Palmin effective January 1, 2006, whereby he agreed to serve as our president and chief executive officer for an initial term of two years at an annual salary of \$225,000. The agreement is automatically renewed for successive one-year terms unless notice of termination is provided by either party at least 90 days prior to the end of such term. The agreement was renewed for an additional one-year term on January 1, 2009 in accordance with its terms. On December 17, 2007, the Board of Directors approved an increase in Mr. Palmin's annual salary to \$270,000 effective January 1, 2008. He is eligible to receive an annual cash bonus at the discretion of the compensation committee and he is entitled to participate in our employee fringe benefit plans or programs generally available to our senior executives. The agreement provides that in the event that we terminate Mr. Palmin without cause or he resigns for good reason (as defined below), we will (i) pay Mr. Palmin his pro rata share of the average of his annual bonus paid during the two fiscal years preceding his termination; (ii) pay Mr. Palmin his base salary for 11 months after the date of termination; (iii) continue to provide him benefits for 11 months after the date of termination; and (iv) fifty percent of his unvested stock options will vest. The agreement also contains a non-compete provision, which prohibits Mr. Palmin from competing with us for one year after termination of his employment with us.

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

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

On July 15, 2005, we entered into an employment agreement with Christopher J. Pazoles whereby he agreed to serve as our vice president of research and development for an initial term of two years. The agreement is automatically renewed for successive one-year terms unless notice of termination is provided by either party at least 60 days prior to the end of such term. The agreement was renewed for an additional one-year term on July 15, 2008 in accordance with its terms. The agreement provides for minimum salary and bonus amounts during the first two years of his employment. These minimum amounts have been satisfied. Dr. Pazoles' agreement provides that he is entitled to participate in our employee fringe benefit plans or programs generally available to our senior executives. The agreement further provides that in the event that we terminate Dr. Pazoles without cause or he resigns for good reason (as defined below), we will (i) pay Dr. Pazoles his base salary through the remainder of the term of his employment agreement in monthly installments; (ii) continue to provide him benefits for 12 months after the date of termination; and (iii) pay, on a prorated basis, any minimum bonus or other payments earned.

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

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

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

### Outstanding Equity Awards at Fiscal Year-End

The following table sets forth certain information regarding stock options held as of December 31, 2008 by the executive officers named in the summary compensation table.

Name	Year of Grant	Individual Grants		Exercise or base price (\$/share)	Expiration date
		Number of securities underlying unexercised options (#) exercisable	Number of securities underlying unexercised options (#) unexercisable		
Harry S. Palmin	2008(1)	—	400,000	\$ 0.43	12/15/2018
	2007(1)	66,666	133,334	0.45	12/17/2017
	2006(1)	100,000	50,000	0.91	12/11/2016
	2005(2)	250,000	—	0.01	1/31/2015
	2005(2)	150,000	—	0.01	3/31/2015
	2004(3)	330,000	—	0.01	4/1/2014
	2003(4)	7,130	—	0.70	8/1/2013
Christopher J. Pazoles	2008(1)	—	200,000	\$ 0.43	12/15/2018
	2007(1)	41,666	83,334	0.45	12/17/2017
	2006(1)	66,666	33,334	0.91	12/11/2016
	2005(5)	200,000	—	0.01	4/8/2015
	2004(6)	16,667	—	0.01	4/1/2014
Kristin C. Schuhwerk	2008(1)	—	200,000	\$ 0.43	12/15/2018
	2007(1)	41,666	83,334	0.45	12/17/2017
	2006(1)	50,000	25,000	0.91	12/11/2016
	2005(7)	100,000	—	2.20	7/1/2015

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

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

### Director Compensation

*Summary Compensation:* The following table sets forth certain information about the compensation we paid or accrued with respect to our directors who served during the year ended December 31, 2008.

<b>Name and Principal Position</b>	<b>Year</b>	<b>Director Fees (\$ (3))</b>	<b>Option Awards (\$ (4))</b>	<b>All other compensation (\$)</b>	<b>Total (\$)</b>
Stephen A. Hill, Chairman (1)	2008	\$ 38,000	\$ 37,924	\$ —	\$ 75,924
Michael J. Doyle, Director (1)	2008	30,250	37,924	—	68,174
Sim Fass, Director (1)	2008	30,250	37,924	—	68,174
James S. Manuso, Director (1)	2008	23,000	37,924	—	60,924
David B. McWilliams, Director (1)	2008	26,750	37,924	—	64,674
Simyon Palmin, Director and director of Russian relations (2)	2008	—	—	88,133	88,133
Howard M. Schneider, Director (1)	2008	36,750	37,924	—	74,674



Simyon Palmin resigned from our board of directors on August 12, 2008. He remained an employee of the company until August 31, 2008 and provided consulting services to us for the remainder of the year. Other compensation for Mr. Palmin represents salary and bonus he received in his capacity as director of Russian relations for the Company and consulting fees paid to him for the months of September through December.

- (1) As of December 31, 2008, outstanding options to purchase common stock held by directors were as follows: Dr. Hill 270,000; Mr. Doyle 270,000; Dr. Fass 270,000; Dr. Manuso 220,000; Mr. McWilliams 322,778; Mr. Schneider 170,000.
- (2) As of December 31, 2008, Mr. Palmin held 300,000 options to purchase common stock. In addition, The Liberty Irrevocable Trust 2008, a trust for which his wife Alla is sole trustee, held 170,000 options to purchase common stock. The total of 470,000 options had been granted to Mr. Palmin during 2004 and 2005 in his capacity as chairman and chief executive officer.
- (3) Director fees include all fees earned for director services including quarterly fees, meeting fees and committee chairman fees.
- (4) The fair value of each stock award was estimated on the grant date using the Black-Scholes option-pricing model. See Note 6 to the financial statements for a description of the assumptions used in estimating the fair value of stock options.

During 2008, we paid our non-employee directors a cash fee of \$5,000 per quarter. The non-employee directors also received a fee of \$1,500 for any board or committee meeting attended and \$750 for each telephonic board or committee meeting in which the director participated. We also paid our chairman an additional annual fee in the amount of \$15,000, each non-employee director who serves as the chair of the audit committee an additional annual fee of \$10,000 and each non-employee director who serves as the chairman of the compensation and nominating and corporate governance committees an additional annual fee of \$5,000. We reimbursed directors for reasonable out-of-pocket expenses incurred in attending board and committee meetings and undertaking certain matters on our behalf. Directors who are our employees do not receive separate fees for their services as directors. There has been no change to cash fees payable to non-employee directors for 2009.

During 2008, each non-employee director received an annual stock option grant of 40,000 shares of our common stock at the closing price of our common stock on the first trading day of the fiscal year. On December 15, 2008, options to purchase 80,000 shares of our common stock were granted for 2009 to each of our non-employee directors at the closing price of our common stock on that day. Both of these option grants vest on a quarterly basis over a two-year period.

#### Equity compensation plans

The following table provides information as of December 31, 2008 regarding shares authorized for issuance under our equity compensation plans, including individual compensation arrangements.

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

#### Equity compensation plan information

Plan category	Number of shares to be issued upon exercise of outstanding options, warrants and rights (#) (a)	Weighted-average exercise price of outstanding options, warrants and rights (\$) (b)	Number of shares remaining available for future issuance under equity compensation plans (excluding shares reflected in column (a)) (#) (c)
Equity compensation plans approved by stockholders	4,826,047	\$ 0.61	230,000
Equity compensation plans not approved by stockholders	2,453,778	\$ 0.57	0
<b>Total</b>	<b>7,279,825</b>	<b>\$ 0.60</b>	<b>230,000</b>

**ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS**

At the close of business on March 20, 2009, there were issued and outstanding 43,975,656 shares of our common stock. The following table provides information regarding beneficial ownership of our common stock as of March 20, 2009:

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

The address of each executive officer and director is c/o Novelos Therapeutics, Inc., One Gateway Center, Suite 504, Newton, Massachusetts 02458. The persons named in this table have sole voting and investment power with respect to the shares listed, except as otherwise indicated. The inclusion of shares listed as beneficially owned does not constitute an admission of beneficial ownership. Shares included in the "Right to Acquire" column consist of shares that may be purchased through the exercise of options that vest within 60 days of March 20, 2009.

<u>Name and Address of Beneficial Owner</u>	<u>Shares Beneficially Owned (3)</u>			<u>Percentage</u>
	<u>Outstanding</u>	<u>Right to Acquire</u>	<u>Total</u>	
Liberty Irrevocable Trust 2008 (1) 99-60 Florence Street, Apt. 4A Chestnut Hill, MA 02467	1,975,481	470,000	2,445,481	5.5%
Harry S. Palmin (2)	641,118	903,796	1,544,914	3.4%
Christopher J. Pazoles	0	324,999	324,999	*
Kristin C. Schuhwerk	0	191,666	191,666	*
Stephen A. Hill	0	166,250	166,250	*
Michael J. Doyle	0	185,000	185,000	*
Sim Fass	0	185,000	185,000	*
James S. Manuso	0	122,500	122,500	*
David B. McWilliams	0	237,778	237,778	*
Howard M. Schneider	100,000	85,000	85,000	*
All directors and officers as a group (11 persons)	741,118	2,601,988	3,343,106	7.2%

\* Less than one percent.

(1) Shares outstanding include 236,542 shares owned by Alla Palmin, trustee of the Liberty Irrevocable Trust 2008. Shares in the "Right to Acquire" column include 300,000 options to purchase common stock held by Simyon Palmin, a founder of Novelos, a director until August 15, 2008, the father of Harry Palmin and husband of Alla Palmin.

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

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

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

The following table illustrates the pro forma beneficial ownership of our common stock that would result in the event of an automatic conversion of all of the outstanding shares of our Series E preferred stock into common stock. All outstanding shares of Series E preferred stock automatically convert in the event the volume weighted average price of our common stock, calculated in accordance with the terms of the Series E preferred stock, exceeds \$2.00 for 20 consecutive trading days, provided there is an effective registration statement covering the resale of the shares of common stock so issuable. At the current conversion price of \$0.65, the automatic conversion of all outstanding shares of Series E preferred stock would result in the issuance of 49,649,445 shares of common stock. In the table below, share holdings have been presented in total for groups of associated funds or companies. Such presentation is not intended to represent that such funds or companies are under common control.

<b>Name and Address of Beneficial Owner</b>	<b>Outstanding</b>	<b>Issuable upon automatic conversion of Series E preferred stock</b>	<b>Total pro forma ownership (1)</b>	<b>Pro forma ownership percentage (2)</b>
Xmark affiliated funds (3) 90 Grove Street Ridgefield, CT 06877	0	9,082,045	9,082,845	9.7%
Orbimed affiliated funds (4) 767 Third Avenue, 30 <sup>th</sup> Floor New York, NY 10017	0	10,878,150	10,878,150	11.6%
Knoll affiliated funds (5) 666 Fifth Avenue, Suite 3702 New York, NY 10103	1,677,785	9,247,776	10,925,561	11.7%
Hunt Bioventures 1900 N. Akard Street Dallas, TX 75201	0	5,056,860	5,056,860	5.4%
Purdue Pharma, L.P. (6) One Stamford Forum 201 Tresser Blvd. Stamford, CT 06901-3431	0	15,384,614	15,384,614	16.4%

- (1) Pro forma ownership does not include 21,096,150 shares of common stock issuable upon exercise of outstanding warrants, due to the effect of the blocker provisions described in Note 3 of the preceding table.
- (2) Based on 93,625,101 shares of common stock outstanding, which reflects the number of shares of common stock outstanding as of March 20, 2009, plus the total number of shares issuable upon conversion of all of the outstanding shares of Series E preferred stock.
- (3) Includes Xmark Opportunity Partners LLC, Xmark Opportunity Fund, Ltd., Xmark Opportunity Fund, L.P., Xmark JV Investment Partners, LLC.
- (4) Includes Orbimed Advisors LLC, Caduceus Capital Master Fund Limited, Caduceus Capital II, LP, UBS Eucalyptus Fund, L.L.C., PW Eucalyptus Fund, Ltd., and Summer Street Life Sciences Investors LLC.
- (5) Includes Knoll Capital, Knoll Special Opportunities Fund II Master Fund, Ltd., Europa International, Inc.
- (6) On February 12, 2009, Purdue Pharma L.P. transferred its shares of Series E Preferred Stock and warrants to purchase common stock of Novelos to Beacon Company and Rosebay Medical Company L.P., which are independent associated companies of Purdue Pharma L.P.

#### **ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE**

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

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

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

#### **Director Independence**

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

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

Aggregate fees for professional services by Stowe & Degon LLC for the years ended December 31, 2008 and December 31, 2007 were:

	<u>2008</u>	<u>2007</u>
Audit	\$81,500	\$81,500
Audit Related	—	14,125
Tax	—	—
All Other	—	—
Total	<u>\$81,500</u>	<u>\$95,625</u>

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

*Audit-Related Fees:* Audit-related fees were for professional services rendered in connection with consents and assistance with review of registration statements filed with the SEC during 2007.

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

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

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

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

Our audit committee has not established any pre-approval policies or procedures that would allow our management to engage Stowe & Degon LLC to provide any specified services with only an obligation to notify the audit committee of the engagement for those services. None of the services provided by Stowe & Degon LLC for 2008 or 2007 were obtained in reliance on the waiver of the pre-approval requirement afforded in SEC regulations.

**PART IV**

**ITEM 15. EXHIBITS**

<b>Exhibit No.</b>	<b>Description</b>	<b>Filed with this Form 10-K</b>	<b>Incorporated by Reference</b>		
			<b>Form</b>	<b>Filing Date</b>	<b>Exhibit No.</b>
2.1	Agreement and plan of merger among Common Horizons, Inc., Nove Acquisition, Inc. and Novelos Therapeutics, Inc. dated May 26, 2005		8-K	June 2, 2005	99.2
2.2	Agreement and plan of merger between Common Horizons and Novelos Therapeutics, Inc. dated June 7, 2005		10-QSB	August 15, 2005	2.2
3.1	Certificate of Incorporation		8-K	June 17, 2005	1
3.2	Certificate of Designations of Series E convertible preferred stock		8-K	February 18, 2009	4.1
3.3	Certificate of Designations of Series C cumulative convertible preferred stock		10-QSB	May 8, 2007	3.2
3.4	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 S. Palmin dated January 31, 2006		8-K	February 6, 2006	99.1
10.3**	2000 Stock Option and Incentive Plan		SB-2	November 16, 2005	10.2
10.4 **	Form of 2004 non-plan non-qualified stock option		SB-2	November 16, 2005	10.3
10.5 **	Form of non-plan non-qualified stock option used from February to May 2005		SB-2	November 16, 2005	10.4
10.6 **	Form of non-plan non-qualified stock option used after May 2005		SB-2	November 16, 2005	10.5
10.7	Form of common stock purchase warrant issued in March 2005		SB-2	November 16, 2005	10.6
10.8	Form of securities purchase agreement dated May 2005		8-K	June 2, 2005	99.1
10.9	Form of subscription agreement dated September 30, 2005		8-K	October 3, 2005	99.1
10.10	Form of Class A common stock purchase warrant dated September 30, 2005		8-K	October 3, 2005	99.3
10.12	Consideration and new technology agreement dated April 1, 2005 with ZAO BAM		10-QSB	August 15, 2005	10.2
10.13	Letter agreement dated March 31, 2005 with The Oxford Group, Ltd.		10-QSB	August 15, 2005	10.3
10.14	Form of securities purchase agreement dated March 2, 2006		8-K	March 3, 2006	99.2

Exhibit No.	Description	Filed with this Form 10-K	Incorporated by Reference		
			Form	Filing Date	Exhibit No.
10.15	Form of common stock purchase warrant dated March 2006		8-K	March 3, 2006	99.3
10.16**	2006 Stock Incentive Plan		10- QSB	November 6, 2006	10.1
10.17	Form of Incentive Stock Option under Novelos Therapeutics, Inc.'s 2006 Stock Incentive Plan		8-K	December 15, 2006	10.1
10.18	Form of Non-Statutory Stock Option under Novelos Therapeutics, Inc.'s 2006 Stock Incentive Plan		8-K	December 15, 2006	10.2
10.19	Form of Non-Statutory Director Stock Option under Novelos Therapeutics, Inc.'s 2006 Stock Incentive Plan		8-K	December 15, 2006	10.3
10.20	Securities Purchase Agreement dated April 12, 2007		10- QSB	May 8, 2007	10.1
10.21	Letter Amendment dated May 2, 2007 to the Securities Purchase Agreement		10- QSB	May 8, 2007	10.2
10.22	Registration Rights Agreement dated May 2, 2007		10- QSB	May 8, 2007	10.3
10.23	Agreement to Exchange and Consent dated May 1, 2007		10- QSB	May 8, 2007	10.5
10.25	Form of Common Stock Purchase Warrant dated May 2, 2007 issued pursuant to the Securities Purchase Agreement dated April 12, 2007		10- QSB	May 8, 2007	4.1
10.26	Form of Common Stock Purchase Warrant dated May 2, 2007 issued pursuant to the Agreement to Exchange and Consent dated May 2, 2007		10- QSB	May 8, 2007	4.2
10.27	Securities Purchase Agreement dated March 26, 2008		8-K	April 14, 2008	10.1
10.28	Amendment to Securities Purchase Agreement dated April 9, 2008		8-K	April 14, 2008	10.2
10.29	Registration Rights Agreement dated April 11, 2008		8-K	April 14, 2008	10.3
10.30	Form of Common Stock Purchase Warrant dated April 11, 2008 issued pursuant to the Securities Purchase Agreement dated March 26, 2008		8-K	April 14, 2008	4.3
10.31	Warrant Amendment Agreement dated April 11, 2008		8-K	April 14, 2008	10.5

Exhibit No.	Description	Filed with this Form 10-K	Incorporated by Reference		
			Form	Filing Date	Exhibit No.
10.32	Amendment to Registration Rights Agreement dated April 11, 2008		8-K	April 14, 2008	10.4
10.33	Securities Purchase Agreement dated August 14, 2008		8-K	August 18, 2008	10.1
10.34	Securities Purchase Agreement dated February 11, 2009		8-K	February 18, 2009	10.1
10.35	Registration Rights Agreement dated February 11, 2009		8-K	February 18, 2009	10.2
10.36	Series D Preferred Stock Consent and Agreement to Exchange dated February 10, 2009		8-K	February 18, 2009	10.3
10.37	Warrant Amendment Agreements dated February 11, 2009		8-K	February 18, 2009	10.4
10.38	Amendment No. 2 to Registration Rights Agreement dated February 11, 2009		8-K	February 18, 2009	10.5
10.39	Collaboration Agreement dated February 11, 2009(*)	X			
31.1	Certification of chief executive officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	X			
31.2	Certification of chief financial officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	X			
32.1	Certification of chief executive officer and chief financial officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	X			

\* Portions of the exhibit have been omitted pursuant to a request for confidential treatment.

