

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, 2011

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

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

Commission File Number 333-119366

**NOVELOS THERAPEUTICS, INC.**

(Exact name of Registrant as specified in its Charter)

**Delaware**  
(State or other jurisdiction  
of incorporation or organization)

**04-3321804**  
(I.R.S. Employer Identification No.)

**One Gateway Center, Suite 504**  
**Newton, Massachusetts 02458**  
(Address of principal executive offices and zip code)

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

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

<u>Title of Class</u>	<u>Name of each exchange on which registered</u>
None	Not Applicable

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

**None**

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

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

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

Yes  No

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

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

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

(Do not check if a smaller reporting company)

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

Yes  No

The aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold, or the average bid and asked price of such common equity, as of June 30, 2011 was \$22,703,402.

As of March 2, 2012 there were 36,907,824 shares of the registrant's \$0.00001 par value common stock outstanding.

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NOVELOS THERAPEUTICS, INC.

FORM 10-K

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

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## PART I

### Item 1. Business.

#### Business of Novelos

Novelos Therapeutics, Inc. (“Novelos” or the “Company”) is a pharmaceutical company developing compounds for the treatment of cancer. On April 8, 2011, Novelos entered into a business combination with Collectar, Inc. (“Collectar”), a privately held Wisconsin corporation that designed and developed products to detect, treat and monitor a wide variety of human cancers (the “Acquisition”). Following the Acquisition, we have been developing novel drugs for the treatment and diagnosis of cancer. We believe our three cancer-targeted compounds (referred to as LIGHT, HOT and COLD) are selectively taken up and retained in cancer cells, including cancer stem cells, versus normal cells. Thus, our therapeutic compounds appear to directly kill cancer cells while minimizing harm to normal cells. This offers the potential for a paradigm shift in cancer therapy by providing efficacy versus all three major drivers of mortality in cancer: primary tumors, metastases and stem cell-based relapse. I-124-CLR1404 (LIGHT) is a small-molecule cancer-targeted positron emissions tomography (“PET”) imaging agent. We believe LIGHT has first-in-class potential and Phase 1-2 clinical trials are ongoing. I-131-CLR1404 (HOT) is a small-molecule, broad-spectrum, cancer-targeted molecular radiotherapeutic that delivers cytotoxic (cell-killing) radiation directly and selectively to cancer cells and cancer stem cells. We believe HOT also has first-in-class potential. HOT Phase 1b dose-escalation trial is ongoing and we expect HOT to enter Phase 2 trials in the first quarter of 2013 as a monotherapy for solid tumors with significant unmet medical need, subject to additional funding. CLR1404 (COLD), a cancer-targeted non-radioactive chemotherapy, works primarily through Akt (a serine/threonine protein kinase) inhibition. We plan to file an Investigational New Drug (“IND”) application with the United States Food and Drug Administration (“FDA”) for COLD in the first quarter of 2013, subject to additional funding. Together, we believe our compounds are able to “find, treat and follow” cancer anywhere in the body in a novel, effective and highly selective way.

#### Market Overview

Our target market is broad and represents the market for the treatment and diagnosis of cancer. According to Drug Discovery News (April 2009) and PharmaLive (October 8, 2009), the global market for cancer pharmaceuticals reached an estimated \$66 billion in 2007, nearly doubling from \$35 billion in 2005 and is expected to grow to \$80 billion by 2012. Furthermore, the US National Cancer Institute (January 12, 2011) estimates that the overall cost of treating cancer in the US will increase to \$158 billion by 2020 from \$125 billion in 2010 and Global Industry Analysts (GIA) forecasts the global market for cancer therapies to reach \$225 billion by 2017 (November 2011). According to BCC Research (April 2011), the total market for next-generation cancer diagnostics was \$776 million in 2010 and is growing at a compounded annual growth rate of 47%, to reach a forecast market size of \$5.3 billion in 2015.

#### Technology Overview

Our compounds are alkylphospholipids (“APLs”) that interact with lipid rafts, which are specialized microdomains within cell membranes. Importantly, the core chemical structure shared across all three products provides selective targeting of cancer cells, including cancer stem cells, in preference to normal cells (due to enrichment of lipid rafts in the former). COLD was deliberately designed to contain iodine (in the form of the stable, non-radioactive isotope, I-127), thus enabling additional, distinct products differing only with respect to the form of iodine they contain – HOT contains short-lived radioactive I-131 and LIGHT contains the even more short-lived radioactive I-124. As a result, three cancer-targeted product profiles have been generated from a single chemical structure that is the foundation of our technology platform – a chemotherapeutic agent, COLD, a molecular radiotherapeutic agent, HOT and a diagnostic/imaging agent, LIGHT.

Our core technology platform is based on research conducted by Collectar's founder and our Chief Scientific Officer, Dr. Jamey Weichert, beginning in 1994 at the University of Michigan ("U. Mich."), where alkyphospholipid analogs were initially designed, synthesized, radiolabeled, and evaluated. Since 1998, Dr. Weichert has continued his research at the University of Wisconsin ("U. Wisc.") and subsequently founded Collectar in 2002 to further develop and commercialize the technology. Collectar obtained exclusive rights to the related technology patents owned by U. Mich. in 2003 and continued development of the platform while obtaining ownership of numerous additional patents and patent applications (lasting until 2025, 2028 and 2030 without extensions) prior to the Acquisition.

## **Products in Development**

### *LIGHT (labeled with a shorter-lived radioisotope, iodine-124)*

LIGHT is a small-molecule imaging agent that we believe has first-in-class potential for selective detection of tumors and metastases in a broad range of cancers. LIGHT is comprised of a small, non-pharmacological quantity of CLR1404 (COLD, acting as a cancer-targeted delivery and retention vehicle) labeled with the shorter-lived radioisotope, iodine-124, a new PET imaging isotope. PET imaging used in conjunction with CT scanning has now become the imaging method of choice in oncology. In studies to date, LIGHT selectively illuminated malignant tumors in 52 of 54 animal models of cancer, demonstrating evidence of broad-spectrum, cancer-selective uptake and retention. Investigator-sponsored Phase 1-2 trials of LIGHT as a PET imaging agent are ongoing at the University of Wisconsin. The investigator-sponsored IND for LIGHT was submitted on March 28, 2003 and was approved by the FDA on April 25, 2003. The IND is held by Dr. Lance Hall at the University of Wisconsin, who both initiates and conducts the investigation and under whose immediate direction the investigational drug is administered. Novelos provides funding for the studies and the data is shared with Novelos while the study progresses and at the conclusion of the study. The trials include brain metastases, lung cancer and, starting in the second quarter of 2012, other solid tumors. These human trials, if successful, will serve two important purposes. First, they would provide proof-of-concept for LIGHT itself as a PET imaging agent with the potential to supplant the current "gold standard" agent, 18-fluoro-deoxyglucose (FDG), due to what we believe to be LIGHT's superior cancer-specificity and more favorable logistics of clinical use. Second, they would accelerate clinical development of HOT by predicting efficacy and enabling calculation of efficacious doses of HOT for Phase 2 trials.

Chemically, LIGHT is 18-(p-[I-124]iodophenyl) octadecyl phosphocholine, identical to COLD except that the iodine is the radioactive isotope, I-124, which has a radiation half-life of 4 days.

According to Bio-Tech Systems (November 2010), sales of FDG in the US in 2009 were approximately \$300 million and projected to grow to approximately \$900 million in 2017. FDG accumulates in any tissue having increased glucose metabolism compared to surrounding tissue. As a result and in contrast to LIGHT, FDG is not selective for malignant tumors. FDG localizes in certain normal tissue such as heart, kidney and brain tissues that also have high glucose metabolism. FDG is also known to localize in inflammatory sites. Other major limitations to the use of FDG are found in pelvic imaging due to the high renal (kidney) clearance of the compound. These characteristics of FDG, therefore, decrease its diagnostic specificity for certain malignancies. FDG is no longer covered by patent and is typically manufactured onsite at PET imaging medical facilities because of its limited (110 minute) half-life.

We compared LIGHT and FDG side by side (24 hours apart) in the same tumor-bearing mouse that was also treated with carageenan to induce inflammation. As expected, FDG demonstrated significant uptake into the inflammatory lesion and organs such as heart and bladder compared to the malignant tumors, which were poorly imaged. LIGHT, on the other hand, showed no uptake into the inflammatory lesion and organs, yet clear and demonstrable uptake into the tumors.

Additionally, the radioisotopic half-life of only 110 minutes for fluorine-18 labeled agents, such as FDG, severely limits their delivery range relative to the point of manufacture. I-124 has a four-day half-life that permits worldwide distribution of LIGHT from one manufacturing location. Additionally, the longer half-life affords a longer imaging window of up to seven days following injection.