\*\* Management contract or compensatory plan.



## SIGNATURES

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

### NOVELOS THERAPEUTICS, INC.

By:       /s/ Harry S. Palmin      

Harry S. Palmin

Title: President, Chief Executive Officer

Date:       March 30, 2009      

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

By:       /s/ Harry S. Palmin      

Harry S. Palmin

Title: Chief Executive Officer and Director (Principal Executive Officer)

Date:       March 30, 2009      

By:       /s/ Joanne M. Protano      

Joanne M. Protano

Title: Chief Financial Officer (Principal Accounting Officer)

Date:       March 30, 2009      

By:       /s/ Stephen A. Hill      

Stephen A. Hill

Title: Chairman of the Board of Directors

Date:       March 30, 2009      

By:       /s/ Michael J. Doyle      

Michael J. Doyle

Title: Director

Date:       March 30, 2009      

By:       /s/ Sim Fass      

Sim Fass

Title: Director

Date:       March 30, 2009      

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**COLLABORATION AGREEMENT**

**by and between**

**NOVELOS THERAPEUTICS, INC.**  
**(a Delaware corporation)**

**and**

**MUNDIPHARMA INTERNATIONAL CORPORATION LIMITED**  
**(a Bermuda limited company)**

**February 11, 2009**

(Portions of this exhibit have been omitted pursuant to Rule 24b-2 under the Securities Exchange Act of 1934, as amended and filed separately with the Securities and Exchange Commission. Omitted portions are indicated herein by brackets.)

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## COLLABORATION AGREEMENT

THIS COLLABORATION AGREEMENT (this "Agreement"), effective as of February 11, 2009 (the "Effective Date"), is made between Novelos Therapeutics, Inc., a Delaware corporation ("Novelos"), having a place of business at One Gateway Center, Suite 504, Newton, Massachusetts, and Mundipharma International Corporation Limited, a Bermuda limited company ("Collaborator"), having a place of business at 14 Par-la-Ville Road, P.O. Box HM2332, Hamilton HMJX Bermuda, with respect to the following facts:

### RECITALS

A. Novelos has intellectual property rights, technology and know-how related to oxidized glutathione-based compounds for the treatment of cancer and hepatitis.

B. The Parties desire to enter into a collaborative program pursuant to which Novelos will grant Collaborator an exclusive License in the Territory (capitalized terms used but not defined in these Recitals shall have the meanings defined below) to develop, manufacture, market and sell the Licensed Products on the terms and conditions set forth below.

NOW THEREFORE, in consideration of the foregoing premises and the mutual covenants set forth below, the Parties agree as follows:

### 1. DEFINITIONS

**1.1. Definitions.** For purposes of this Agreement, the terms set forth in this Section 1 shall have the respective meanings set forth below:

1.1.1. "Action" shall mean all charges, complaints, actions, suits, proceedings, hearings, investigations, claims, demands, judgments, orders, decrees, stipulations or injunctions.

1.1.2. "Affiliate" shall mean, with respect to either Party, any person, firm, trust, corporation or other entity or combination thereof which directly or indirectly (a) controls a Party, (b) is controlled by a Party, or (c) is under common control with a Party; the terms "control" and "controlled" meaning ownership of fifty percent (50%) or more, including ownership by trusts with substantially the same beneficial interests, of the voting and equity rights of such person, firm, trust, corporation or other entity or combination thereof or the power to direct the management of such person, firm, trust, corporation or other entity or combination thereof.

1.1.3. "Agreement" shall have the meaning set forth in the preamble, together with all appendices, exhibits and schedules attached hereto, as the same may be amended or supplemented from time to time, by written agreement of the Parties.

1.1.4. "Alliance Manager" shall have the meaning set forth in Section 4.1.1.

1.1.5. "API" shall mean the active pharmaceutical ingredient of a product.

1.1.6. "BAM" shall mean the Russian private joint stock company BAM, having a principal place of business at Pskovskaya Str., 17, St Petersburg 190 121, Russia.

1.1.7. "BAM-RL" shall mean the Russian private joint stock company BAM – Research Laboratories, having a principal place of business at Pskovskaya Str., 17, St Petersburg 190 121, Russia.

1.1.8. "2000 BAM Agreement" shall mean the Technology, Assignment, Legal Protection and Consideration Agreement dated June 20, 2000 between BAM-RL and Novelos.

1.1.9. "2005 BAM Agreement" shall mean the Technology, Assignment, Legal Protection and Consideration Agreement dated April 1, 2005 between BAM and Novelos

1.1.10. "Bankruptcy Code" shall mean, as applicable, the U.S. Bankruptcy Code, as amended from time to time, and the rules and regulations and guidelines promulgated thereunder or the bankruptcy laws of any Governmental Authority, as amended from time to time, and the rules and regulations and guidelines promulgated thereunder.

1.1.11. "CMC" shall mean chemistry, manufacturing and controls.

1.1.12. "CTD" shall mean a Common Technical Document providing for a harmonized structure and format for an NDA suitable for submission for Regulatory Approval in the Territory, consistent with the ICH Guidelines.

1.1.13. "Co-Chair" shall have the meaning set forth in Section 4.2.4.

1.1.14. "Collaborator" shall have the meaning set forth in the preamble of this Agreement.

1.1.15. "Collaborator Indemnitees" shall have the meaning set forth in Section 11.1.1.

1.1.16. "Collaborator Know-How" shall mean, information, procedures, instructions, techniques, data, technical information, knowledge and experience (including, without limitation, toxicological, pharmaceutical, clinical, non-clinical and medical data, health registration data and marketing data), designs, dossiers and technology relating to or concerned with the Licensed Products (or any of their components or constituent parts) owned or controlled by Collaborator and used in connection with the Licensed Products, whether now existing or developed by or on behalf of Collaborator or its Affiliates after the date of this Agreement, in written, electronic or other form; provided, however, that the Collaborator Know-How shall not include the Collaborator Patents, the Novelos Know-How or the Novelos Patents.

1.1.17. "Collaborator Patents" shall mean all Patents owned or controlled by Collaborator throughout the Territory that claim any improvements upon or modifications to the inventions and discoveries disclosed or claimed in any of the Novelos Patents or which claim the manufacture or use of any composition of matter or method of use relating to the Licensed Products and/or relating to GSSG in any combination with heavy metals.



1.1.18. “Collaborator Technology” shall mean any Collaborator Patents and Collaborator Know-How and other discoveries and technical information developed, owned or controlled by Collaborator related to the Licensed Products. All Collaborator Technology (except published Collaborator Patents) shall be the Confidential Information of Collaborator.

1.1.19. “Collaborator Trials” shall mean the following trials in respect of the Lead Product to be conducted by Collaborator: (i) the Label Expansion Trial, and (ii) any bridging or other studies that are required by the Japanese Regulatory Authorities to be conducted to obtain Regulatory Approval in Japan, provided that the Collaborator decides such trials are commercially viable to conduct pursuant to Section 4.9.2(c), in each case as such trials may be modified after the Effective Date in consultation with the JCC.

1.1.20. “Commercially Reasonable Efforts” shall mean a level of resources, efforts and urgency to develop and commercialize the Lead Product applied by a Party that is consistent with such Party’s practices in actively pursuing the development and commercialization of its other pharmaceutical products at a similar stage of product life to the Lead Product and of similar market potential, profit potential and strategic value, based on conditions prevailing at the relevant time, taking into account, without limitation, competing products, market demand, proprietary position, safety, regulatory status, medical or scientific developments in the field of oncology, any adverse governmental intervention and any potential legal liability or other legal issues.

1.1.21. “Confidential Information” shall mean, with respect to a Party, all secret, confidential, proprietary or non-publicly available information, data and materials of any kind whatsoever, and all tangible and intangible embodiments thereof of any kind whatsoever, which is disclosed by such Party or its Affiliates (the “Disclosing Party”) to the other Party or its Affiliates (the “Receiving Party”) pursuant to this Agreement, together with analyses, data, compilations, studies or other documents or records prepared by the Receiving Party or its representatives that contain or otherwise reflect or are generated from such disclosed information, and, (i) if disclosed in writing or other tangible medium, is marked or identified in writing as confidential at the time of disclosure to the Receiving Party or (ii) if otherwise disclosed or if not so marked or identified in writing, is identified as confidential at the time of disclosure to the Receiving Party and is summarized and identified as confidential in writing or by electronic means within thirty (30) days after such disclosure or which would reasonably be understood to be confidential. Notwithstanding the foregoing, Confidential Information of a Party shall not include information which, and only to the extent, the Receiving Party can establish by written documentation or electronic records (a) has been publicly known prior to disclosure of such information by the Disclosing Party to the Receiving Party; (b) has become publicly known without fault on the part of the Receiving Party, subsequent to disclosure of such information by the Disclosing Party to the Receiving Party; (c) has been received by the Receiving Party at any time from a source, other than the Disclosing Party, rightfully having possession of and the right to disclose such information free of confidentiality obligations; (d) has been otherwise known by the Receiving Party free of confidentiality obligations prior to disclosure of such information by the Disclosing Party to the Receiving Party; or (e) has been independently developed (as demonstrated by contemporaneous written or electronic evidence maintained in the ordinary course of business by the Receiving Party) by employees or agents of the Receiving Party without access to or use of such information disclosed by the Disclosing Party to the Receiving Party.

1.1.22. “Disclosing Party” shall have the meaning set forth in Section 1.1.21.

1.1.23. “Effective Date” shall have the meaning set forth in the preamble of this Agreement.

1.1.24. “EMEA” shall mean the European Medicines Agency.

1.1.25. “European Registration Trial” shall have the meaning set forth in Section 4.7.1.

1.1.26. “FDA” shall mean the United States Food and Drug Administration.

1.1.27. “First Commercial Sale” shall mean the first sale, or other distribution for consideration, of a Licensed Product to a Third Party by Collaborator or its Affiliate or Sublicensee in a country in the Territory following grant of a Regulatory Approval and Pricing Approval for a Licensed Product in such country, but excluding distributions for purposes of product demonstrations, test marketing, clinical trial purposes or compassionate or similar uses.

1.1.28. “Force Majeure” shall have the meaning set forth in Section 15.9.

1.1.29. “GCP” shall mean the current Good Clinical Practice standards for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials, including without limitation the requirements in 21 C.F.R. Parts 11, 50, 54, 56, 312, and 314 and principles detailed in ICH Guidelines, that provide assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected.

1.1.30. “Generic Product Competition” shall mean where generic products that are chemically equivalent to the relevant Licensed Product are being legally sold in a country of the Territory and Collaborator’s volume market share in such country is reduced as a result of the availability of such generic products by twenty percent (20%) or more of the market share by volume in the country(ies) where the generic products are being sold, as evidenced by IMS data.

1.1.31. “GLP” shall mean the current Good Laboratory Practices as promulgated under the Act at 21 C.F.R. Part 58 and principles detailed in ICH Guidelines related to laboratory practice.

1.1.32. “GMP” shall mean all applicable standards relating to current Good Manufacturing Practices for fine chemicals, API, intermediates, bulk products or finished pharmaceutical products, including without limitation (i) the principles detailed in the Act at 21 U.S.C. 351(a)(2)(B), in U.S. FDA regulations at 21 C.F.R. Parts 210 and 211 and in The Rules Governing Medicinal Products in the European Community, Volume IV, Good Manufacturing Practice for Medicinal Products, (ii) the principles detailed in ICH Guidelines relating to the manufacture of API and finished pharmaceuticals, (iii) Laws promulgated by any Governmental Authority having jurisdiction over the manufacture of compounds or Licensed Products or any components of either of the foregoing, or (iv) guidance documents (including advisory opinions, compliance policy guides and guidelines) promulgated by any Governmental Authority having jurisdiction over the manufacture of compounds or Licensed Products, which guidance documents are being implemented within the pharmaceutical manufacturing industry.

1.1.33. "Governmental Authority" shall mean any (i) federal, state, local, foreign or international government; (ii) court, arbitral or other tribunal or governmental or quasi-governmental authority of any nature (including any governmental agency, political subdivision, instrumentality, branch, department, official, or entity); or (iii) body exercising, or entitled to exercise, any administrative, executive, judicial, legislative, police, regulatory, or taxing authority or power of any nature pertaining to government.

1.1.34. "GSSG" shall mean oxidized glutathione.

1.1.35. "ICH Guidelines" shall mean the guidelines of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use.

1.1.36. "Improvement" shall mean all discoveries, concepts, ideas, confidential information, trade secrets, and know-how relating to the Licensed Products, the Novelos Technology and/or the Collaborator Technology, whether patentable or not, made or conceived during the Agreement by Novelos or its Affiliates, Collaborator or its Affiliates, any Sublicensees, or any combination thereof, alone or together, including, but not limited to, all processes, new uses of known processes, methods, articles of manufacture, machines, instrumentation, chemical composition of matter, techniques, and formulae.

1.1.37. "Independent Data" shall mean, with respect to the Licensed Products, all data, including without limitation, toxicological, pharmaceutical, clinical, non-clinical and medical data, health registration data and marketing data, developed or procured by or on behalf of a Sponsoring Party or its Affiliates in an Independent Trial in respect of which the Non-Sponsoring Party has not paid to the Sponsoring Party fifty percent (50%) of its out-of-pocket development costs.

1.1.38. "Independent Trial" shall have the meaning set out in Section 4.7.5.

1.1.39. "JCC" shall mean the Joint Consultative Committee established by the Parties pursuant to Section 4.2.

1.1.40. "Label Expansion Trial" shall mean a Phase II clinical study of the Lead Product in first-line advanced NSCLC to be conducted by Collaborator to support a broader use of the Lead Product in combination with other platinum-based chemotherapy agents instead of a more limited use of the Lead Product in combination with carboplatin and paclitaxel, which is a combination used more commonly in the USA than in the Territory.

1.1.41. "Laws" shall mean all applicable laws, rules, regulations, judgments, orders, decrees, statutes, ordinances and other requirements of any Governmental Authority or instrumentality within the Territory and any other jurisdiction in which Licensed Products are developed, manufactured or sold, pursuant to the terms of this Agreement.

1.1.42. "Lead Product" shall mean NOV-002, a combination of GSSG and cisplatin (1000:1 molar ratio), including the salts, esters, metabolites, tautomers, isomers, conjugates and complexes thereof.

1.1.43. "Lee's Pharma Agreement" shall mean the Collaboration Agreement dated December 14, 2007 between Novelos and Lee's Pharma (HK) Ltd. pursuant to which Novelos granted an exclusive license to Lee's Pharma (HK) Ltd. to develop, make, have made, register, use, market, sell, have sold, import, distribute and offer for sale the Lead Product, NOV-205 or any product containing GSSG and to exploit the Novelos Technology in the Lee's Pharma Territory.

1.1.44. "Lee's Pharma Territory" shall mean Hong Kong, Macau, the People's Republic of China and Taiwan.

1.1.45. "License" shall have the meaning set forth in Section 2.1.

1.1.46. "Licensed Products" shall mean all pharmaceutical preparations in all dosage strengths, formulations and methods of administration that contain the Lead Product or any other combination of GSSG and any heavy metal in any molar ratio, including in each case the salts, esters, metabolites, tautomers, isomers, conjugates and complexes thereof and any Improvements thereto made by either Party individually or jointly by the Parties as set forth in Section 2.4.

1.1.47. "Losses" shall have the meaning set forth in Section 11.1.1.

1.1.48. "MAA" shall mean marketing authorization application.

1.1.49. "NDA" shall mean a new drug application or supplemental new drug application or any amendments or supplements thereto in CTD format.

1.1.50. "Net Sales" shall mean with respect to Licensed Products sold, licensed or otherwise distributed (hereinafter "Sale"), the gross amount invoiced or otherwise charged to Third Parties in an arm's length transaction in connection with the Sale of the Licensed Products by Collaborator or any Affiliate of Collaborator or any Sublicensee for all Licensed Products sold by Collaborator or any Affiliate of Collaborator or any Sublicensee in the Territory, less the following amounts actually deducted or allowed:

(a) transport, freight and insurance costs;

(b) sales and excise taxes and duties;

(c) normal and customary trade, quantity and cash discounts and rebates;

(d) amounts repaid, discounted or credited by reason of (i) retroactive price reductions, (ii) discounts, or (iii) rebates, which are, in each case, imposed upon Collaborator, its Affiliates or Sublicensees by any Governmental Authority or non-Governmental Authority with the authority to impose such price reductions, discounts or rebates;

(e) any credits or allowances for damaged goods, returns, rebates, delayed ship order credits or rejections, to the extent these deductions actually pertain to a Sale.

For Licensed Products distributed to Third Parties in other than an arm's length transaction (for example, at less than fair market value), excluding distributions for purposes of product demonstrations, test marketing, clinical trial purposes or compassionate or similar uses, the amount of Net Sales attributed to such Licensed Products shall be the fair market value of the Licensed Products based on the Sale in an arm's length transaction of comparable amounts thereof.

1.1.51. "Non-Sponsoring Party" shall have the meaning set forth in Section 4.8.5.

1.1.52. "NOV-205" shall mean a mixture of GSSG and inosine developed by Novelos which acts as a hepatoprotective agent with immunomodulating and anti-inflammatory properties and is currently in Phase 1b clinical trials in the U.S.A.

1.1.53. "Novelos" shall have the meaning set forth in the preamble of this Agreement.

1.1.54. "Novelos Indemnitees" shall have the meaning set forth in Section 11.1.2.