### **HOT (iodine-131 radiolabeled compound)**

HOT is a small-molecule, broad-spectrum, cancer-targeted molecular radiotherapeutic that we believe has first-in-class potential. HOT is comprised of a small, non-pharmacological quantity of CLR1404 (COLD), acting as a cancer-targeted delivery and retention vehicle and incorporating a cytotoxic dose of radiotherapy (in the form of iodine-131, a radioisotope that is already in common use to treat thyroid and other cancer types). It is this “intracellular radiation” mechanism of cancer cell killing, coupled with delivery to a wide range of malignant tumor types that we believe imbues HOT with broad-spectrum anti-cancer activity. Selective uptake and retention has also been demonstrated in cancer stem cells compared with normal cells, offering the prospect of longer lasting cancer remission. In 2009, we filed an IND with the FDA to study HOT in humans. In early 2010, we successfully completed a Phase 1a dosimetry trial demonstrating initial safety, tumor imaging and pharmacokinetic consistency and establishing a starting dose for a Phase 1b dose-escalation trial. Radiation dosimetry measures how much radiation is absorbed by tumors and body organs in order to optimize delivery of radiation therapy. The ongoing Phase 1b dose-escalation trial is aimed at determining the Maximum Tolerated Dose of HOT. We plan to initiate HOT Phase 2 efficacy trials as a monotherapy for solid tumors with significant unmet medical need as soon as a minimal efficacious dose is established, provided that we obtain the additional funding necessary for that purpose. We may determine such an effective dose upon seeing a tumor response in the Phase 1b trial or calculating it from ongoing PET imaging trials in cancer patients with LIGHT (since PET imaging is quantitative, enabling determination of tumor radiation exposure at a given dose level). Preclinical *in vitro* (in cell culture) and *in vivo* (in animals) experiments have demonstrated selective killing of cancer cells along with a benign safety profile. HOT’s anti-tumor/survival-prolonging activities have been demonstrated in more than a dozen xenograft models (human tumor cells implanted into animals) including breast, prostate, lung, glioma (brain), pancreatic, ovarian, uterine, renal and colorectal cancers and melanoma. In all but two models, a single administration of a well-tolerated dose of HOT was sufficient to demonstrate efficacy. In view of HOT’s selective uptake and retention in a wide range of solid tumors and in cancer stem cells, its single-agent efficacy in xenograft models and its non-specific mechanism of cancer-killing (radiation), we expect first to develop HOT as a monotherapy, initially for solid tumors.

Chemically, HOT is 18-(p-[I-131]iodophenyl) octadecyl phosphocholine, identical to COLD except that the iodine in its structure is the radioactive (“hot”) isotope, I-131, which has a radiation half-life of eight days.

Single intravenous, well-tolerated doses of HOT administered therapeutically in animals (i.e., after primary tumors were established) have been observed to result in significant anti-tumor and/or survival benefit compared to control animals in mouse xenograft tumor models including ovarian, pancreatic, non-small cell lung, triple-negative breast, prostate, glioma, colorectal and kidney cancers. Survival benefit generally reflected the degree of tumor growth suppression. Efficacy was also seen in a xenograft model employing human uterine sarcoma cells which over-express efflux pumps known to underlie resistance to many standard chemotherapeutic drugs. The broad *in vivo* efficacy profile of HOT across many tumor types is reflected in the fact that selective tumor localization of LIGHT (which uses the same cancer-targeting drug delivery and retention vehicle as HOT) has been demonstrated in over 50 xenograft, spontaneous and transgenic cancer models. HOT was also tested in combination with a standard efficacious dose of gemcitabine in a pancreatic cancer xenograft model. Single doses of HOT or gemcitabine given alone were equally efficacious while the combination therapy was significantly more efficacious than either treatment alone (additive). In each xenograft study, the dose of HOT was ~100  $\mu$ Ci, which is at least 50% less than the maximum tolerated dose in mice.

Extensive, IND-enabling, Good Laboratory Practices (GLP) *in vivo* and *in vitro* pre-clinical pharmacokinetic/distribution, toxicology and drug safety studies were successfully completed using non-pharmacological concentrations/doses of COLD consistent with its role as a delivery/retention vehicle in HOT. Tissue distribution studies supported prediction of acceptable human organ exposures and body clearance for HOT. Importantly, and in sharp distinction from biological products labeled with I-131, the small molecule HOT showed very minimal variation in excretion kinetics and tissue distribution among individuals within species or across a 500-fold variation in dose. Single- and repeated-dose animal toxicology studies indicated very high margins of safety (80-200x) over the anticipated maximum human therapy dose of HOT.

In February 2010 we completed a Phase 1a dosimetry trial with a single intravenous dose of 10 mCi HOT in eight patients with relapsed or refractory advanced solid tumors. Single doses of HOT were well tolerated. The reported adverse events were all considered minimal, manageable and either not dose limiting or not related to HOT. There were no serious adverse events reported. Analysis of total body imaging and blood and urine samples collected over 42 days following injection indicated that doses of HOT expected to be therapeutically effective can be administered without harming vital organs. Two subjects (one with colorectal cancer metastasized to lung and another with prostate cancer) had tumors that were imaged with 3D nuclear scanning (SPECT/CT) on day 6 after administration of HOT. Uptake of HOT into tumor tissue (but not adjacent normal tissue or bone marrow) was clearly demonstrated in both subjects. Echoing animal studies, pharmacokinetic analyses demonstrated a prolonged half-life of radioactivity in the plasma after HOT administration (approximately 200 hours) and that there was no significant variation in excretion or radiation dosimetry among subjects. The trial established an initial dose of 12.5 mCi / m<sup>2</sup> (for example, 20 mCi dose for a patient with 1.6m<sup>2</sup> body surface area) for the Phase 1b escalating dose trial that is ongoing.

The primary objective of this Phase 1b dose-escalation trial in patients with a range of advanced solid tumors is to define the Maximum Tolerated Dose (MTD) of HOT. In addition to determining the MTD, the Phase 1b trial is intended to evaluate overall tumor response (using standard RESIST I criteria) and safety. Concurrently, separate studies are expected to generate quantitative imaging data in cancer patients using LIGHT. These imaging trials with LIGHT are expected to predict efficacy and enable calculation of a minimal efficacious dose of HOT for Phase 2 trials, planned to begin in early 2013, in the event we obtain the additional funding necessary for that purpose, with an initial focus on solid tumors with significant unmet medical need. Based on its broad-spectrum mechanism of action and wide-ranging single agent activity in animal cancer models, HOT is anticipated to be used as monotherapy through proof-of-concept clinical trials, with subsequent exploration of combination with chemotherapeutic agents (a number of which are known to be radiosensitizers and thus with potential to enhance the efficacy of HOT).

Tumor treatment with radioactive isotopes has been used as a fundamental cancer therapeutic for decades. The goals of targeted cancer therapy — selective delivery of effective doses of isotopes that destroy tumor tissue, sparing of surrounding normal tissue, and non-accumulation in vital organs such as the liver and kidneys — remain goals of novel therapies as well. We believe our isotope delivery technology is poised to achieve these goals. Because, to date, HOT has been shown to reliably and near-universally accumulate in cancer cells and because the therapeutic properties of the iodine-131 are well known, we believe the risk of non-efficacy in human clinical trials is less than that of other cancer therapies at this stage of development, although no assurance can be given.

Other targeted radiotherapies include the marketed drugs Zevalin® (90Y, Spectrum Pharmaceuticals) and Bexxar® (I-131, GSK). In both cases, tumor-targeting is monoclonal antibody-based and limited to non-Hodgkins lymphoma, which is a type of cancer involving cells of the immune system. Thus, these agents are not appropriate comparators for HOT because of their limited therapeutic utility (only one type of tumor) and because their target indication is often well-managed by other drugs (unlike HOT, which has potential to treat tumor types for which the current standard of care is associated with very poor outcomes). Notably, both Zevalin® and Bexxar® were approved on the basis of objective response rates (shrinking of tumors) without data to support improvement in survival, suggesting that regulatory approval of radiopharmaceuticals may be based on relatively shorter and smaller pivotal clinical trials than is often the case in oncology.

In conclusion, we believe that HOT is not subject to the full extent of development risk typically associated with early-stage cancer therapeutics for the following reasons:

- HOT is selectively taken up by and retained in cancer versus normal cells and its delivery vehicle (COLD) is intended to be given to patients in sub-pharmacological doses, resulting in an improved safety profile compared to standard chemotherapy.
- HOT does not rely on inhibition or enhancement of a specific pathway; it works by exposing cancer cells to sustained lethal radiation from within.
- To date, HOT (as demonstrated with LIGHT studies) has shown near-universal cancer-specific retention in more than 50 *in vivo* tumor models, making the molecule potentially effective in numerous cancer types (broad-spectrum) as compared to type-specific therapies.
- We believe we have completed all applicable preclinical safety, pharmacology and toxicology studies that we believe will be required for an NDA including both single-dose and multi-dose studies.
- HOT is a small molecule that is easily characterized and synthesized and is therefore not subject to scale-up and manufacturing risks typically associated with large molecules such as monoclonal antibodies.
- HOT exploits a new cancer-selective delivery and retention mechanism, but is paired with a proven and effective radioisotope (I-131) for therapy.