1.1.55. "Novelos Know-How" means all discoveries, information, procedures, instructions, techniques, data, technical information, knowledge and experience (including, without limitation, toxicological, pharmaceutical, clinical, non-clinical and medical data, health registration data and marketing data), designs, dossiers and technology relating to or concerned with the Licensed Products (or any of their components or constituent parts) owned or controlled by Novelos and used in connection with the Licensed Products, whether now existing or developed by or on behalf of Novelos or its Affiliates after the date of this Agreement, in written, electronic or other form; provided, however, that the Novelos Know-How shall not include the Novelos Patents, the Collaborator Know-How or the Collaborator Patents.

1.1.56. "Novelos Patents" shall mean all Patents owned or controlled by Novelos throughout the world that claim the manufacture or use of any composition of matter or method of use relating to the Licensed Products and relating to oxidized glutathione in any combination with heavy metals, which are set forth in **Attachment 1** to this Agreement.

1.1.57. "Novelos Technology" shall mean the Novelos Patents and Novelos Know-How. All Novelos Technology (except published Novelos Patents) shall be Confidential Information of Novelos.

1.1.58. "Novelos Trials" shall mean the Phase II and Phase III clinical trials being or to be conducted by or on behalf of Novelos for the Lead Product, which are summarized in **Attachment 2** to this Agreement, as may be modified after the Effective Date in consultation with the JCC.

1.1.59. "NSCLC" shall mean non-small cell lung cancer.

1.1.60. "Party" shall mean Novelos or Collaborator and, when used in the plural, shall mean Novelos and Collaborator collectively.

1.1.61. "Patents" shall mean any patents and pending patent applications that have issued or may be issued in any country, including (i) all provisional and non-provisional applications, substitutions, divisions, confirmations, continuations, continuations-in-part, registrations, supplementary protection certificates and any renewals of any of the above; (ii) all letters patent granted thereon, and all patents-of-addition, re-issues, re-examinations and extensions or restorations by existing or future extension or restoration mechanisms; and (iii) all supplementary protection certificates, together with any foreign counterpart thereof.

1.1.62. "Pricing Approval" shall mean the licenses, registrations, authorizations and approvals of any Regulatory Authority in the Territory necessary for the pricing and/or reimbursement of the Licensed Products in each country of the Territory.

1.1.63. "Receiving Party" shall have the meaning set forth in Section 1.1.21.

1.1.64. "Regulatory Approval" shall mean the technical, medical and scientific licenses, registrations, authorizations and approvals of any Regulatory Authority in the Territory, necessary for the distribution, marketing, promotion, offer for sale, use, import, export or sale of the Licensed Products in the Territory, but excluding Pricing Approval.

1.1.65. "Regulatory Authority" shall mean any international, national (e.g., the Medicines and Healthcare products Regulatory Agency (the "MHRA")), supra-national (e.g., EMEA), regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity involved in the granting of Regulatory Approval and/or Pricing Approval in the Territory.

1.1.66. "Royalties" shall have the meaning set forth in Section 3.1.2.

1.1.67. "Royalty Period" shall have the meaning set forth in Section 3.2.1.

1.1.68. "Sale" shall have the meaning set forth in Section 1.1.50.

1.1.69. "Sponsoring Party" shall have the meaning set forth in Section 4.8.5.

1.1.70. "Sublicensee" shall mean a non-Affiliate sublicensee appointed by Collaborator in one or more countries of the Territory and approved by Novelos in accordance with Section 2.2(ii), or a non-Affiliate sublicensee appointed by Novelos in one or more countries outside the Territory, as the case may be.

1.1.71. "Term" shall have the meaning set forth in Section 13.1.

1.1.72. "Territory" shall mean the countries listed in **Attachment 3** hereto.

1.1.73. "Third Party" shall mean any person or entity other than Collaborator, Novelos or an Affiliate or Sublicensee of Collaborator or Novelos.

1.1.74. "Trademarks" shall mean the trademarks, domain names and internet sites to be selected and owned by Collaborator under which the Licensed Products will be promoted, marketed and sold by Collaborator and its Affiliates and Sublicensees in the Territory in accordance with Section 6.3.

1.1.75. "USA" shall mean the United States of America, its territories and possessions.

## **1.2. Interpretations.**

1.2.1. In the event an ambiguity or a question of intent or interpretation arises, this Agreement will be construed as if drafted jointly by the Parties and no presumption or burden of proof will arise favoring or disfavoring either Party by virtue of the authorship of any provisions of this Agreement. The language in this Agreement is to be construed in all cases according to its fair meaning.

1.2.2. The definitions of the terms herein apply equally to the singular and plural forms of the terms defined. Whenever the context may require, any pronoun will include the corresponding masculine, feminine and neuter forms. The words "include", "includes" and "including" will be deemed to be followed by the phrase "without limitation." Unless the context requires otherwise, (i) any definition of or reference to any agreement, instrument or other document herein will be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein or therein), (ii) any reference to any Laws herein will be construed as referring to such Laws as from time to time enacted, repealed or amended, (iii) any reference herein to any person will be construed to include the person's successors and assigns, (iv) the words "herein", "hereof" and "hereunder", and words of similar import, will be construed to refer to this Agreement in its entirety and not to any particular provision hereof, (v) any reference herein to the words "mutually agree" or "mutual written agreement" will not impose any obligation on either Party to agree to any terms relating thereto or to engage in discussions relating to such terms except as such Party may determine in such Party's sole discretion, (vi) all references herein to Sections or Attachments will be construed to refer to Sections and Attachments to this Agreement, (vii) the word "days" means calendar days unless otherwise specified, (viii) except as otherwise expressly provided herein all references to "\$" or "dollars" refer to the lawful money of the U.S., and (ix) the words "copy" and "copies" and words of similar import when used in this Agreement include, to the extent available, electronic copies, files or databases containing the information, files, items, documents or materials to which such words apply.

## **2. LICENSE**

**2.1. Grant.** During the Term hereof and subject to the other terms and conditions of this Agreement, Novelos hereby grants to Collaborator (i) the exclusive, royalty-bearing, non-transferable and non-sublicenseable (except as set forth in Section 2.2 hereof) right to research, register, develop, make, have made, use, warehouse, promote, market, sell, have sold, import, distribute, and offer for sale the Licensed Products solely and exclusively in the Territory and (ii) the exclusive, non-transferable and non-sublicenseable (except as set forth in Section 2.2 hereof) right to exploit the Novelos Technology in the Territory solely for the purpose of researching, registering, developing, making, having made, using, warehousing, promoting, marketing, selling, having sold, importing, distributing and offering for sale the Licensed Products in the Territory (the foregoing rights referred to hereinafter as the "License").

**2.2. Sublicense.** Collaborator shall be entitled to sublicense its License under Section 2.1 (i) to any of its Affiliates without Novelos's approval and (ii) to Sublicensees with Novelos's prior written approval, such approval not to be unreasonably delayed or withheld. Collaborator shall guarantee the performance of its Affiliates and Sublicensees under this Agreement with respect to any sublicense granted pursuant to this Section 2.2.

**2.3. Limitations and Reservations.** Novelos reserves for itself all rights not granted herein, including, but not limited to, (i) the irrevocable right to research, register, develop, make, have made, use, warehouse, market, sell, have sold, import, distribute, and offer for sale the Licensed Products outside of the Territory, and (ii) the irrevocable right to exploit the Novelos Technology outside of the Territory. Except for the license set forth in Section 2.1(ii), no title in or to the Novelos Technology is transferred to Collaborator pursuant to this Agreement, and no title in or to any Collaborator Technology is transferred to Novelos pursuant to this Agreement.

**2.4. Improvements.** Any Improvement shall be owned exclusively by the Party who discovered, created or developed such Improvement. If such Improvement rises to the level of a patentable invention, then the Party who discovered, created or developed it shall be the sole owner of any Patents related to such Improvement. Such Party shall be responsible for the preparation, filing, prosecution and maintenance of any Patent covering such an Improvement, and shall bear the costs associated with obtaining and maintaining any such Patent. Any Improvement discovered, created or developed during any joint trials that the Parties elect to conduct pursuant to Section 4.7.4 shall be jointly owned by the Parties in proportion to the Parties' respective financial contribution to such joint trial, and Collaborator shall be responsible for the preparation, filing, prosecution and maintenance of any Patent covering such a joint Improvement in the Territory, and Novelos shall be responsible for the preparation, filing, prosecution and maintenance of any such Patent outside the Territory, with each Party bearing the costs associated with obtaining and maintaining any such Patent in their respective geographic territories. To the extent that any Improvement discovered, created or developed by or on behalf of Novelos relates to the Licensed Products, including new dosage forms, formulations and methods of administration, such Improvements will be communicated to Collaborator and licensed to Collaborator pursuant to Section 2.1 hereof without additional compensation, unless such Improvements are discovered, created or developed by or on behalf of Novelos in an Independent Trial, in which case such Improvements will be automatically licensed to Collaborator pursuant to Section 2.1 upon receipt by Novelos of Collaborator's cash payment of fifty percent (50%) of the out-of-pocket development costs in accordance with the procedure set forth in Section 4.8.5. To the extent that any Improvement discovered, created or developed by or on behalf of Collaborator relates to the Licensed Products, including new dosage forms, formulations and methods of administration, such Improvements will be communicated to Novelos and automatically licensed to Novelos without any compensation, unless such Improvements are discovered, created or developed by or on behalf of Collaborator in an Independent Trial, in which case such Improvements will be automatically licensed to Novelos upon receipt by Collaborator of Novelos' cash payment of fifty percent (50%) of the out-of-pocket development in accordance with the procedure set forth in Section 4.8.5.



**2.5. Non-Competition.** In further consideration of the payments made and to be made under this Agreement, Novelos agrees that during the Term it shall not, and shall not grant rights to an Affiliate or a Third Party to, research, register, develop, make, have made, use, warehouse, promote, market, sell, have sold, offer for sale, import, distribute or commercialize pharmaceutical products containing the Licensed Products or NOV-205 for any indication in the field of oncology in the Territory. For the avoidance of doubt, nothing in this Agreement shall be construed to prevent Novelos from developing, registering, making, using, selling, commercializing or otherwise engaging in any activities **outside** the Territory pertaining to pharmaceutical products containing the Licensed Products or NOV-205 for any indication or granting rights to an Affiliate or a Third Party to do any of the foregoing **outside** the Territory, provided that such activities do not interfere with Collaborator's rights under this Agreement inside the Territory, as determined in accordance with the decision making provisions of Section 4.5.

### 3. PAYMENTS

**3.1. License Fee and Royalties.** For the License granted in Section 2.1 of this Agreement, Collaborator shall make the following payments to Novelos, subject to the recovery by Collaborator of the costs of the European Registration Trial in accordance with the mechanism set forth in Section 4.7.1:

3.1.1. milestone payments in the amounts described in **Attachment 4**, at the times set forth in **Attachment 4**, such payment shall be made within 30 days of reaching the applicable milestone;

3.1.2. a royalty on Net Sales of the Licensed Products in the percentages described in **Attachment 5 – Part A** (“Royalties”); and

3.1.3. super royalty payments in the amounts described in **Attachment 5 – Part B**, at the times set forth in **Attachment 5 – Part B**, such payment shall be made within thirty (30) days of reaching the applicable Net Sales thresholds.

#### **3.2. Calculations and Payment of Royalties.**

3.2.1. Unless set forth otherwise on **Attachment 5 – Part A**, Royalties shall be paid in quarterly (based on a calendar year beginning on January 1st and ending on December 31<sup>st</sup>) increments (the “Royalty Period”). Royalties shall be calculated for each Royalty Period as of the last day of each such Royalty Period. Payment of Royalties with respect to each Royalty Period shall be due within forty-five (45) days after the end of each Royalty Period, beginning with the Royalty Period in which the First Commercial Sale of a Licensed Product occurs.

3.2.2. Within forty-five days of the end of each Royalty Period (whether or not Royalties are due), Collaborator shall deliver to Novelos true and accurate reports, giving such particulars of the business conducted by Collaborator and its Affiliates and Sublicensees under this Agreement as shall be pertinent to an accounting of Royalties and other payments under this Agreement. Reports shall include at least the following on a Licensed Product-by-Licensed Product and country-by-country basis:

- (a) The units/packs of Licensed Products used, sold, licensed, or otherwise distributed;
- (b) The calculation of Net Sales;
- (c) Total amount due under this Agreement (including, without limitation, the manner in which all amounts were calculated);
- (d) Upon request by Novelos, any other information that is reasonably necessary for the purpose of showing the amounts payable to Novelos hereunder and/or the manner in which such amounts were calculated and/or the compliance by Collaborator with the diligence provisions of Section 4.9 and 6.1 hereof; and
- (e) If no payment shall be due, then the report shall so state.

**3.3. Records.** Collaborator shall keep at its principal place of business, or upon written notice to Novelos, the principal place of business of the appropriate division to which this Agreement relates, accurate records in sufficient and customary detail such that the amounts payable may be verified. During the Term and for a period of three (3) years following termination, Collaborator, its Affiliates and Sublicensees shall permit a Third Party accounting firm appointed by Novelos and reasonably acceptable to Collaborator to inspect, audit and copy its books and records regarding the sale of Licensed Products, during normal business hours, provided that Collaborator, its Affiliates or Sublicensees, as applicable, has received at least thirty (30) business days' prior written notice regarding the foregoing. Novelos may request its Third Party accounting firm to conduct such audit no more than once in any twelve (12) month period at any one location. Such records shall include but not be limited to invoice registers and original invoices; product sales analysis reports; price lists, accounting general ledgers; sublicense and distributor agreements; product catalogues and marketing materials; sales tax returns; and shipping documents. Such examination shall be made at Novelos's expense, except that if such examination discloses a shortage of eight percent (8%) or more in the amount of Royalties or other payments due Novelos for any year, then, in addition to paying the shortage of Royalties, Collaborator shall reimburse Novelos for the cost of such examination or audit, including any professional fees and out of pocket costs incurred by Novelos. A written confidentiality agreement will be required before the Third Party accounting firm commences such an examination or audit, and the results of the audit shall be treated as Confidential Information unless and until a related legal Action (including arbitration) is taken.

**3.4. Payments.** All amounts owing to either Party under this Agreement shall be paid in U.S. dollars, by check or other instrument representing immediately available funds payable to the receiving Party or in a wire transfer sent to an account specified by the receiving Party, if any are listed. If Collaborator (or an Affiliate or Sublicensee) invoices or otherwise charges Third Parties in connection with the Sale of the Licensed Products in a currency other than U.S. dollars, Royalties payable shall be expressed in their U.S. dollar equivalent based on the rate of exchange applicable on the last working day of the corresponding Royalty Period as published in the Wall Street Journal. Although Collaborator and Novelos may arrange for direct payment to Novelos by an Affiliate or Sublicensee of Collaborator (as applicable), Collaborator shall remain responsible for all unpaid amounts due pursuant to this Agreement.

**3.5. Overdue Payments.** Overdue payments shall bear simple interest until paid at an annual rate of two percent (2%) or the maximum rate allowed by law, whichever is lower. Interest accruing under this Section 3.5 shall be due on demand.

**3.6. Taxes.** Collaborator is responsible for all taxes related to this Agreement and the transactions contemplated hereby, except taxes based on net income or gross receipts of Novelos. If Collaborator is required by applicable law to deduct any taxes, assessments or other charges from or in respect of any amounts payable to Novelos under this Agreement, such deduction shall be made and paid to the relevant taxing authority or other Governmental Authority in accordance with all applicable laws, and only the remaining amount after such deduction shall be paid to Novelos hereunder. The amounts payable by Collaborator to Novelos pursuant to this Section 3.6 shall in no event be increased by such taxes, assessments or other charges. The Parties shall reasonably cooperate in completing and filing documents required under the provisions of any applicable tax treaty or under any other applicable law, and take any other reasonable actions in order to enable Collaborator to make such payments to Novelos without any deduction or withholding. In addition, upon Novelos' request, Collaborator shall furnish Novelos with proof of payment of any taxes, assessment or charges deducted hereunder.

**3.7. Termination Report and Payment.** Within forty-five (45) days after the date of termination of this Agreement (pursuant to Section 13 of this Agreement), Collaborator shall make a final report and payment to Novelos as set forth in this Agreement for the then-current Royalty Period.

## **4. DEVELOPMENT**

### **4.1. Alliance Manager.**

4.1.1. Each Party shall appoint one employee representative who possesses a good understanding of and experience in technical development and regulatory issues and the requisite experience to act as its alliance manager for this relationship (the "Alliance Manager"). As soon as the Lead Product has achieved Regulatory Approval in any of the United Kingdom, Germany, France, Spain or Italy, then each Party shall replace its respective Alliance Manager with an employee representative who possesses a good understanding of commercialization and marketing issues to act as its Alliance Manager in respect of the launch, promotion, marketing sale and distribution of the Lead Product in the Territory.

4.1.2. Each Party may replace its respective Alliance Manager at any time upon written notice to the other. Any Alliance Manager may designate a substitute with due qualification and authority to temporarily perform the functions of that Alliance Manager. Each Alliance Manager shall be charged with creating and maintaining a collaborative work environment between the Parties, including coordinating JCC meetings in conjunction with the Co-Chairs. The Alliance Managers will meet and confer on a regular basis, as often as necessary but not less than once per month, either in person or by teleconference, to discuss the status of the Parties' alliance under this Agreement. Each Alliance Manager will also be responsible for:

(a) coordinating the relevant functional representatives of the Parties in developing and executing strategies and plans for the Lead Product at the relevant phase of development and commercialization in an effort to ensure consistency and efficiency within and outside the Territory;

(b) providing a single point of communication for seeking consensus both internally within the respective Party's organization and together regarding key strategy and planning issues within the Territory;

(c) identifying and raising cross-Party issues to the JCC in a timely manner;

(d) coordinating and ensuring during the technical development and Regulatory Approval phase of the Lead Product, the pursuit of cooperative and consistent technical development and regulatory efforts for the Lead Product within the Territory; and

(e) coordinating and ensuring during the launch and commercialization phase of the Lead Product, the development of appropriate internal and external communications with respect to the Lead Product in the Territory.

#### **4.2. Joint Consultative Committee.**

4.2.1. The Parties shall establish a Joint Consultative Committee ("JCC") to consult and collaborate on all operational matters related to the Lead Product in the Territory, including all pre-clinical development, CMC, clinical development, manufacturing, regulatory, launch strategy and marketing matters.

4.2.2. The JCC shall consist of an equal number of three (3) representatives of each Party, which shall include each Party's Alliance Manager. JCC members shall be appropriately qualified and experienced to make a meaningful contribution to JCC meetings. The names of the initial members of the JCC shall be provided by each Party to the other Party within thirty (30) days after the Effective Date. A Party's JCC members may be replaced with an appropriately qualified representative at any time upon written advance notice to the other Party.

4.2.3. In the event a JCC representative from either Party is unable to attend or participate in a meeting of the JCC, the Party who designated such representative may designate an appropriately qualified substitute representative for the meeting, in its sole discretion.

4.2.4. Each Party shall appoint one of its JCC representatives to co-chair the meetings (each, a "Co-Chair"). The Co-Chairs shall (i) coordinate and prepare the agenda and ensure the orderly conduct of the meetings; (ii) attend each meeting; and (iii) prepare and issue minutes of each meeting within thirty (30) days thereafter accurately reflecting the discussions and decisions of the JCC. Such minutes from each meeting shall not be finalized until each Co-Chair representing each Party has reviewed and confirmed the accuracy of such minutes in writing. The Co-Chairs shall solicit agenda items from JCC representatives and provide an agenda along with appropriate information for such agenda reasonably in advance of any meeting. It is understood that such agenda will include all items requested by either Co-Chair for inclusion therein. In the event the Co-Chair from either Party is unable to attend or participate in a JCC meeting, the Party who designated such Co-Chair may designate a substitute Co-Chair for such meeting in its sole discretion.

### **4.3. JCC Responsibilities.**

4.3.1. The JCC shall have the following responsibilities:

(a) collaborate closely on developing the specific plans for the development and commercialization of the Lead Product in the Territory; and

(b) share information and keep the other Party informed of any issues affecting the development and commercialization of the Lead Product within and/or outside the Territory.

4.3.2. The JCC shall act solely in an advisory and consultative capacity with respect to matters concerning the development and commercialization of the Lead Product both within and outside the Territory.

4.3.3. The JCC shall conduct its discussions in good faith with a view to operating to the mutual benefit of the Parties and in furtherance of the successful development and commercialization of the Lead Product in the Territory.

### **4.4. JCC Meetings.**

4.4.1. The JCC shall have its initial meeting within sixty (60) days after the Effective Date. Thereafter, the JCC shall meet as frequently as required, but in no event less than once every three calendar months.

4.4.2. The JCC meetings may be conducted by telephone, videoconference or in person as determined by the Co-Chairs; provided that, at least once every six (6) months, a meeting shall be held in person. All in-person JCC meetings shall be held on an alternating basis between Novelos' head office in Massachusetts and the office of Collaborator's Affiliate in Cambridge, United Kingdom. Each Party shall be responsible for its own expenses relating to such meetings. As appropriate, other employee representatives or agents of the Parties may attend JCC meetings as non-voting observers and/or presenters. Each Party may also call for special meetings of the JCC to resolve particular matters requested by such Party that are within the areas of responsibility of the JCC. Each Co-Chair shall provide its Party's representatives with no less than fifteen (15) business days' notice of each regularly scheduled meeting, and no less than ten (10) business days' notice of any special meetings called by either Party. The initial meeting shall take place at Novelos' head office in Massachusetts.

#### 4.5. Decision Making.

4.5.1. Subject to Section 4.5.2, (i) all decisions with respect to matters relating to the Licensed Products outside the Territory shall be made solely by Novelos and Affiliates, with such decisions to be made in a fair and reasonable manner and in conformity with this Agreement, including without limitation Section 4.3.3, and (ii) all decisions with respect to matters relating to the Licensed Products within the Territory shall be made solely by Collaborator and its Affiliates, with such decisions to be made in a fair and reasonable manner and in conformity with this Agreement, including without limitation Section 4.3.3.

4.5.2. In the event that a decision made or proposed to be made by Novelos or its Affiliates or Third Party licensees or Sublicensees with respect to the Licensed Products is reasonably believed by Collaborator to have an actual or potential material adverse effect on a matter relating to the Licensed Products within the Territory, Collaborator will refer the matter to the JCC for good faith discussion and consideration, with the aim of resolving the issue promptly and collaboratively in accordance with the principles of Section 4.3.3. If the issue cannot be resolved within thirty (30) days of its referral to the JCC, the Parties shall refer the matter to their respective executive officers referred to in Section 15.6.2 to reach consensus in accordance with Section 15.6.3. In the event that the Parties' executive officers do not reach consensus with respect to a particular matter after endeavoring in good faith for thirty (30) days to do so, then the mediation and alternative dispute resolution provisions set forth in Sections 15.6.4 and 15.6.5 and in **Attachment 9** shall apply.

#### 4.6. Pre-Clinical, CMC Development and Manufacturing Development.

4.6.1. On the Effective Date, the Parties anticipate that each of: (i) the CMC work program set out in **Attachment 6**, (ii) the pre-clinical work program set out in **Attachment 7**, and (iii) the manufacturing development work program set out in **Attachment 8**, will be required by the EMEA in respect of the Lead Product in the Territory. Furthermore, Novelos anticipates that the work programs set out in **Attachments 6, 7 and 8** are substantially the same as those that will be required by the FDA in respect CMC development, pre-clinical development and manufacturing of the Lead Product for the USA, although the FDA may elect to waive one or more of the activities or guidelines set out in **Attachments 6, 7 or 8**. The Parties accordingly agree to work collaboratively to the fullest extent possible with the aim of expediting development of the Lead Product in the Territory and eliminating any potential duplication of effort in performing the work programs set out in **Attachments 6, 7 and 8** in accordance with the following provisions:

(a) Within thirty (30) days of the Effective Date, the Parties will review the content of **Attachments 6, 7 and 8** and compile a mutually agreed list of questions to be submitted by Novelos to the FDA for advice, including a formal request for the FDA's written confirmation as to whether any of the specific work activities or guidelines specified in **Attachments 6, 7 or 8** will not be required for development of the Lead Product for the USA. Novelos will inform Collaborator promptly upon receipt of a reply from the FDA to such request.

(b) Novelos shall be responsible for undertaking, at its cost, each of the following: (i) the CMC development work program set out in Attachment 6, (ii) the pre-clinical development work program set out in **Attachment 7**, and (iii) the manufacturing development work program set out in **Attachment 8**, in each case, in accordance with the specific guidelines listed therein, except to the extent that the FDA confirms in writing in accordance with sub-paragraph (a) above that it waives or will not require completion of a specified activity or adherence to a specified guideline set out in any of **Attachment 6, 7 or 8**. In such case, if the Collaborator believes that notwithstanding the FDA's position, such activity or guideline will be required in the Territory, then, at Collaborator's cost, Collaborator shall carry out such activity either by itself or by appointing Novelos or a Third Party to carry out such activity on Collaborator's behalf, as appropriate in the circumstances but in Collaborator's sole discretion, and the resulting data from such activity shall constitute Collaborator's Independent Data.

**4.7. Clinical Development.** Each Party shall use Commercially Reasonable Efforts to undertake its respective clinical development activities set forth below, all of which shall be conducted in accordance with GLP and GCP as applicable:

4.7.1. Collaborator shall be responsible for carrying out the Collaborator Trials at its cost in the Territory. However, in the unlikely event that the EMEA requires the Collaborator to conduct an additional clinical trial for the Lead Product in first-line advanced stage NSCLC in order to obtain Regulatory Approval for that indication in the European Union (the "European Registration Trial"), then the Collaborator shall be entitled, in its sole discretion, **either** (i) to convert the Label Expansion Trial into the European Registration Trial, subject to sub-paragraphs (a) and (c) below, **or** (ii) to commence a new Phase III clinical trial for the Lead Product in first-line advanced stage NSCLC as the European Registration Trial, subject to sub-paragraphs (b) and (c) below:

(a) If Collaborator elects to convert the Label Expansion Trial into the European Registration Trial, Collaborator shall pay for the full cost of the Label Expansion Trial and the European Registration Trial (i.e. pre- and post-conversion costs) and recover that full combined cost by reducing subsequent milestones, Royalty and super royalty payments to Novelos, as follows: Collaborator shall reduce each subsequent milestone, Royalty and super royalty payment due to Novelos pursuant to Section 3 by up to, but not more than, 50% until all costs paid by Collaborator in connection with the Label Expansion Trial and European Registration Trial, both pre- and post-conversion, have been recovered.

(b) If Collaborator elects to commence a new Phase III clinical trial for the Lead Product in first-line advanced stage NSCLC as the European Registration Trial, instead of converting the Label Expansion Trial, Collaborator shall pay for the full cost of such new Phase III trial and recover the full cost by reducing subsequent milestones, Royalty and super royalty payments to Novelos as follows: Collaborator shall reduce each subsequent milestone, Royalty and super royalty payment due to Novelos pursuant to Section 3 by up to, but not more than, 50% until all costs paid by Collaborator in connection with the European Registration Trial have been recovered.

(c) For the avoidance of doubt, if the FDA concludes that the results of the Novelos Trials are unsatisfactory or inadequate for obtaining regulatory approval of the Lead Product in first-line advanced stage NSCLC in the USA, Collaborator shall have no obligation to conduct or to continue any clinical trials of the Lead Product in any indication in the Territory, whether by way of conversion of the Label Expansion Trial specified in Section 4.7.1(i) or commencement of a new Phase III clinical trial specified in Section 4.7.1(ii) or otherwise.

4.7.2. Novelos shall conduct and complete the Novelos Trials as soon as practicable at its cost, as well as any other FDA clinical requirements. Novelos shall forward the final study report for each Novelos Trial to Collaborator within three (3) months after completion of each such trial in accordance with the applicable protocol.

4.7.3. Novelos shall provide Collaborator with a copy of the full NDA in CTD format for the Lead Product for the indication of NSCLC (first-line advanced stage) at least five (5) business days prior to its submission to the FDA.

4.7.4. The Parties may discuss and decide whether or not to conduct additional joint clinical trials of any of the Licensed Products from time to time, which, if agreed by the Parties, shall be carried out in accordance with a joint clinical development plan to be agreed in writing by the Parties and which shall identify the Parties' responsibilities with respect to the administration and funding of the agreed joint clinical trials.

4.7.5. In addition, each Party may decide, in its sole discretion, to conduct and fund further development work, including toxicology, formulation and pharmaceutical development, pharmacoeconomic analyses, market research, non-clinical studies and/or clinical trial(s) of the Licensed Products in its respective territory without any financial contribution or involvement of the other Party (an "Independent Trial") and with no right of access to the data or intellectual property resulting therefrom by the non-contributing Party unless it pays fifty percent (50%) of the cost of generating such data or intellectual property, respectively, in accordance with the procedure set forth in Section 4.8.5.

4.7.6. Novelos shall provide clinical trial supplies to Collaborator, if so requested, at the cost charged to Novelos by its contract manufacturers.

#### **4.8. Data Sharing.**

4.8.1. All data generated by or on behalf of Novelos shall be the property of Novelos; all data generated by or on behalf of Collaborator or its Affiliates or Sublicensees shall be the property of Collaborator. All data generated by or on behalf of the Parties jointly in accordance with Section 4.7.4 above shall be the joint property of the Parties in proportion to their respective financial contributions to the generation of such data.

4.8.2. On the Effective Date, Novelos shall deliver, or will have previously delivered, to Collaborator all Novelos Know-How in existence on such date. In addition, Novelos shall provide free of charge to Collaborator all results and data generated from time to time in the Novelos Trials on a timely basis, including a copy of the final study report issued in each Novelos Trial within fifteen (15) days of such report's completion.



4.8.3. All data generated by or on behalf of Collaborator at its cost, including without limitation any data arising from the Label Expansion Trial (if not converted to the European Registration Trial pursuant to Section 4.7.1 and the costs thereof recovered from Novelos pursuant to Section 4.7.1(a)), pre-clinical, CMC, clinical and/or manufacturing development work not required by the FDA but conducted by or on behalf of Collaborator pursuant to Section 4.6.1(b), shall only be made available to Novelos upon Collaborator's receipt of a cash payment equal to fifty percent (50%) of the documented out-of-pocket development costs incurred by Collaborator in generating such data.

4.8.4. Collaborator shall provide free of charge to Novelos all data generated from time to time in the European Registration Trial, on the basis that Collaborator's costs of conducting such trial are to be recovered in full from Novelos from a reduction in Royalties, super-royalties and milestones in accordance with the mechanism set forth in Section 4.7.1(a) and (b).

4.8.5. The Independent Data generated from time to time in any Independent Trials conducted and funded by a Party (the "Sponsoring Party"), including final study reports issued in such Independent Trials, shall be owned by the Sponsoring Party and shall not be provided to the other Party (the "Non-Sponsoring Party") unless such Non-Sponsoring Party makes a cash payment equal to fifty percent (50%) of the documented out-of-pocket development costs incurred by the Sponsoring Party. Within fifteen (15) days of the Sponsoring Party's receipt of the Non-Sponsoring Party's payment, the Independent Data generated in such Independent Trial shall be provided to the Non-Sponsoring Party, which may share such data with its Affiliates and Sublicensees as it sees fit. For the avoidance of doubt, the Label Expansion Trial to be conducted by Collaborator shall constitute an Independent Trial and the resulting data shall be Collaborator's Independent Data, unless or until the Label Expansion Trial is converted into the European Registration Trial pursuant to Section 4.7.1 and the pre- and post-conversion costs are to be recovered in full from Novelos from a reduction in Royalties, super-royalties and milestones in accordance with the mechanism set forth in Section 4.7.1(a).

4.8.6. Notwithstanding the foregoing provisions of this Section 4.8, (i) in no event shall a Party be obligated to disclose to the other Party protected health information obtained in its clinical trials, and (ii) the Parties shall exchange adverse event information regarding the Licensed Products on a timely basis in accordance with a separate pharmacovigilance agreement to be entered into by the Parties by not later than ninety (90) days after the Effective Date.

#### **4.9. Collaborator Commitment to Development of Lead Product.**

4.9.1. Subject to Novelos' fulfillment of its obligations under Sections 4.6 and 4.7 and subject further to Sections 6.2 and 6.4, Collaborator shall use its Commercially Reasonable Efforts to develop and to bring the Lead Product to market throughout the Territory.

4.9.2. Collaborator shall **not** be considered to have used Commercially Reasonable Efforts in Japan as required under Section 4.9.1 with respect to the Lead Product unless the Collaborator does the following:

(a) Within six (6) months of the Effective Date, Collaborator shall submit a written request to the Japanese Regulatory Authorities for advice with respect to the pre-clinical, clinical and CMC development work program required for NDA equivalent submission to the Japanese Regulatory Authorities;

(b) Within three (3) months of Collaborator's receipt of advice from the Japanese Regulatory Authorities requested pursuant to sub-paragraph (a) above, Collaborator shall create a pre-clinical, CMC and clinical development plan for the Lead Product in Japan for discussion with the JCC;

(c) Within six (6) months of Collaborator's receipt of advice from the Japanese Regulatory Authorities requested pursuant to sub-paragraph (a) above and discussion of the Japanese development plan specified in sub-paragraph (b) above with the JCC, Collaborator will decide whether or not it is commercially viable to commence any bridging or other studies that are required by the Japanese Regulatory Authorities to be conducted to obtain Regulatory Approval for the Lead Product in Japan;

(d) Within 12 months after receiving Regulatory Approval and Pricing Approval from the Japanese Regulatory Authorities, make a commercial scale launch of the Lead Product in Japan.

4.9.3. Collaborator shall **not** be considered to have used Commercially Reasonable Efforts in the European Union as required under Section 4.9.1 with respect to the Lead Product unless the Collaborator does the following:

(a) Within six (6) months of the Effective Date, request an EMEA meeting or national equivalent(s) for the purpose of determining the regulatory requirements for an MAA submission in the European Union;

(b) Within twelve (12) months of the receipt of the later of (i) the FDA's advice pursuant to Section 4.6.1 and (ii) the EMEA's or other Regulatory Authority's advice referred to in sub-paragraph (a) above, commence any pre-clinical, CMC or manufacturing development work for the Lead Product that the FDA has confirmed in writing is not required for approval in the USA as described in Section 4.6.1, but which Collaborator believes (or the EMEA or other Regulatory Authority has advised) would be required for MAA submission in the European Union;

(c) Within twelve (12) months of the Effective Date, initiate the Label Expansion Trial in the European Union; and

(d) Within six (6) months of successful completion of the later of (i) the Label Expansion Trial and (ii) the first to be completed of (A) the Novelos Trials or (B) the European Registration Trial, if conducted pursuant to Section 4.7.1, submit an MAA for the Lead Product to the EMEA, provided that Collaborator determines in its sole judgment that it has sufficient data for inclusion in the MAA to support a submission that will achieve Regulatory Approval from the EMEA.

**4.10. Development of Other Licensed Products.** In the event that the Parties wish to develop any further Licensed Products from time to time in addition to the Lead Product, such development activities, if agreed by the Parties, shall be undertaken following provisions and principles that are consistent with the development of the Lead Product under this Section 4. In such event, the Parties shall agree in good faith to a written development plan for such additional Licensed Products which shall identify the Parties' respective responsibilities and obligations relating to the specific Licensed Products to be developed.

## **5. REGULATORY ACTIVITIES.**

**5.1. Responsibility.** Collaborator shall be solely responsible for all regulatory filings and related submissions with respect to of the Lead Product and any other Licensed Products that the Parties agree to develop pursuant to Section 4.10 in the Territory (including, without limitation, obtaining all Regulatory Approvals and Pricing Approvals required to sell the Licensed Products in the Territory) and shall bear all costs in connection therewith. Collaborator will be the sole interface with and otherwise handle all correspondence, meetings and other interactions with the relevant Regulatory Authorities concerning the Regulatory Approvals of the Lead Product and any other Licensed Products in the Territory. Novelos will provide whatever assistance Collaborator may reasonably request to allow Collaborator to fulfill its obligations under this Section 5.1 and Sections 4.9 and 6.1, subject to the provisions of Section 4.8.5. All Regulatory Approvals in the Territory will be held in the name of Collaborator or an Affiliate or Sublicensee of the Collaborator, provided that, upon termination of this Agreement (other than for breach by Novelos) Collaborator shall, to the extent legally permissible, cause such Regulatory Approvals to be transferred to Novelos or to its designee, subject to Section 13.4.