## **COLD**

COLD is a cancer-targeted chemotherapy that, in pre-clinical experiments, has been observed to inhibit the phosphatidylinositol 3-kinase (PI3K)/Akt survival pathway and induce apoptosis through caspase activation and inhibit cell proliferation in cancer cells versus normal cells. Caspases are molecules that can stimulate apoptosis. COLD also exhibits significant *in vivo* efficacy in mouse xenograft tumor models, including non-small cell lung cancer and triple-negative breast cancers, producing long-lasting tumor growth suppression and significantly increased survival. We believe COLD has the potential to be best-in-class versus other Akt inhibitors in development and believe that COLD has important advantages over competitor agents including:

- Selective uptake and retention by cancer cells/cancer stem cells compared to normal cells/stem cells. This results in significantly greater potency of COLD as an inhibitor of cell proliferation in cancer cells versus normal cells (greater than a 10-fold difference), and
- Suitability for intravenous administration, avoiding dose-limiting gastrointestinal toxicity seen with orally administered Akt-inhibiting alkyl phosphocholines (APCs) and potentially enabling greater systemic drug exposure and, hence, Akt-inhibition in cancer cells, resulting in superior efficacy.

Chemically, COLD is 18-(p-[I-127] iodophenyl) octadecyl phosphocholine, an APC subtype within the alkyl-phospholipid (APL) class of anti-tumor agents that includes perifosine, miltefosine and eldefosine. The iodine atom in its structure is the stable, non-radioactive (“cold”) isotope, I-127.

COLD exhibits significant *in vivo* efficacy in mouse xenograft tumor models, including non-small cell lung cancer and triple-negative breast cancers. In these models, human cancer cells are transplanted into and then grow and sometimes metastasize in immunosuppressed animals. Tumor-bearing mice treated therapeutically (i.e., after primary tumors were established) with intravenous COLD (100-times the mass dose used as a carrier in the radiotherapy agent, HOT) once a week for 5 weeks, showed almost complete suppression of tumor growth compared to saline-treated control animals. Tumor growth suppression by COLD was maintained long after the end of the treatment period. Importantly, survival in COLD-treated groups at experiment termination (100-200 days post tumor-cell injection) was 90% or more compared to 20% or less in control groups. Additionally, in a side-by-side comparison, COLD was much more effective in suppressing tumor growth and increasing survival in the lung cancer model than a standard dosing regimen of erlotinib (Tarceva<sup>®</sup>, a marketed epidermal growth factor receptor kinase inhibitor).

The *in vivo* efficacy of COLD is believed to be at least in part the result of selective inhibition of the apoptosis-suppressing PI3K/Akt signaling pathway in cancer cells. This pathway, which is activated by growth factors such as PDGF (platelet-derived growth factor), EGF (epidermal growth factor), and insulin, is overactive in many human cancers and contributes to cell growth, proliferation, survival and resistance to radiation and chemotherapeutics. COLD selectively inhibits Akt activation in human cancer cells compared to normal proliferating cells (e.g., human fibroblasts). At the same concentrations, COLD induces apoptosis through caspase activation and suppresses proliferation in a wide range of human cancer cell lines including prostate carcinoma, ovarian carcinoma, triple-negative breast carcinomas, pancreatic adenocarcinoma and non-small cell lung cancer. At these concentrations, COLD does not inhibit proliferation of normal cells.

Other cancer targeting APCs have also been reported to be active in xenograft models and to selectively inhibit tumor cell proliferation via a mechanism that involves induction of apoptosis through caspase activation subsequent to inhibition of Akt activation and signaling. However, APCs are generally dose-limited *in vivo* (including in man) by side effects stemming from the necessity for their oral administration (due to their hemolytic properties), thus limiting Akt inhibition and anti-tumor efficacy. In contrast, data to date support the contention that COLD can be safely administered intravenously at doses that we believe will result in greater drug exposure compared to other APCs and, thus, in greater Akt inhibition and improved efficacy.