**5.2. Correspondence.** The Parties will promptly and in accordance with applicable Law provide to each other copies of any documents or correspondence received from any Governmental Authority anywhere in the world, including any minutes from a meeting with respect thereto, relating to the Licensed Products or the Novelos Technology, but in no event more than ten (10) business days after each Party's receipt thereof. The Parties will provide each other with any documents or correspondence to be submitted to any Governmental Authority that relate to the Novelos Technology in sufficient time to allow the other Party a reasonable opportunity to comment thereon.

## **6. MARKETING, SELLING AND COMMERCIALIZATION.**

**6.1. Commercialization Efforts.** Collaborator shall use its Commercially Reasonable Efforts to market the Lead Product throughout the Territory, subject to Novelos' fulfillment of its obligations under Sections 4.6 and 4.7 and subject further to Sections 6.2 and 6.4.

**6.2. Pricing/Reimbursement and Product Launch.** Collaborator, at its cost, will be responsible for applying for, obtaining and maintaining all Pricing Approvals and planning launch sequencing activities related to the Lead Product and any other Licensed Products that the Parties agree to develop pursuant to Section 4.10 within the Territory. The Parties agree that the foregoing does not require simultaneous pursuit by Collaborator of Regulatory Approvals and Pricing Approvals for the Lead Product or any other Licensed Products in all countries of the Territory. Notwithstanding any other term of this Agreement, Collaborator shall not be required to pursue Regulatory Approvals and/or Pricing Approvals in any countries of the Territory in respect of which Collaborator reasonably concludes that launching and selling the Lead Product or any other Licensed Products in such country(ies) will not be commercially viable due to the likelihood of an unfavorable Pricing Approval in such country(ies) or that such Regulatory Approvals and/or Pricing Approvals are likely to have a material adverse effect on the registration, reimbursement approval or commercialization of the Lead Product and/or other Licensed Products elsewhere in the Territory. In such event, Collaborator's decision not to pursue Regulatory Approvals and/or Pricing Approvals in such country(ies) shall not be deemed a breach of Collaborator's obligations under this Section 6 or its obligation to use Commercially Reasonable Efforts in Japan and the European Union in respect of the Lead Product to the extent provided under Section 4.9 and as set forth in Section 6.1.

**6.3. Collaborator Trademarks.**

6.3.1. Collaborator will select and own the Trademarks for promoting, marketing and selling the Licensed Products in the Territory. Collaborator shall have the sole responsibility for the selection, filing, maintenance and protection of such Trademarks, except that such Trademarks shall be pre-approved by Novelos, which approval shall not be unreasonably withheld or delayed. All expenses for (i) registration of such Trademarks, and (ii) bringing, maintaining and prosecuting any Action to protect or defend such Trademarks will be borne by Collaborator and Collaborator will retain all recoveries therefrom. Upon termination of this Agreement, Collaborator will continue to have unrestricted ownership of such Trademarks in the Territory.

6.3.2. Novelos shall not use the Trademarks except as needed to fulfill its obligations under this Agreement (e.g., providing packaging that bears the Trademark in connection with supplying Licensed Products to Collaborator). Novelos will use the Trademarks in association with the Licensed Products in accordance with the guidelines and standards of use provided by Collaborator to Novelos from time to time.

6.3.3. Each Party and their Affiliates retains all rights to its trademarks, trade dress, logos, slogans, designs, and domain names as well as any modifications thereof which are not specific to the Licensed Products.

6.3.4. Each Party shall notify the other Party promptly upon learning of any actual, alleged or threatened infringement of any Trademarks or of any unfair trade practices, trade dress imitation, passing off of counterfeit goods, or like offenses relating to the Licensed Products.

6.3.5. Novelos hereby covenants and agrees not, either alone or in cooperation with any Third Party, to bring any Action against Collaborator or its Affiliates or Sublicensees asserting or claiming any interest in any of the Trademarks, or to do anything which may adversely affect the validity or enforceability of any Trademarks or any variation thereof, under any Law providing for registration of trademarks, service marks, trade names, designs, or the like in the Territory.

**6.4. Commercialization.** Collaborator shall not be obliged to launch or otherwise commercialize the Licensed Products in any country of the Territory due to one or more of the following circumstances: (i) the actual or threatened (in writing) infringement of a Third Party's intellectual rights by activities undertaken or to be undertaken in accordance with this Agreement in such country, provided that Collaborator's outside intellectual property counsel in the relevant jurisdiction (which counsel must be reasonably acceptable to Novelos) provides a written legal opinion stating that such infringement claim is colorable in the relevant jurisdiction, (ii) the suspension or withdrawal of any of the Regulatory Approvals for the Licensed Products anywhere in the Territory, or (iii) an unfavorable Pricing Approval in a country that Collaborator reasonably believes would have a material adverse effect on the commercialization of the Licensed Products elsewhere in the Territory (in which case Collaborator's obligations solely in the country in which the unfavorable Pricing Approval was received shall be excused). In case any such circumstance exists, Collaborator shall retain the exclusive rights and License granted under this Agreement in respect of such country(ies), and Novelos shall not itself or through an Affiliate launch or commercialize the Licensed Products in such countries or grant any license or rights to Commercialize the Licensed Products to any Third Parties in such country(ies) while such circumstance continues.

**6.5. Control.** Collaborator will have full and complete decision-making authority with respect to all commercialization and marketing activities relating to any and all sales of the Licensed Products in the Territory, subject to Collaborator's obligation to use Commercially Reasonable Efforts in respect of such activities.

## **7. MANUFACTURING.**

**7.1. Manufacturer Selection.** As soon as possible after the Effective Date, the JCC shall meet to evaluate and select a contract manufacturer already approved, or likely to be approved, by the EMEA or another Regulatory Authority in the European Union for supply of API and finished packs of the Lead Product to the Territory. The manufacturer evaluation and selection shall be made in good faith by the Parties on a closely collaborative basis with the mutually agreed aims of maximizing efficiencies, minimizing lead timelines to regulatory submissions, optimizing the manufacturing structure and supply routing for the Lead Product and reducing the potential for duplication of effort in producing GMP batches of Lead Product for submission to the Regulatory Authorities.

**7.2. GMP Batches.** Novelos shall appoint the selected contract manufacturer to produce, at Novelos' cost, the two GMP batches of Lead Product that are required by the FDA for NDA submission in the USA. If further GMP batches of Lead Product are required by the FDA, such additional batches shall be produced at Novelos' cost. If no further batches of Lead Product are required by the FDA but are required by the EMEA or other Regulatory Authorities in the Territory for MAA submission, such batches shall be produced at Collaborator's sole cost.

**7.3. Novelos as Manufacturer.** If the Parties decide that the optimal manufacturing structure and supply routing is for Novelos to be responsible for the manufacture and supply of Lead Product for distribution and sale by Collaborator and its designated Affiliates and Sublicensees in the Territory, then:

7.3.1. Novelos or its Third Party contract manufacturer approved by the EMEA or a national Regulatory Authority in the European Union will manufacture, package and supply the Lead Product to Collaborator or its designated Affiliates and Sublicensees in accordance with GMP and EMEA requirements;

7.3.2. Collaborator shall pay for such supplies of the Lead Product at Novelos' documented costs or Novelos' documented Third Party costs and be responsible for all shipping costs and all import costs related thereto; and

7.3.3. the Parties will enter into a separate manufacturing and supply agreement setting out the commercial, technical and legal terms and conditions governing such arrangement within sixty (60) days of the Parties' decision to appoint Novelos to manufacture, or to have manufactured, the Lead Product.

**7.4. Collaborator as Manufacturer.** Collaborator shall have the option, at its election at any time, to manufacture the Licensed Products itself or to appoint a designated Affiliate or Third Party manufacturer, and Novelos will take all necessary steps to facilitate the technology transfer necessary to permit Collaborator or its designated Affiliate or Third Party manufacturer to do so, in accordance with Section 7.5. below. All reasonable, documented costs incurred by Novelos in connection with such technology transfer shall be reimbursed by Collaborator.

**7.5. Technology Transfer.** If Collaborator elects to manufacture the Licensed Products itself or to appoint a designated Affiliate or Third Party manufacturer to do so, Novelos will undertake at Collaborator's cost the technology transfer necessary to permit Collaborator or its Affiliate or a Third Party manufacturer to manufacture the Licensed Products. Novelos will provide all reasonable and necessary assistance to facilitate Collaborator's ability to transfer the technology of manufacturing the Licensed Products to a manufacturing facility designated by Collaborator. Novelos' support during the technology transfer process will include (i) access to all of Novelos' engineering subcontractors, documents and design drawings, (ii) direct support on-site at the installation of commercial scale manufacturing capacity at the facility designated by Collaborator, and (iii) technology transfer of the manufacturing process. Novelos will develop and provide to Collaborator comprehensive, Licensed Product-specific, development reports suitable for use in the technology transfer and filings with the appropriate Regulatory Authority.

## **8. CONFIDENTIALITY**

**8.1. Limited Disclosure and Use.** Each of Novelos and Collaborator shall hold in confidence any Confidential Information disclosed by the Disclosing Party or any Third Party as a result of this Agreement, and each of Novelos and Collaborator shall protect the confidentiality thereof with the same degree of care that it exercises with respect to its own information of a like nature, but in no event less than reasonable care. Without the prior written consent of the Disclosing Party, a Receiving Party shall not use, disclose, or distribute any Confidential Information, in whole or in part, except as required to perform such Party's obligations or exercise such Party's rights hereunder, or as required to comply with subpoena or order from a court or other governmental body. Access to the Disclosing Party's Confidential Information shall be restricted to the Receiving Party's Associates, employees, agents, consultants and advisers, who, in each case, need to have access to carry out a permitted use and are bound in writing to maintain the confidentiality of such Confidential Information.

**8.2. Effect of Termination.** Each Party shall, upon termination of this Agreement, immediately discontinue use of the other's Confidential Information. Within a reasonable time after termination of this Agreement, but in no event later than thirty (30) days thereafter, all materials containing such Confidential Information shall be returned by the Receiving Party or (with the Disclosing Party's prior written consent) destroyed provided that the Receiving Party's legal advisers may retain one archival copy of the Confidential Information for purposes of determining the Receiving Party's obligations in respect thereof.

**8.3. Unauthorized Use; Remedies.** If either Party becomes aware or has knowledge of any unauthorized use or disclosure of the other Party's Confidential Information, it will promptly notify the other Party of such unauthorized use or disclosure. Each Party understands and agrees that the wrongful disclosure of the other Party's Confidential Information may result in serious and irreparable damage to the other Party, that the remedy at Law for any breach of this covenant may be inadequate, and that the Disclosing Party will be entitled to seek injunctive relief, enjoining or restraining any person from any violation or threatened violation of this Section 8, without prejudice to any other rights and remedies to which it may be entitled.

**8.4. Exclusive Property.** All Confidential Information is the sole and exclusive property of the Disclosing Party and the permitted use thereof by the Receiving Party for purposes of its performance hereunder will not be deemed a right, license or covenant, either express or implied, of the Receiving Party to use any such Confidential Information for any other purpose.

## **9. REPRESENTATIONS; WARRANTIES**

### **9.1. Limited Representation and Warranty.**

9.1.1. Novelos represents and warrants the following to Collaborator as of the Effective Date:

- (a) Novelos is a corporation duly organized, validly existing and in good standing under the laws of Delaware, with its principal place of business as indicated in the preamble of this Agreement;
- (b) Novelos has the requisite corporate power and authority and the legal right to conduct its business as now conducted and hereafter contemplated to be conducted;
- (c) Novelos has the requisite corporate power, authority and legal right to execute and deliver this Agreement, to grant rights granted to Collaborator hereby and to perform Novelos' obligations hereunder, and the person or persons executing this Agreement on its behalf has been duly authorized to do so by all requisite corporate action. The execution, delivery and performance of this Agreement do not and will not violate (i) the certificate of incorporation or bylaws of Novelos or (ii) any provision of any indenture, agreement or other instrument or document to which Novelos is a party or by which any of its assets or properties is bound or affected;

(d) Novelos is the owner of, or has exclusive rights (for at least as long as the Term) to all of the Novelos Patents and Novelos Know-How in existence on the Effective Date and such Novelos Patents and Novelos Know-How are free from any liens, encumbrances or Third Party claims;

(e) Except as set forth on Schedule 9.1.1(e), no authorization, consent, approval, license, permit, exemption of or filing or registration with or notification to, any court or Governmental Authority will be necessary for the (i) valid execution, delivery or performance of this Agreement by Novelos, (ii) the consummation of the transactions contemplated hereby, or (iii) prevention of any termination of any right, privilege, license or agreement relating to the Novelos Technology or the continuation thereof following the date hereof. No consent, approval or authorization of any person is required in connection with the execution or delivery of this Agreement by Novelos, other than the consent from the holders of Novelos' Series D Preferred Convertible Preferred Stock, such consent to be received prior to signing of this Agreement, the grant of the License to Collaborator or the performance by Novelos of any other obligation under this Agreement, or, if any such consent, approval or authorization is required (in addition to the aforementioned consent of the holders of Novelos' Series D Convertible Preferred Stock), Novelos has obtained that person's consent prior to the date hereof;

(f) To the best of Novelos' knowledge, after due inquiry, Novelos has complied with all Laws in connection with the prosecution of the Novelos Patents, including without limitation the duty of candor owed to any patent office pursuant to such Laws;

(g) Novelos has not granted any rights with respect to the Licensed Products and/or the Novelos Technology in the Territory, in each case to any person or entity other than Collaborator;

(h) There are no claims or investigations pending or threatened against Novelos or any of its Affiliates, at Law or in equity, or before or by any Governmental Authority relating to the Licensed Products and/or the Novelos Technology;

(i) Neither Novelos nor any of its Affiliates is under any obligation to any person, contractual or otherwise, that is in violation of the terms of this Agreement or that would impede the fulfillment of Novelos' obligations hereunder. Neither Novelos nor any of its Affiliates will enter into any obligation to any person or entity, contractual or otherwise, that is in violation of the terms of this Agreement or that would impede the fulfillment of Novelos' obligations hereunder;

(j) To the best of Novelos' knowledge, the Novelos Technology includes all intellectual property rights in the possession, custody or control of Novelos which are reasonably necessary for the exploitation of the Licensed Products by Collaborator in accordance with the terms of this Agreement;



(k) To the best of Novelos' knowledge, no Third Party is infringing or has infringed the Novelos Technology;

(l) At the date hereof, Novelos has no notice, and is not aware, that the exercise of Collaborator's rights granted under this Agreement infringes or conflicts with any Third Party intellectual property rights, and to the best of its knowledge the exercise of Collaborator's rights granted under this Agreement will not infringe or conflict with any Third Party intellectual property rights and will not incur any obligation to any Third Party;

(m) All material renewal and maintenance fees due as of the Effective Date with respect to the prosecution and maintenance of the Novelos Patents within the U.S. and the Territory have been paid;

(n) Novelos has allowed, and will continue to allow, Collaborator access to all material information in its possession or control (i) containing the results of all preclinical testing and human clinical testing of the Licensed Products and (ii) concerning side effects, injury, toxicity or sensitivity reaction and incidents or severity thereof with respect to Licensed Products;

(o) Novelos has not licensed or granted any rights in connection with GSSG or the Licensed Products to any Third Party in any indication in the Territory.

(p) The inventors named in the Novelos Patents listed in **Attachment 1** are, to Novelos' knowledge, all of the true inventors for such Novelos Patents and have assigned, or are under a written obligation to assign, to Novelos all of their right, title and interest to such Novelos Patents and the inventions described therein;

(q) Novelos does not know of any problems concerning the safety or efficacy of the Lead Product (including any of its ingredients) or of any questions raised by any Regulatory Authority and Novelos has informed Collaborator of any questions raised by the FDA, and of all adverse drug reactions known to Novelos relating to the Lead Product or its use;

(r) There is no Action related to, nor has Novelos received any written notice of termination under, either the 2000 BAM Agreement or the 2005 BAM Agreement, and to the knowledge of Novelos, neither BAM-RL nor Novelos is in default of any material obligation under the 2000 BAM Agreement and neither BAM nor Novelos is in default of any material obligation under the 2005 BAM Agreement;

(s) Novelos has not provided any data, information or assistance to BAM, BAM-RL or any other BAM affiliated entity that would enable BAM, BAM-RL or any other BAM affiliated entity to prepare a MAA or to apply for or achieve regulatory approval of any Licensed Products in the countries of [ \* ]; and

(t) to the best of Novelos' knowledge, none of BAM, BAM-RL or any other BAM affiliated entity has applied for regulatory approval of any Licensed Products in the countries of [ \* ], and Novelos is not aware of any plans by BAM, BAM-RL or any other BAM affiliated entity to apply for regulatory approval of any Licensed Products in the countries of [ \* ].

Novelos acknowledges that Collaborator is relying, and is entitled to rely, on the foregoing representations and warranties.

9.1.2. Collaborator represents and warrants the following to Novelos as of the Effective Date:

- (a) Collaborator has the right, power and authority to enter into and perform its obligations under this Agreement;
- (b) Collaborator is a corporation duly organized, validly existing and in good standing under the laws of Bermuda, with its principal place of business as indicated in the preamble of this Agreement;
- (c) Collaborator has the requisite corporate power and authority and the legal right to conduct its business as now conducted and hereafter contemplated to be conducted;
- (d) Other than consents, authorizations, filings, notices and other acts that have been obtained or anticipated in this Agreement, no consent or authorization of, filing with, notice to or other act by or in request of, any Governmental Authority or any other person, in the name of Collaborator, is required in connection with the execution, delivery, performance, validity or enforceability of this Agreement;
- (e) Collaborator is not aware of any fact or circumstance that would prevent it from complying with applicable Laws with respect to the development and commercialization of the Licensed Products in the Territory.

Collaborator acknowledges that Novelos is relying, and is entitled to rely, on the foregoing representations and warranties.