Non-APC Akt inhibitors in development are not cancer-targeting and thus have the potential for an unfavorable therapeutic index (due to non-selective inhibition of Akt, and hence proliferation) in normal versus cancer cells. In contrast, selective uptake and retention of COLD results in greater than a 10-fold more potent inhibition of Akt activity and cell proliferation in cancer cells versus normal cells.

The development path for COLD includes evaluation in a standard battery of IND-enabling pre-clinical tests and scaled-up manufacture. In parallel, we intend to test COLD in mouse xenograft tumor models in combination with standard chemotherapeutic agents to demonstrate synergies as have been reported for perifosine. These additional pre-clinical data will enable estimation of COLD plasma levels associated with *in vivo* efficacy, establish a starting dose for the initial Phase 1 clinical trial and facilitate selection of target indications. We plan to submit an IND application to the FDA in the first quarter of 2013, in the event we obtain the additional funding necessary for that purpose.

## Technology

LIGHT, HOT and COLD are alkylphospholipids (“APLs”) that interact with specialized microdomains within cell membranes (called “lipid rafts”) and, as a result, whose molecular targets are located at cellular membranes. Importantly, the core chemical structure shared across all three products provides selective targeting of cancer cells in preference to normal cells (due to enrichment of lipid rafts in the former). COLD was deliberately designed to contain iodine (in the form of the stable, non-radioactive isotope, I-127), thus enabling additional, distinct products differing only with respect to the form of iodine they contain – HOT contains short-lived radioactive I-131 and LIGHT contains even more short-lived I-124. As a result, three cancer-targeted product profiles have been generated from a single chemical structure — a chemo-therapeutic agent (COLD), a molecular radiotherapeutic agent (HOT) and a diagnostic/imaging agent (LIGHT).

Using a fluorescent-labeled analog of COLD (CLR1501 or “GLOW1”), selective uptake and retention has been demonstrated in cancer cells *in vitro*. Twenty-four hours after treatment, a variety of human tumor cell types (melanoma, colorectal, uterine, pancreatic, ovarian, glioblastoma) show six- to ten-fold more staining with GLOW1 relative to normal cells (e.g., skin fibroblasts). Significantly, uptake/retention was also seen in cancer stem cells, which are known to be relatively resistant to both chemotherapy and radiation and may therefore contribute to eventual relapse of disease following conventional chemotherapy.

Malignant tumor targeting, including targeting of cancer stem cells, has also been demonstrated *in vivo*. For example, mice without intact immune systems, and inoculated with Panc-1 (pancreatic carcinoma), were injected with CLR1502 (“GLOW2”, a fluorescent-labeled analog of COLD that is active in the near-infrared range) 24 or 96 hours prior to imaging. *In vivo* optical imaging showed pronounced accumulation of GLOW2 in tumors versus non-target organs and tissues. Similarly, PET imaging of tumor-bearing animals (colon, glioma, triple negative breast and pancreatic tumor xenograft models) administered the imaging agent LIGHT clearly shows selective uptake and retention by both primary tumors and metastases, including cancer stem cells. Furthermore, PET/CT analysis following co-injection of HOT (for therapy) and LIGHT (for imaging) revealed time-dependent tumor shrinkage and disappearance (over 9 days) in a cancer xenograft model. Finally, we believe that the capability of our technology to target cancer stem cells *in vivo* was demonstrated by treating tumor-bearing mice with GLOW1 and then removing the tumor and isolating cancer stem cells, which continued to display GLOW1 labeling even after three weeks in cell culture.

The basis for selective tumor targeting of our compounds lies in differences between the plasma membranes of cancer cells as compared to those of most normal cells. Specifically, cancer cell membranes are highly enriched in “lipid rafts”. Lipid rafts are specialized regions of the membrane phospholipid bilayer that contain high concentrations of cholesterol and sphingolipids and serve to organize cell surface and intracellular signaling molecules (e.g., growth factor and cytokine receptors, the phosphatidylinositol 3-kinase (P13K)/Akt survival pathway). Lipid rafts are central to the activity of our compounds in two ways:

1. Lipid rafts are portals of entry for APLs such as LIGHT, HOT and COLD. The marked selectivity of our compounds for cancer cells versus non-cancer cells is due to the fact that cancer cells have far more lipid rafts. In addition to accumulating in lipid rafts, LIGHT, HOT and COLD are transported into the cytoplasm, where they distribute to organelle membranes (mitochondria, ER, lysosomes) but not the nucleus.
2. Lipid rafts also regulate signaling-based cell functions including apoptosis and cell proliferation, and COLD disrupts this regulation. For example, one key signaling pathway that is regulated by interactions with lipid rafts and phospholipids is the phosphatidylinositol 3-kinase (PI3K)/Akt pathway. Akt (a serine/threonine protein kinase) is activated in lipid raft regions via phosphorylation by PI-dependent kinases and goes on to phosphorylate anti-apoptotic proteins (e.g., Bcl-xL and FLIP) resulting in their inactivation and thus promotion of tumor cell survival. COLD pharmacologically inhibits the activation of Akt. In cancer cells, Akt inhibition is associated with induction of apoptosis and decreased cell proliferation/survival.