9.1.3. Each Party represents and warrants that (a) this Agreement has been duly executed and delivered by such Party and is a valid and binding obligation enforceable against such Party in accordance with its terms (except as such enforceability may be limited by the availability of equitable remedies); and (b) neither the execution, delivery and performance of this Agreement, nor the consummation of the transactions contemplated hereby will violate or conflict with or constitute a default under any contractual obligation applicable to such Party.

9.1.4. Neither of the Parties is aware of any Action instituted by any Governmental Authority that questions or threatens the validity of this Agreement.

**9.2. Disclaimer of Warranties.** EXCEPT AS OTHERWISE SET FORTH IN THIS AGREEMENT, THE FOREGOING REPRESENTATIONS AND WARRANTIES ARE IN LIEU OF ALL OTHER REPRESENTATIONS AND WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE AND THE STATUTORY WARRANTY OF INFRINGEMENT.

## 10. COVENANTS

### 10.1. Mutual Covenants.

10.1.1. **Compliance and Cooperation.** Each Party will maintain in full force and effect all necessary licenses, permits and other authorizations required by Law to carry out its duties and obligations under this Agreement. Each Party will comply in all material respects with all Laws applicable to its activities under this Agreement. The Parties will handle and store the Licensed Products in compliance in all material respects with all applicable Laws. Each Party will keep all records and reports required to be kept by applicable Laws. The Parties will reasonably cooperate with one another with the goal of ensuring full compliance in all material respects with applicable Laws. Each Party will cooperate with the other to provide such letters, documentation and other information on a timely basis as the other Party may reasonably require to fulfill its reporting and other obligations under applicable Laws to applicable Regulatory Authorities.

10.1.2. **Grant of Rights.** Each Party will not during the Term of this Agreement, grant any right to any Third Party which would conflict with the rights granted to the other Party hereunder or enter into any agreement which would impair its ability to perform its obligations under this Agreement.

10.1.3. **No Use of Names or Trademarks.** Except as otherwise provided in this Agreement, neither Party will use the other Party's name in connection with any publication or promotion without the other Party's prior written consent. Neither Party will use the other Party's corporate or product logo or trademark in any manner without the other Party's prior written consent.

10.1.4. **Good Practices.** Each Party will ensure that its respective obligations to develop the Licensed Products under this Agreement are carried out in accordance with GCP, GLP and GMP.

### 10.2. Covenants of Novelos. Novelos hereby covenants to and with Collaborator that:

(a) it will not take any action that would prevent Collaborator from developing and commercializing the Licensed Products under the Agreement;

(b) it will perform all acts necessary or desirable to carry out the intent of this Agreement and will maintain the Novelos Technology in full force and effect including, without limitation, timely payment of fees due thereunder;

(c) it will not, at any time after the Effective Date, and until the Agreement is terminated, in any manner whatsoever, be a party to or subject to any agreement in the Territory which would violate the terms of this Agreement;

(d) it will cooperate and consult with Collaborator with respect to Collaborator's obligations to obtain the appropriate Regulatory Approvals for the Licensed Products in the Territory;

(e) it will maintain, defend and enforce the Novelos Patents;

(f) it will use its best efforts to ensure that the Novelos Patents and Novelos Know-How remain free from any liens, encumbrances or Third Party claims (other than permitted liens or encumbrances agreed upon in advance by Collaborator);

(g) it will not represent itself as an agent or partner of Collaborator for any purpose, unless required by Law, nor pledge Collaborator's credit, or make any representations, warranties or guarantees with respect to the specifications, features or capabilities of the Licensed Products that conflict with the Licensed Product's NDA; and

(h) Novelos will comply with the material terms of both the 2000 BAM Agreement and 2005 BAM Agreement. During the Term, Novelos will not terminate the 2000 BAM Agreement pursuant to Section 24 thereof or the 2005 BAM Agreement. Novelos shall further not terminate, during the Term, the 2000 BAM Agreement for cause pursuant to Section 23 thereof without the prior written consent of Collaborator, which shall not be unreasonably withheld or delayed; provided always that Novelos shall provide Collaborator with prior written notice of its desire to terminate the 2000 BAM Agreement pursuant to Section 23 thereof at least thirty (30) days prior to the date Novelos desires to effect such termination. If Novelos receives a notice of breach from BAM-RL pursuant to Section 23 of the 2000 BAM Agreement or a notice of breach under the 2005 BAM Agreement, then Novelos shall promptly inform Collaborator of the notice and of the plan to cure the breach. If Novelos does not plan to, or is unable to, cure the breach within the time period allowed, then Collaborator shall have the right to cure the breach on Novelos' behalf. Any monies paid by Collaborator to BAM-RL or BAM pursuant to either the 2000 BAM Agreement or 2005 BAM Agreement, including any consideration payable thereunder or other amounts paid in order to cure Novelos' breach as described in this Section 10.2(h) shall be deducted from the next payment of Royalties, super-royalties or milestones due from Collaborator to Novelos.

(i) In the event that the Lee's Pharma Agreement is terminated for any reason and the Lee's Pharma Territory reverts to Novelos, Novelos shall notify Collaborator in writing within ten (10) business days of such termination. Collaborator shall have a continuing right for a period of three (3) months after receipt of such notification from Novelos to elect to add the Lee's Pharma Territory to the Territory under this Agreement in respect of the Licensed Products (but for the avoidance of doubt, not in respect of NOV-205), during which three (3) month period Novelos shall not directly or indirectly negotiate or enter into any agreement with a Third Party in respect of the Licensed Products in the Lee's Territory. If Collaborator confirms in writing to Novelos within such three (3) month period that it wishes to include the Lee's Pharma Territory within the Territory under this Agreement in respect of the Licensed Products, Collaborator shall exercise such right by paying a fee of \$[ \* ] to Novelos, and upon Novelos' receipt of such payment, the Lee's Pharma Territory shall automatically become part of the Territory hereunder and shall thereafter be governed by all of the relevant terms and conditions of this Agreement. If Collaborator declines such right or fails to confirm in writing to Novelos within such three (3) month period that it wishes to include the Lee's Pharma Territory within the Territory under this Agreement in respect of the Licensed Products, then Novelos shall have no further obligations to Collaborator in relation to the Licensed Products in the Lee's Pharma Territory.

(j) Novelos shall use its best efforts to obtain from BAM, BAM-RL and/or any other relevant BAM entity, within six (6) months of the Effective Date, the exclusive, sublicenseable right to research, register, develop, make, have made, use, warehouse, promote, market, sell, have sold, import, distribute, and offer for sale the Licensed Products in the countries of [ \* ], and immediately upon Novelos obtaining such rights, the countries of [ \* ] shall automatically become part of the Territory under this Agreement at no cost to Collaborator and shall thereafter be governed by all of the relevant terms and conditions of this Agreement.

(k) Novelos will not provide, directly or indirectly, any data or information to BAM, BAM-RL or any other BAM affiliated entity that may be used by BAM, BAM-RL or any other BAM affiliated entity to prepare a MAA or to apply for or achieve regulatory approval of any Licensed Products in the countries of [ \* ].

**10.3. Covenants of Collaborator.** Collaborator hereby covenants to and with Novelos that:

(a) it will promote, market, distribute and sell the Licensed Products in accordance with all applicable Laws in the Territory;  
and

(b) it will not, at any time after the Effective Date, and until the Agreement is terminated, in any manner whatsoever, be a party to or subject to any agreement in the Territory which would violate the terms of this Agreement.

## **11. INDEMNIFICATION AND INSURANCE**

### **11.1. Indemnification.**

11.1.1. Novelos shall, at its sole expense, indemnify, defend and hold harmless Collaborator, its Affiliates or Sublicensees and its or their respective officers, directors, agents and employees (the "Collaborator Indemnitees") from and against any and all losses, claims, damages, liabilities, costs and expenses (including reasonable attorneys' fees and court costs) (collectively "Losses") from any Third Party Actions arising out of or resulting from (i) gross negligence or willful misconduct by Novelos, its Affiliates or licensees (other than Collaborator), (ii) breach by Novelos of any its representations, warranties, covenants or agreements under this Agreement, (iii) the Licensed Products manufactured by or on behalf of Novelos or its Affiliates or its Third Party licensees or Sublicensees and supplied to Collaborator or its Affiliates or Sublicensees, and/or (iv) the Licensed Products marketed, promoted, distributed, used or sold by or on behalf of Novelos or its Affiliates or its Third Party licensees or Sublicensees outside the Territory, and all activities related thereto; provided, however, that in all cases referred to in this Section 11.1.1, Novelos will not be liable to indemnify Collaborator for any Losses of Collaborator to the extent that such Losses were caused by: (a) the gross negligence or willful misconduct or wrongdoing of Collaborator or its Affiliates or Sublicensees, or (b) any breach by Collaborator of its representations, warranties, covenants or agreements under this Agreement.

11.1.2. Collaborator shall, at its sole expense, indemnify, defend and hold harmless Novelos, its Affiliates and its or their respective officers, directors, agents and employees (the "Novelos Indemnitees") from and against any Losses from any Third Party Actions arising out of or resulting from (i) gross negligence or willful misconduct by Collaborator, its Affiliates or Sublicensees, (ii) breach by Collaborator of any its representations, warranties, covenants or agreements under this Agreement, (iii) the Licensed Products manufactured by or on behalf of Collaborator or its Affiliates or Sublicensees and supplied to Novelos or its Affiliates or Third Party licensees, and/or (iv) the Licensed Products marketed, promoted, distributed or sold by or on behalf of Collaborator or its Affiliates or Sublicensees in the Territory, and all activities related thereto; provided, however, that in all cases referred to in this Section 11.1.2, Collaborator will not be liable to indemnify Novelos for any Losses of Novelos to the extent that such Losses were: (a) were caused by the gross negligence or willful misconduct or wrongdoing of Novelos, or (b) were caused by any breach by Novelos of its representations, warranties, covenants or agreements under this Agreement, or (c) are covered by Novelos' indemnification of Collaborator pursuant to Section 11.1.1.

11.1.3. Novelos and Collaborator shall notify each other promptly in writing upon learning of any Third Party Action in respect of which indemnification may be sought under Section 11.1.1 or Section 11.1.2, as the case may be. The indemnifying Party shall actively defend against every claim using counsel approved by the indemnified Party, such approval not to be unreasonably withheld or delayed, shall promptly inform the indemnified Party and its attorneys of all developments concerning the indemnified Party and shall generally consult with the indemnified Party regarding the strategy of the defense of any claim. To the extent allowed by Law, the Novelos Indemnitees and the Collaborator Indemnitees, as the case may be, shall reasonably cooperate with the indemnifying Party in defending or settling any such claim. No settlement of any claim for which indemnification is sought, shall be made without the prior written approval of the indemnifying Party. The indemnifying Party will have sole control over the defense and/or settlement, subject to the Novelos Indemnitees and the Collaborator Indemnitees, as the case may be, right to select and use their own counsel at their sole cost and expense.

**11.2. Insurance.** With effect from the initiation of the first clinical trial of any Licensed Product, Novelos, Collaborator and their respective Affiliates and Sublicensees and Third Party licensees of Novelos shall obtain and carry in full force and effect insurance with the coverages and limits as are reasonably adequate to ensure that each Party can meet its respective obligations to the other Party pursuant to Section 11.1, the nature and extent of which insurance shall be commensurate with usual and customary industry practices for similarly situated companies. Such insurance will be written by a reputable insurance company and the insured Party shall give thirty (30) days written notice to the other Party prior to any cancellation, endorsement or other change (but only ten (10) days' written notice in the event of cancellation for non-payment of premium). Upon request, each Party will provide the other Party with appropriate certificates of insurance reflecting its respective obligations pursuant to this Section 11.2; provided that with the exception of maintaining insurance coverage that may be required by Law for conducting clinical trials, Collaborator may fulfill its obligations under this Section 11.2 by means of self-insurance arrangements.

## 12. PROTECTION OF INTELLECTUAL PROPERTY RIGHTS

**12.1. Cooperation of Collaborator.** Collaborator will, upon request of Novelos, execute all documents and perform all lawful acts that Novelos considers necessary or advisable to (a) secure its intellectual property rights hereunder, including having its employees and the employees of its Affiliates execute when appropriate, patent and other applications and assignments thereof to Novelos, or persons designated by it, (b) provide reasonable assistance to Novelos in enforcing Novelos's rights in the Novelos Technology, including the Novelos Patents, including, without limitation, testifying in any suit or proceeding involving any of said Novelos Technology or executing any documents deemed necessary or advisable by Novelos in connection with such enforcement, all without further consideration than provided for herein. Novelos agrees that reasonable travel and out of pocket expenses for such assistance incurred by Collaborator at the request of Novelos under this Section 12.1 will be reimbursed by Novelos.

**12.2. Third Party Infringement.** Each Party shall promptly inform the other Party of any suspected infringement in the Territory of any Novelos Patent by a Third Party. Promptly thereafter the Parties shall confer about the suspected infringement and its likely legal and economic impact. The Parties shall have the rights to institute an Action for infringement of the Novelos Patent against such Third Party in accordance with the following:

(a) If the Parties agree to institute an Action jointly against a Third-Party infringer based upon any Novelos Patent, the Action shall be brought in both their names, the out-of-pocket costs thereof shall be borne equally or as mutually agreed to, and any recovery or settlement shall be shared equally or as mutually agreed to. The Parties shall agree to the manner in which they shall exercise control over such legal Action. Each Party may, if it so desires, also be represented by separate counsel of its own selection, the fees for which counsel shall be paid by that Party. Should either Party wish to abandon an Action commenced under the provisions of this Section 12.2, it shall give timely notice to the other Party which may, if it so desires, continue prosecution of such Action, provided, however, that unless the sharing of expenses and of recovery in such Action are otherwise agreed upon between the Parties, the Party prosecuting the Action shall bear the entire cost of such litigation, including, without limitation, the legal expenses incurred in connection with the Action, and shall be entitled to retain the entire amount of any recovery or settlement.

(b) In the absence of an agreement to institute an Action jointly regarding a Third-Party infringement, Novelos may institute the Action and, at its option, join Collaborator as a plaintiff, in which case, Novelos shall bear the entire cost of such Action, including, without limitation, the legal expenses of Collaborator, and shall be entitled to retain the entire amount of any recovery or settlement.

(c) In no event shall Collaborator prosecute any Action against a Third Party infringer of a Novelos Patent without Novelos's prior written consent. Collaborator's sole remedy for Novelos's refusal to prosecute a Third Party infringer of a Novelos Patent shall be to terminate the Agreement pursuant to Section 13.3.

### **13. TERM AND TERMINATION; REVERSION OF RIGHTS**

**13.1. Term of Agreement.** Unless otherwise terminated as expressly provided herein, this Agreement and the License granted hereunder shall commence on the Effective Date and continue on a country-by-country basis within the Territory until:

(a) with respect to each country of the Territory in which a Novelos Patent was in effect on the Effective Date, the earlier of (i) the expiration of the last of the Novelos Patents covering the Licensed Products in such country and (ii) a final judgment of any Governmental Authority that any of the Novelos Patents covering the Licensed Products, which Collaborator in its sole judgment deems necessary to exercise its rights under this Agreement, are invalid, obvious or otherwise unenforceable in such country, and

(b) with respect to each country of the Territory in which a Novelos Patent was not in effect on the Effective Date, the earlier of (i) the occurrence of Generic Product Competition in such country and (ii) the expiration of fifteen (15) years from the Effective Date

(the "Term"). Upon expiration of the Term in a country of the Territory under this Section 13.1, Collaborator shall have a royalty-free, fully paid-up license for the grant of rights under Section 2 in such country of the Territory.

#### **13.2. Novelos Right to Terminate.**

13.2.1. Novelos shall have the right (without prejudice to any of its other rights conferred on it by this Agreement or otherwise) to terminate this Agreement if Collaborator or any of its Affiliates:

(a) is in default in payment of any amount or other consideration or reimbursement required under this Agreement, and Collaborator fails to remedy any such default within thirty (30) days after written notice thereof by Novelos;

(b) is in breach of or defaults with respect to any material provision of this Agreement and Collaborator fails to remedy any such breach or default within sixty (60) days after written notice thereof by Novelos; or

(c) files any Action to challenge any of Novelos's rights in the Novelos Technology, and such right to terminate shall be immediate upon the filing of such Action.

13.2.2. In the event that Novelos has the right to terminate this Agreement for any of the reasons stated in Section 13.2.1(a) – (c), at the election of Novelos, exercised in its sole discretion by written notice to Collaborator, and in lieu of terminating this Agreement, Novelos may (i) declare the License rights granted under this Agreement to be non-exclusive, and grant to such Third Parties any and all additional non-exclusive rights to the Technology as Novelos shall determine in its sole discretion; or (ii) declare the License granted under this Agreement to be non-exclusive in the specific country or countries in the Territory in which Collaborator has breached its obligations, and grant to such Third Parties in such country or countries any and all additional non-exclusive rights to the Technology as Novelos shall determine in its sole discretion; or (iii) terminate the License granted under this Agreement in the specific country or countries in the Territory in which Collaborator has breached its obligations.



### 13.3. Collaborator Right to Terminate.

13.3.1. Collaborator shall have the right (without prejudice to any of its other rights conferred on it by this Agreement or otherwise) to terminate this Agreement if Novelos:

- (a) is in default in payment of any amount or other consideration or reimbursement required under this Agreement, and Novelos fails to remedy any such default within thirty (30) days after written notice thereof by Collaborator; or
- (b) is in breach of or defaults with respect to any material provision of this Agreement and Novelos fails to remedy any such breach or default within sixty (60) days after written notice thereof by Collaborator; or
- (c) (i) applies for or consents to the appointment of, or the taking of possession by, a receiver, custodian, trustee or liquidator of itself or of all or a substantial part of its property, (ii) makes a general assignment for the benefit of its creditors, (iii) commences a voluntary case under the Bankruptcy Code, (iv) files a petition seeking to take advantage of any Laws relating to bankruptcy, insolvency, reorganization, winding-up, or composition or readjustment of debts, (v) fails to controvert in a timely and appropriate manner, or acquiesce in writing to, any petition filed against it in any involuntary case under the Bankruptcy Code, (vi) takes any corporate action for the purpose of effecting any of the foregoing, (vii) has a proceeding or case commenced against it in any court of competent jurisdiction, seeking (A) its liquidation, reorganization, dissolution or winding-up, or the composition or readjustment of its debts, (B) the appointment of a trustee, receiver, custodian, liquidator or the like of all or any substantial part of its assets, or (C) similar relief under the Bankruptcy Code, or an order, judgment or decree approving any of the foregoing is entered and continues unstayed for a period of sixty (60) days, or (viii) has an order for relief against it entered in an involuntary case under the Bankruptcy Code.

13.3.2. Should any serious and unexpected events or issues occur with respect to the safety of Licensed Products, as a result of which, any Regulatory Approval is terminated or suspended in the Territory, or a Regulatory Authority directs or requests discontinuance of development, use or sale of a Licensed Product anywhere in the world, then Collaborator's obligations under this Agreement with respect to that Licensed Product will be suspended until such serious safety event is resolved and the Regulatory Authority has given approval again to distribute the Licensed Product. Collaborator may, upon written notice to Novelos, terminate this Agreement pursuant to this Section 13.3.2 if the Agreement is suspended pursuant to this Section 13.3.2 for a period in excess of 12 months.

13.3.3. Collaborator may terminate this Agreement immediately on written notice to Novelos in the event that either the 2000 BAM Agreement or 2005 BAM Agreement terminates for any reason unless Collaborator has otherwise consented to such termination as set forth in Section 10.2(i).

13.3.4. Collaborator may terminate this Agreement at any time by written notice to Novelos at least thirty (30) days prior to the termination date specified in the notice.

**13.4. Effect of Termination.** Upon the expiration or termination of this Agreement on a country-by-country basis within the Territory, each of the following will occur:

13.4.1. Upon the termination of this Agreement under Section 13.2.1, 13.3.2 or 13.3.4, Collaborator and its Affiliates shall immediately cease using the Novelos Technology for any purpose and shall also immediately cease making, having made, using, selling, and importing the Licensed Products, and shall return to Novelos, or deliver or destroy as Novelos directs, the Licensed Products, all copies of the Novelos Technology and any Confidential Information then in its possession in accordance with Section 8.2, all of the foregoing to be returned, delivered or destroyed at Collaborator's cost. Furthermore, all of the rights granted pursuant to Section 2.1 shall revert to Novelos, Collaborator shall provide Novelos with access to all data pertaining to the Licensed Products in the Territory developed pursuant to this Agreement (other than Independent Data and Improvements arising in any Independent Trial of Collaborator if Novelos has not paid fifty percent (50%) of the costs of such data in accordance with Section 4.8.5) and Collaborator shall assign or cause to be assigned to Novelos all filings pertaining to the Licensed Products (including any regulatory filings and certifications and trademark and Patent applications, Regulatory Approvals and Pricing Approvals that are in the name of Collaborator or any of its Affiliates) with all of such rights, data, applications, filings and approvals to be delivered, assigned or transferred at Collaborator's cost; provided, however, Collaborator shall not assign or otherwise transfer ownership of Independent Data or Improvements arising in any Independent Trials.

13.4.2. Upon the termination of this Agreement under Section 13.3.1 or 13.3.3, Collaborator may choose, in its sole discretion, either:

(a) along with its Affiliates, to immediately cease using the Novelos Technology for any purpose and also to immediately cease making, having made, using, selling, and importing the Licensed Products, and to return to Novelos, or deliver or destroy as Novelos directs, the Licensed Products, all copies of the Novelos Technology and any Confidential Information then in its possession in accordance with Section 8.2, all of the foregoing to be returned, delivered or destroyed at Novelos' cost. Furthermore, all of the rights granted pursuant to Section 2.1 shall revert to Novelos, Collaborator shall provide Novelos with access to all data pertaining to the Licensed Products in the Territory developed pursuant to this Agreement (other than Independent Data and Improvements arising in any Independent Trial of Collaborator if Novelos has not paid fifty percent (50%) of the costs of such data in accordance with Section 4.8.5) and Collaborator shall assign or cause to be assigned to Novelos all filings pertaining to the Licensed Products (including any regulatory filings and certifications and trademark and Patent applications, Regulatory Approvals and Pricing Approvals that are in the name of Collaborator or any of its Affiliates), with all of such rights, data, applications, filings and approvals to be delivered, assigned or transferred at Novelos' cost; provided, however, Collaborator shall not assign or otherwise transfer ownership of Independent Data or Improvements arising in any Independent Trials;

(b) to require that Novelos promptly takes, and Novelos hereby agrees to take, such actions as Collaborator may reasonably request, in order to transfer to Collaborator, or its designated Affiliates or Sublicensees, free of charge, in respect of the Territory only: all of Novelos' right, title and interest in and to, the Licensed Products, Novelos Technology, access to any data relating to said Licensed Products, all licenses and like permissions and certifications then in Novelos' possession or control required for Collaborator to exercise its rights under Section 2.1, including without limitation the right to research, register, develop, make, have made, use, warehouse, promote, market, sell, have sold, offer for sale, import, distribute or commercialize pharmaceutical products containing the Licensed Products. In the event of such an assignment, Novelos will, at its expense and Collaborator's request, deliver, execute and/or deliver or cause to be delivered, all such assignments, consents, documents or further instruments of transfer or license, and take or cause to be taken all such actions as may be reasonably necessary to effectuate such transfer. Novelos will further reconvey and release to Collaborator all rights and privileges originally granted to it under this Agreement such that all such rights and privileges will vest with Collaborator. Collaborator will, in such circumstances, pay to Novelos the Royalties on Licensed Products set forth in Section 3 and **Attachment 5 – Part A** after deducting the Collaborator's cost of curing the consequences of Novelos' breach that resulted in termination under Section 13.3.1 or Section 13.3.3. Such other provisions hereof as are necessary to administer the calculation and payment of such royalties will also survive such termination, including without limitation, any audit, payment and record retention provisions. Collaborator will thereafter be free to exercise its rights under the License to the Licensed Product in the Territory as it may see fit, and Novelos and its Affiliates or Sublicensees will not take any actions or make any omissions to prevent Collaborator therefrom.

13.4.3. If the rights under Section 2.1 are terminated only in specific countries of the Territory pursuant to Section 13.2.2 rather than throughout the Territory, the obligation to provide access to data and to assign filings pursuant to Sections 13.4.1 and 13.4.2 shall be limited to the specific countries with respect to which such rights have been terminated.

13.4.4. Notwithstanding the termination or expiration of this Agreement for any reason, the following provisions shall survive:

(a) Collaborator's obligation to pay fees and royalties and costs hereunder that are accrued and remaining unpaid or unperformed under the terms of this Agreement prior to such termination;

(b) Any Novelos obligation to reimburse Collaborator for the European Registration Trial costs that may exist pursuant to Section 4.7.1(a) or (b), as applicable, and that are accrued and remaining unreimbursed prior to such termination;

(c) Sections 2.3, 2.4 (the first three sentences only), 3.3, 3.7, 6.3.1 (last sentence), 6.3.3, 6.3.5, 8, 9, 10.1.3, 11, 12, 13.1 (last sentence only), 13.4, 14 and 15;

(d) any cause of action or claim of Collaborator or Novelos, accrued or to accrue, because of any breach or default of this Agreement by the other Party; and

(e) Collaborator, its Affiliates and Sublicensees shall, after termination, be entitled to sell any inventory of Licensed Products that have been manufactured at the time termination takes effect, provided that any Royalties payable on such sales are paid by Collaborator, subject to any applicable recovery for the European Registration Trial costs pursuant to Section 4.7.1(a) or (b) as applicable.

#### **14. LIMITATION OF LIABILITY**

EXCEPT FOR VIOLATIONS OF NOVELOS'S INTELLECTUAL PROPERTY RIGHTS AND FOR DAMAGES CAUSED BY A PARTY'S GROSS NEGLIGENCE OR INTENTIONAL MISCONDUCT, IN NO EVENT SHALL A PARTY BE LIABLE TO THE OTHER PARTY FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES, WHETHER OR NOT THE PARTY ALLEGEDLY CAUSING THE DAMAGE HAS BEEN ADVISED OF THE POSSIBILITY THEREOF. THIS SECTION 14 SHALL NOT BE CONSTRUED TO LIMIT ANY PARTY'S INDEMNIFICATION OBLIGATIONS UNDER SECTION 11.1 HEREOF. IN NO EVENT SHALL NOVELOS'S LIABILITY EXCEED ONE HUNDRED PERCENT (100%) OF THE AMOUNTS THAT HAVE BEEN PAID TO IT UNDER THIS AGREEMENT.

#### **15. GENERAL**

##### **15.1. Waivers and Amendments.**

(a) This Agreement may be amended, modified or supplemented only by a written instrument executed by the Parties hereto.

(b) No waiver of any provision of this Agreement, or consent to any departure from the terms hereof, shall be effective unless the same shall be in writing and signed by the Party waiving or consenting thereto. No failure on the part of a Party to exercise, and no delay in exercising, any right or remedy hereunder shall operate as a waiver thereof, nor shall any single or partial exercise of any such right or remedy by such Party preclude any other or further exercise thereof or the exercise of any other right or remedy. The waiver by a Party hereto of a breach of any provision of this Agreement shall not operate as a waiver of any subsequent breach. All rights and remedies hereunder are cumulative and are in addition to and not exclusive of any other rights and remedies provided by Law.

**15.2. Entire Agreement.** This Agreement and the Attachments hereto constitute the entire agreement among the Parties hereto with respect to the subject matter hereof and supersede all prior agreements and understandings, whether written or oral, between the Parties, in connection with such subject matter. There are no covenants, promises, agreements, warranties, representations, conditions or undertakings, either oral or written, between the Parties other than as set forth herein.

**15.3. Severability.** If any provision of this Agreement is found invalid or unenforceable by a court of competent jurisdiction, such provision shall be enforced to the maximum extent permissible by Law and the other provisions of this Agreement shall remain in full force and effect.

**15.4. Relationship of the Parties.** This Agreement shall not be interpreted to constitute the appointment of one Party the agent or legal representative of the other Party for any purpose whatsoever, and neither Party shall hold itself out as an agent of the other Party. This Agreement creates no relationship of joint venturers, partners, Affiliates, employment or principal and agent between or among the Parties, and each of the Parties is acting as an independent contractor. Neither Party is granted herein any right or authority to, and shall not attempt to, assume or create any obligation or responsibility for or on behalf of any other Party. Neither Party shall have any authority to bind the other Party to any contract, whether of employment or otherwise, and each Party shall bear all of its respective expenses for its operations, including, without limitation, the compensation of its employees and salespersons and the maintenance of its offices, service and warehouse facilities. Each Party shall each be solely responsible for its own employees and salespersons and for the acts and the things done by them.

**15.5. Notices.** All notices, instructions and other communications hereunder or in connection herewith will be in writing, will be sent to the addresses below (or at such other address for a Party as shall be specified by like notice) and will be: (a) delivered personally; (b) sent by registered or certified mail, return receipt requested, postage prepaid; (c) sent via a reputable nationwide overnight courier service; or (d) sent by facsimile transmission. Any such notice, instruction or communication will be deemed to have been delivered (i) upon receipt if delivered by hand, (ii) three business days after it is sent by registered or certified mail, return receipt requested, postage prepaid, (iii) one business day after it is sent via a reputable nationwide overnight courier service, or (iv) when transmitted with electronic confirmation of receipt, if transmitted by facsimile (if such transmission is prior to 5:00 p.m. local time on a business day; otherwise, on the next business day following such transmission).

For Novelos:

NOVELOS THERAPEUTICS, INC.  
One Gateway Center, Suite 504,  
Newton, Massachusetts 02458  
Attention: Harry S. Palmin,  
President and CEO  
Telephone: +1 617-244-1616 x11  
Fax: +1 617-860-1170  
Email: [hpalmin@novelos.com](mailto:hpalmin@novelos.com)

For Collaborator:

Mundipharma International Corporation Limited  
14 Par-la-Ville Road  
P.O. Box HM2332  
Hamilton HMJX  
Bermuda  
Attention: Douglas Docherty, General Manager  
Telephone: +(441) 295 6480  
Fax: +(441) 292 1472  
[Douglas.docherty@mundipharma.bm](mailto:Douglas.docherty@mundipharma.bm)

with a copy to:

Foley Hoag LLP  
155 Seaport Boulevard  
Boston, MA 02210,  
Attention: Paul Bork, Esq.  
Telephone: +1 617-832-1113  
Fax.: +1 617-832-7000  
Email: [pbork@foleyhoag.com](mailto:pbork@foleyhoag.com)

with copies to:

Mundipharma International Limited  
Cambridge Science Park  
Milton Road, Cambridge CB4 0GW, United Kingdom  
Attention: Managing Director, and  
European General Counsel

Chadbourne & Parke LLP  
30 Rockefeller Plaza  
New York, NY 10112  
Attention: Stuart D. Baker  
Telephone: (212) 408-5100  
Fax: (212) 541-5369

**15.6. Governing Law, Jurisdiction and Dispute Resolution.**

15.6.1. This Agreement, including the interpretations, performance, enforcement, breach or termination hereof and any remedies relating hereto, shall be governed by, and construed and enforced in accordance with, the substantive laws of the State of New York, USA, without giving effect to its conflicts of laws rules. Courts located in New York County, New York, USA shall have exclusive jurisdiction over claims relating to this Agreement.

15.6.2. Unless otherwise set forth in this Agreement, in the event of a dispute arising under this Agreement between the Parties and/or their Affiliates, such dispute shall be referred to the respective executive officers of the Parties designated below, or their successors, for good faith negotiations attempting to resolve the dispute. The designated executive officers are as follows:

For Collaborator:	Regional Director, Europe
For Novelos:	President and CEO

15.6.3. Any dispute or claim arising out of or relating to this Agreement (other than with respect to Patent, copyright, trademark or trade secret rights), or to the breach, termination, or validity of this Agreement, will be resolved as follows: the executive officers of each Party referred to in Section 15.6.2 above will meet to attempt to resolve such dispute by good faith negotiations. If such executive officers cannot resolve the dispute within 30 days after a Party requests such a meeting, then each Party will attempt in good faith to settle the dispute by mediation pursuant to Section 15.6.4.

15.6.4. The mediation of any dispute is to be administered by JAMS or such other mediator as may be mutually agreed to by the Parties. If mediation is unsuccessful within 30 days after the Parties request mediation pursuant to Section 15.6.3, the Parties may then resort to the alternative dispute resolution procedures set forth in **Attachment 9**.

15.6.5. Notwithstanding anything to the contrary in Sections 15.6.2, 15.6.3 and 15.6.4, if either Party in its sole judgment believes that any such dispute could cause it irreparable harm, such Party (a) will be entitled to seek equitable relief in order to avoid such irreparable harm, and (b) will not be required to follow the procedures set forth in the foregoing Sections 15.6.2, 15.6.3 and 15.6.4.

**15.7. Counterparts.** This Agreement may be executed in two or more counterparts, all of which shall be considered one and the same agreement and shall become effective when two or more counterparts have been signed by each of the Parties and delivered to the other Party, it being understood that both Parties need not sign the same counterpart. Facsimile execution and delivery of this Agreement by either Party shall be legal, valid and binding execution and delivery of such document for all purposes.

**15.8. Assignment.** This Agreement is personal to the Parties, and neither Party shall assign any of its rights or delegate any of its obligations hereunder, provided, however, that (i) Novelos may assign this Agreement to any successor by consolidation, merger or other corporate action, or to a corporation or other business entity to which the Novelos may sell all or substantially all of its business, provided that such assignment is part of the transfer of the business, and (ii) Collaborator may assign this Agreement, in whole or in part, to any of its Affiliates.

**15.9. Force Majeure.** Neither Party shall be liable for failure to perform any of its obligations under this Agreement when such failure is due to war, terrorism, epidemic, explosion, failure of public utilities or common carriers, fire, flood, earthquake, storm, strikes, labor troubles or other industrial disturbances, legal restriction, act or pronouncement by any Governmental Authority or Regulatory Authority, shortages of raw materials, riot, insurrection, or any other cause beyond the reasonable ability of the Party affected thereby to foresee and avoid, and without such Party's fault or negligence ("Force Majeure"), provided that the Party claiming the existence of Force Majeure shall give notice to the other Party not more than seven (7) days after the commencement of the event of Force Majeure, and shall use prompt and diligent efforts to mitigate the effects of Force Majeure. In the event that any event of Force Majeure prevents performance for sixty (60) days or more, any other Party may terminate this Agreement on written notice to the other Party unless the Party affected by the event of Force Majeure is using and continues to use Commercially Reasonable Efforts to remove or cure the Force Majeure event.

**15.10. Further Assurances.** After the Effective Date, the Parties shall, from time to time, execute and deliver such additional instruments, documents, conveyances or assurances and take such other action as shall be necessary or other reasonably requested by the other Party, to confirm and assume the rights and obligations provided for in this Agreement.

**15.11. Intellectual Property.** The Parties acknowledge and agree that the License and all other rights granted under or pursuant to this Agreement are and shall otherwise be deemed to be, for purposes of Section 365(n) of the Bankruptcy Code, licenses of rights to "intellectual property" as defined under Section 101(35A) of the Bankruptcy Code, and that this Agreement is an executory contract governed by Section 365(n) of the Bankruptcy Code in the event that a bankruptcy proceeding is commenced involving Novelos. Collaborator, as the licensee of such rights under this Agreement, shall retain and may fully exercise all of its rights and elections under the Bankruptcy Code. The foregoing provisions of this Section 15.11 are without prejudice to any rights the Parties may have arising under the Bankruptcy Code or other applicable Law.