The pivotal role played by lipid rafts is underscored by the facts that (a) GLOW1 co-localizes with lipid raft components (cholesterol, ganglioside M1) in plasma membranes of cancer cells and (b) disruption of lipid raft architecture suppresses uptake of GLOW1 and radiolabeled COLD into cancer cells.

### **Legacy Products**

Prior to the Acquisition, Novelos had been developing NOV-002, a small-molecule immunomodulating and anti-cancer compound based on a proprietary formulation of oxidized glutathione. NOV-002 has been administered to approximately 1,000 cancer patients in clinical trials and was in Phase 2 development for solid tumors in combination with chemotherapy.

From November 2006 through January 2010, we conducted a Phase 3 trial of NOV-002 plus first-line chemotherapy in advanced non-small cell lung cancer (“NSCLC”) following three Phase 2 trials (two conducted in Russia and one conducted by us in the U.S.) that had demonstrated clinical activity and safety. The Phase 3 trial enrolled 903 patients, 452 of whom received NOV-002. In February 2010, we announced that the primary endpoint of improvement in overall survival compared to first-line chemotherapy alone was not met in this pivotal Phase 3 trial. Following evaluation of the detailed trial data, we announced in March 2010 that the secondary endpoints also were not met in the trial and that adding NOV-002 to paclitaxel and carboplatin chemotherapy was not statistically or meaningfully different in terms of efficacy-related endpoints or recovery from chemotherapy toxicity versus chemotherapy alone. However, NOV-002 was safe and did not add to the overall toxicity of chemotherapy. Based on the results from the Phase 3 trial, we have discontinued development of NOV-002 for NSCLC in combination with first-line paclitaxel and carboplatin chemotherapy. The aggregate costs incurred in connection with our development of NOV-002, including administrative overhead, were approximately \$70 million.

Prior to the Acquisition, Novelos had also been developing NOV-205, a second oxidized glutathione-based compound. NOV-205 had been administered to approximately 200 hepatitis patients in clinical trials and was in Phase 2 development for chronic hepatitis C non-responders. An IND for NOV-205 as a monotherapy for chronic hepatitis C was accepted by the FDA in 2006. A U.S. Phase 1b clinical trial with NOV-205 in patients who previously failed treatment with pegylated interferon plus ribavirin was completed in December 2007. Based on favorable safety results of that trial, in March 2010 Novelos initiated a multi-center U.S. Phase 2 trial evaluating NOV-205 as monotherapy in up to 40 chronic hepatitis C genotype 1 patients who previously failed treatment with pegylated interferon plus ribavirin. Safety was established in twenty patients receiving either 30mg or 60mg of NOV-205 daily for 49 days; however, no viral load reduction was observed.

Further development of NOV-002 and NOV-205 has been suspended. At this time, we expect to devote our resources to the development and commercialization of the Collectar compounds, and we do not expect to conduct any further development of the oxidized glutathione compounds. The IND for NOV-205 was withdrawn on July 5, 2011. We anticipate that the IND for NOV-002 will be placed on inactive status.