**15.12. Press Releases and External Communications.** The Parties will issue the initial press release(s) attached hereto as Attachment 10 on the Effective Date. Thereafter, neither Party shall issue press releases or make public announcements relating to the transactions contemplated by this Agreement without the other Party's prior written approval, which approval shall not be unreasonably withheld or delayed; provided, however, that nothing in this Section 15.12 shall impair either Party's compliance with any requirements of the Securities and Exchange Commission or the national securities exchange or other stock market on which such Party's securities are traded; and, provided further, that Novelos may issue external media and investor communications related to the transactions contemplated by this Agreement if such external media communications are previously approved by Collaborator, which approval shall not be unreasonably withheld or delayed. In connection with any filing by either Party of a copy of this Agreement with the Securities and Exchange Commission (or the national securities exchange or other stock market on which such Party's securities are traded), the filing Party shall endeavor to obtain confidential treatment of economic and trade secret information. At least two business days in advance of filing, the filing Party shall provide to the other Party a copy of the proposed filing and the Parties shall work cooperatively in good faith, taking into consideration the other Party's suggestions, regarding the information for which the filing Party will seek to obtain confidential treatment.

**15.13. Non-Solicitation of Employees.** During the Term, neither Party may, directly or indirectly, recruit or solicit any employee of the other Party who became known to the other Party through contact or interactions for the purposes of negotiating or performing this Agreement, without the prior consent of the other Party, except pursuant to general solicitations not targeted at such employees.

**15.14. Expenses.** Each of the Parties will bear its own direct and indirect expenses incurred in connection with the negotiation and preparation of this Agreement and, except as set forth in this Agreement, the performance of the obligations contemplated hereby and thereby.

**15.15. Headings.** The headings for each Article and Section in this Agreement have been inserted for convenience of reference only and are not intended to limit or expand on the meaning of the language contained in the particular Article, and will be of no force or effect in construing or interpreting any of the provisions of this Agreement.

*[Signature Page Follows]*



IN WITNESS WHEREOF, the Parties have executed, or caused their duly authorized representatives to execute, this Agreement under seal as of the date first written above.

**Novelos Therapeutics, Inc.**

By: /s/ Harry S. Palmin

Name: Harry S. Palmin

Title: President and Chief Executive Officer

**Mundipharma International Corporation Limited**

By: /s/ Douglas Doherty

Name: Douglas Docherty

Title: General Manager

**Schedule 9.1.1(e)**

**Government Consents and Filings**

Novelos will be making various FDA filings in performance of this Agreement.

**Attachment 1**

**Novelos Patents**

US6165979
US6251857
US6312734
US6492329
US7169412
US7371411
EP0869809
EP1131340
JP3547400
JP2007-238577
CA2239874
CA2351354
CH2010/97
CN1207683
HK1042306

**Attachment 2**

**Novelos Trials**

1. A Randomized, Open-Label, Phase 3 Trial of NOV-002 in Combination with Paclitaxel and Carboplatin vs. Paclitaxel and Carboplatin Alone for the Treatment of Advanced Non-small Cell Lung Cancer
2. Phase 2 Trial of Neoadjuvant Treatment with NOV-002 in Combination with Doxorubicin and Cyclophosphamide Followed by Docetaxel in Patients with Stages IIB-IIIC Breast Cancer

Attachment 3

Territory

Albania Andorra Australia Austria Belgium Bosnia-Herzegovina Bulgaria Croatia Cyprus Czech Republic Denmark Finland France Germany Greece Hungary Iceland India Indonesia Ireland Israel Italy Japan Korea (South) Liechtenstein	Luxembourg Macedonia Malaysia Malta Monaco Montenegro Netherlands New Zealand Norway Philippines Poland Portugal Republic of Ireland Romania Serbia Singapore Slovakia Slovenia Spain Sweden Switzerland Thailand Turkey United Kingdom Vietnam
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**Attachment 4**

**Milestone Payments**

Launch of Product for *Non-small cell lung cancer*  
(1st line advanced)

· \$2.5M per country of Territory to maximum of \$25M \$25,000,000

**Each \$2,500,000 milestone payment is separate. That is, the aggregate milestone payments set forth in this Attachment 4 equal \$25,000,000. All amounts are in U.S. dollars.**

The milestone payments set forth in this Attachment are separate from and in addition to the Royalties set forth in Section 3.1.2 (and **Attachment 5 – Part A**) and the super royalty payments set forth in Section 3.1.3 (and **Attachment 5 – Part B**).

**Attachment 5**

**Part A - Royalty Payments**

Column A Royalty Rate	Column B Royalty Rate	Annual Net Sales
[ * ]	[ * ]	\$100,000,000 or less
[ * ]	[ * ]	> \$100,000,000 but less than or equal to \$250,000,000
[ * ]	[ * ]	> \$250,000,000 but less than or equal to \$500,000,000
[ * ]	[ * ]	>\$500,000,000

Column A Royalties

The Royalty rates set forth above in Column A shall apply in each of the countries of the Territory in which any Novelos Patent is in effect on the Effective Date, which are: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Japan, Liechtenstein, Luxembourg, Monaco, Netherlands, Portugal, Spain, Sweden, Switzerland and the United Kingdom. The Royalty rates set forth above in Column A shall remain in effect within a given country in the Territory until such time as (a) there are no longer Novelos Patents in effect within such country or (b) Generic Product Competition occurs. Upon the occurrence of the aforementioned clause (a) and pursuant to Section 13.1, no further Royalties under Section 3.1.2 and this **Attachment 5 – Part A** shall be due in such country and the Collaborator shall have a royalty-free, fully paid-up license for the grant of rights under Section 2. Subject to Section 13.1(a), upon the occurrence of the aforementioned clause (b), the respective royalty rates otherwise specified in Column A of this **Attachment 5 – Part A** shall be reduced to a rate which is the **lesser** of (i) [ \* ] percent ([ \* ]%), and (ii) [ \* ] percent ([ \* ]%) more than the percentage consideration payable by Novelos to BAM pursuant to Clauses 1 and 2 of the current 2005 BAM Agreement for as long as such consideration is payable to BAM under the current 2005 BAM Agreement.

Column B Royalties

The Royalty rates set forth above in Column B shall apply in each of the countries of the Territory in which no Novelos Patent is in effect on the Effective Date and such Royalty rates shall remain in effect for fifteen years from the Effective Date within a given country in the Territory unless and until such time as Generic Product Competition occurs. Upon the occurrence of Generic Product Competition, no further Royalties under Column B shall be due and the Collaborator shall have a royalty-free, fully paid-up license for the grant of rights under Section 2.

For the purpose hereof, "annual Net Sales" shall mean a period commencing January 1<sup>st</sup> and ending December 31<sup>st</sup> of the same year.

For example if annual Net Sales in a particular year are \$600,000,000 of which \$550,000,000 were from countries where Column A applies and \$50,000,000 were from countries where Column B applies, and in the absence of any Generic Product Competition, the Royalties would be calculated as follows:

- (i) a Royalty rate of [ ]% on sales on the first \$100,000,000,
- (ii) plus [ \* ]% on the next \$150,000,000,
- (iii) plus [ \* ]% on the next \$250,000,000,
- (iv) plus [ \* ]% on the next \$50,000,000

and in countries where a Novelos Patent has not been filed

- (v) plus [ \* ]% on the next \$50,000,000
- for a total Royalty of \$[ \* ].

The Royalties set forth in this **Attachment 5 – Part A** are separate from and in addition to the milestone payments set forth in Section 3.1.1 and **Attachment 4** and the super royalty payments set forth in Section 3.1.3 and **Attachment 5 – Part B**.



**Attachment 5 (continued)**

**Part B – Super Royalty Payments**

Super Royalty Payments

- annual Net Sales exceed \$100,000,000 (Territory)            \$[ \* ]
- annual Net Sales exceed \$250,000,000 (Territory)            \$[ \* ]
- annual Net Sales exceed \$500,000,000 (Territory)            \$[ \* ]

Each super royalty payment is separate and may only be earned once. That is, the aggregate amount of the super royalty payments set forth in this **Attachment 5 – Part B** that may be paid to Novelos during the Term if all three thresholds are satisfied is \$60,000,000. All amounts are in U.S. dollars. For the purpose hereof, “annual Net Sales” shall mean a Net Sales made during a period commencing January 1st and ending December 31st of the same year.

The super royalty payments set forth in this **Attachment 5 – Part B** are separate from and in addition to the milestone payments set forth in Section 3.1.1 (and **Attachment 4**) and the Royalties set forth in Section 3.1.2 (and **Attachment 5 – Part A**).

**Attachment 6**

**CMC Work Program**

Work Package	Guideline(s)
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[ 2 pages redacted]

**Attachment 7**

**Pre-Clinical Studies**

Study	International Guideline(s)
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[2 pages redacted]

**Attachment 8**

**Manufacturing Development Work**

required to supply finished product to the Mundipharma Territory

Work Package	Guideline(s)
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**[3 pages redacted]**

## Attachment 9

### Alternative Dispute Resolution

In accordance with Section 15.6 of the Agreement, either Party may initiate an Alternative Dispute Resolution (“ADR”) proceeding as provided herein. The Parties will have the right to be represented by counsel in such a proceeding.

1. To initiate an ADR proceeding, a Party must provide written notice to the other Party of the issues to be resolved by ADR. Within 14 calendar days after its receipt of such notice, the other Party may, by written notice to the Party initiating the ADR, add additional issues to be resolved within the same ADR to the extent disposition of such additional issues are related to the original issues or it otherwise is efficient to address the issues in a common proceeding.

2. Within 21 calendar days following receipt of the original ADR notice, the Parties will select a mutually acceptable neutral to preside in the resolution of any disputes in the ADR proceeding. If the Parties are unable to agree on a mutually acceptable neutral within such period, either Party may request the President of the CPR Institute for Dispute Resolution (the “CPR”), 366 Madison Avenue, 14th Floor, New York, New York 10017, to select a neutral pursuant to the following procedures:

(a) The CPR will submit to the Parties a list of not less than ten candidates within 14 calendar days after receipt of the request, along with a *Curriculum Vitae* for each candidate. Consistent with any other CPR rules governing the impartiality and disinterestedness of the neutral, no candidate may be an employee, director, or shareholder of either Party or any of their subsidiaries or Associates or have an interest in the outcome of the dispute.

(b) Such list will include a statement of disclosure by each candidate of any circumstances likely to affect his or her impartiality.

(c) Each Party will number the candidates in order of preference (with the number one signifying the greatest preference) and will deliver the list to the CPR within seven calendar days following receipt of the list of candidates. If a Party believes a conflict of interest exists regarding any of the candidates, that Party will provide a written explanation of the conflict to the CPR along with its list showing its order of preference for the candidates. Any Party failing to return a list of preferences in the required time allowed will be deemed to have no order of preference.

(d) If the Parties collectively have identified three or fewer candidates deemed to have conflicts, the CPR immediately will designate as the neutral the candidate for whom the Parties collectively have indicated the greatest preference. If a tie should result between two candidates, the CPR may designate either candidate. If the Parties collectively have identified four or more candidates deemed to have conflicts, the CPR will review the explanations regarding the conflicts and if the CPR, in its reasonable discretion, finds the conflicts valid for at least four candidates, it shall issue a new list of not less than ten candidates, in which case the procedures set forth in subparagraphs 2(a) - 2(d) will be repeated.

3. The neutral shall conduct the proceedings with due regard for the Parties' mutual goal of an expeditious, efficient process. There shall be a rebuttable presumption in favor of completing the hearing(s) of an ADR proceeding no later than six (6) months after designation of the neutral and earlier to the extent appropriate, subject to adjustment on good cause shown taking into account the nature and subject of the issue(s) in dispute. The ADR proceeding will take place at a location agreed upon by the Parties. If the Parties cannot agree, the neutral will designate a location other than the principal place of business of either Party or any of their subsidiaries or Associates.

4. The neutral will be paid a reasonable fee plus expenses. The neutral shall have discretion to allocate these fees and expenses, along with the reasonable legal fees and expenses of the prevailing Party (including all expert witness fees and expenses) to the other Party.

5. The rulings of the neutral and the allocation of fees and expenses will be binding, non-reviewable, and non-appealable, and may be entered as a final judgment in any court having jurisdiction. Upon the written mutual consent of the Parties, the neutral may amend or alter any provision of this ADR.

6. Except as provided in paragraph 5 or as required by law, the existence of the dispute, any settlement negotiations, the ADR hearing, any submissions (including exhibits, testimony, proposed rulings, and briefs), and the rulings will be deemed Confidential Information. The neutral will have the authority to impose sanctions for unauthorized disclosure of Confidential Information.



**Attachment 10**

**Press Release**

**\*\*\*CONFIDENTIAL\*\*\* [FOR IMMEDIATE RELEASE]**

**NOVELOS THERAPEUTICS AND MUNDIPHARMA SIGN EXCLUSIVE  
COLLABORATION AGREEMENT IN EUROPE AND JAPAN**

***\$95mil for Cancer Compound through  
Equity Investment, Milestones and Fixed Sales-Based Payments, Plus Royalties***

**NEWTON, Mass., February \_\_, 2009** – **Novelos Therapeutics, Inc. (OTCBB: NVLT)**, a biopharmaceutical company focused on the development of therapeutics to treat cancer and hepatitis, announced today that Novelos signed an exclusive collaboration agreement with Mundipharma International Corporation Limited to commercialize in Europe and Asia / Pacific (excluding China) Novelos' lead compound, NOV-002, which is in a pivotal Phase 3 trial for non-small cell lung cancer under a Special Protocol Assessment (SPA) and Fast Track. NOV-002 has also demonstrated positive results in Phase 2 trials for other cancer indications.

In parallel, Novelos has also closed a private placement with Purdue Pharma L.P. resulting in \$10 million in gross proceeds through the sale of convertible preferred stock and warrants to purchase its common stock. Novelos sold 200 shares of Series E convertible preferred stock, having a stated value equal to \$50,000 per share, a cumulative annual dividend of 9% of stated value and a conversion price of \$0.65 per share of common stock. Purdue also received warrants expiring on December 31, 2015 to purchase an aggregate of 9,230,769 shares of common stock at an exercise price of \$0.65 per share.

Under the terms of the collaboration agreement, Novelos may receive up to \$25 million of launch milestones and \$60 million of fixed sales-based payments. Novelos will receive a double-digit royalty, which increases as the annual sales increase in the licensed territories. Mundipharma will be responsible for certain development activities, regulatory submissions and commercialization of NOV-002 in the licensed territories. Novelos retains all rights and responsibilities in the U.S.A. and the rest of the Americas.

“I am very pleased to be collaborating with Mundipharma and Purdue, which are innovative independent associated pharmaceutical companies with ample resources and a proven track record of developmental and commercialization expertise,” said Harry Palmin, President and CEO of Novelos. “This transaction will provide the remaining capital to complete our pivotal, fully-enrolled, 840-patient Phase 3 lung cancer trial, which is currently expected to conclude in late 2009.”

According to Åke Wikström, Mundipharma's Regional Director – Europe, "NOV-002 is an important addition to our oncology pipeline and reinforces our commitment to increasing the treatment options available for cancer patients and improving their quality of life through the development and commercialization of novel therapeutics."

Ferghana Partners (New York, London and Boston) served as financial and strategic transaction advisor to Novelos. The preferred stock and warrants were issued in a private placement transaction under Regulation D of the Securities Act of 1933 and have not been registered under the Securities Act of 1933, as amended, or any state securities laws, and may not be offered or sold in the United States absent registration with the Securities and Exchange Commission (the "SEC") or an applicable exemption from the registration requirements. Novelos has agreed to file a registration statement with the SEC covering resales of the common stock issuable upon conversion of the newly issued shares of preferred stock and upon exercise of the warrants.

#### **About Mundipharma International Corporation Limited and Purdue Pharma L.P.**

The Purdue/Mundipharma/Napp independent associated companies are privately owned companies and joint ventures covering the world's pharmaceutical markets. The companies have particular expertise in drug delivery systems and these are applied to a range of analgesics, respiratory treatments, and cardiovascular drugs. The companies also have a growing presence in the oncology market, and products in the areas of attention deficit hyperactivity disorder, antiseptics and laxatives. For more information: [www.mundipharma.co.uk](http://www.mundipharma.co.uk)

#### **About Novelos Therapeutics, Inc.**

Novelos Therapeutics, Inc. is a biopharmaceutical company commercializing oxidized glutathione-based compounds for the treatment of cancer and hepatitis. NOV-002, the lead compound currently in Phase 3 development for lung cancer under SPA and Fast Track, acts together with chemotherapy as a chemoprotectant and a chemopotentiator. NOV-002 is also in Phase 2 development for early-stage breast cancer and chemotherapy-resistant ovarian cancer. Novelos has a partnership with Mundipharma to develop and commercialize NOV-002 in Europe and Japan. Novelos' second compound, NOV-205, acts as a hepatoprotective agent with immunomodulating and anti-inflammatory properties. NOV-205 is in Phase 1b development for chronic hepatitis C non-responders. Both compounds have been partnered with Lee's Pharma in China. For additional information about Novelos please visit [www.novelos.com](http://www.novelos.com)

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#### **COMPANY**

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#### **INVESTOR RELATIONS**

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This news release contains forward-looking statements. Such statements are valid only as of today, and we disclaim any obligation to update this information. These statements are subject to known and unknown risks and uncertainties that may cause actual future experience and results to differ materially from the statements made. These statements are based on our current beliefs and expectations as to such future outcomes. Drug discovery and development involve a high degree of risk. Factors that might cause such a material difference include, among others, uncertainties related to the ability to attract and retain partners for our technologies, the identification of lead compounds, the successful preclinical development thereof, the completion of clinical trials, the FDA review process and other government regulation, our pharmaceutical collaborators' ability to successfully develop and commercialize drug candidates, competition from other pharmaceutical companies, product pricing and third-party reimbursement.

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

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

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

Date: March 30, 2009

/s/ HARRY S. PALMIN

Harry S. Palmin  
Principal Executive Officer

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

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

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

Date: March 30, 2009

/s/ JOANNE M. PROTANO

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Joanne M. Protano  
Principal 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-K of Novelos Therapeutics, Inc. (the "Company") for the year ended December 31, 2008, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Harry S. Palmin, Chief Executive Officer and President of the Company, and I, Joanne M. Protano, Chief Financial Officer of the Company, certify, to the best of our knowledge and belief, pursuant to 18 U.S.C. § 1350, adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that:

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

/s/ HARRY S. PALMIN

Harry S. Palmin  
Principal Executive Officer

/s/ JOANNE M. PROTANO

Joanne M. Protano  
Principal Financial Officer

Dated: March 30, 2009

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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