## **Manufacturing**

We manufacture HOT and COLD at our current Good Manufacturing Practices compliant (cGMP) radiopharmaceutical manufacturing facility in Madison, Wisconsin. This facility, consisting of approximately 19,500 square feet, contains offices, laboratories, a radiopharmaceutical research lab, a cGMP radiopharmaceutical manufacturing suite and a cGMP analytical laboratory for product release. Our manufacturing facility holds a State of Wisconsin Department of Health Services Radioactive Materials License which authorizes the use and possession of radioactive material for both manufacturing and distribution activities. This license establishes a possession limit of 9 Curies of iodine-131. The facility also holds a State of Wisconsin DHS Radioactive Materials License which authorizes the use and possession of radioactive materials by Collectar for research and development. The research and development license permits the use and possession of iodine-125, iodine-131 and iodine-124 in quantities sufficient to support in-house HOT manufacturing and other research needs. To date, small quantities of LIGHT have been manufactured by our collaborator, the University of Wisconsin in Madison, at no cost to the Company, in connection with investigator-sponsored clinical trials, pursuant to a materials transfer agreement expiring in June 2013. The materials transfer agreement contains standard provisions for the protection of data and intellectual property and may be terminated by either party at any time before expiration. We are in the process of negotiating a fee-based arrangement with the University of Wisconsin covering the manufacture of LIGHT in the future. If the University was unable to manufacture LIGHT for any reason, we believe we could manufacture it at our Madison facility without material additional investment. We are exploring scaling up production capacity of COLD, via contract manufacturers or at our facility, to support an IND filing and clinical trials, but we have not yet entered into any agreements for the manufacture of COLD. The drug substance is identical for all three products with the exception of the different iodine isotope used in each. The base molecule is a dry powder produced via a six-step synthetic scheme. The release specifications for drug substance have been established and validated. The impurity levels at small scale are very low suggesting that larger scale production should be feasible. We have also demonstrated 24-month stability for the drug substance in desiccated and refrigerated form. We believe our laboratories are well equipped with the appropriate equipment for manufacturing pilot and small-scale batches in accordance with cGMP. We believe we have adequate capacity for any Phase 2 trials of HOT and the potential for larger scale build-out for larger Phase 3 trials. All investigational drug substance and product intended for human use during clinical studies will be manufactured according to ICH guidelines, FDA requirements (CFR part 211) and cGMP.

## **Sales and Marketing**

We have not entered into any joint development or similar partnering agreements with respect to LIGHT, HOT or COLD. We plan to pursue and evaluate all available options to develop, launch and commercialize our compounds. These options presently include, but are not limited to, entering into a partnering arrangement with a pharmaceutical company or various pharmaceutical companies with strong development and commercial expertise and infrastructure in the U.S, Europe and/or Japan. While we currently do not plan to build our own sales force or utilize a contract sales organization for launch and commercialization of our compounds, we may reconsider in the future.

## **Competition**

### *LIGHT*

FDG is the current gold standard for cancer PET imaging. According to Bio-Tech Systems (November 2010), sales of FDG in the US in 2009 were approximately \$300 million and projected to grow to approximately \$880 million in 2017. FDG accumulates in any tissue having increased glucose metabolism compared to surrounding tissue. As a result, and in contrast to LIGHT, FDG is not selective for malignant tumors. FDG localizes in certain normal tissue such as heart, kidney and brain tissues that also have high glucose metabolism. FDG is also known to localize in inflammatory sites. Other major limitations to the use of FDG are found in pelvic imaging due to the high renal (kidney) clearance of the compound. We believe these characteristics of FDG, therefore, decrease its diagnostic specificity for certain malignancies. FDG is no longer covered by patent and is typically manufactured onsite at PET imaging medical facilities because of its limited (110 minute) half-life.

We compared LIGHT and FDG side by side (24 hours apart) in the same tumor-bearing mouse that was also treated with carageenan to induce inflammation. As expected, FDG demonstrated significant uptake into the inflammatory lesion and organs such as heart and bladder compared to the malignant tumors, which were poorly imaged. LIGHT, on the other hand, showed no uptake into the inflammatory lesion and organs, yet clear and demonstrable uptake into the tumors.

Additionally, the radioisotopic half-life of only 110 minutes for fluorine-18 labeled agents, such as FDG, severely limits their delivery range relative to the point of manufacture. I-124 has a four-day half-life that permits worldwide distribution of LIGHT from one manufacturing location. Additionally, the longer half-life affords a longer imaging window of up to seven days following injection.

### *HOT*

HOT's "intracellular radiation" mechanism of cancer cell killing, coupled with delivery to a wide range of malignant tumor types, imbues HOT with broad-spectrum anti-cancer activity. Selective uptake and retention has also been demonstrated in cancer stem cells compared with normal stem cells, offering a prospect of longer lasting cancer remission. Other targeted radiotherapies include the marketed drugs Zevalin® (manufactured by Spectrum Pharmaceuticals) and Bexxar® (manufactured by GlaxoSmithKline). In both cases, tumor-targeting is monoclonal antibody-based and limited to non-Hodgkins lymphoma, which is a type of cancer involving cells of the immune system. Thus, these agents are not appropriate comparators for HOT because of their limited therapeutic utility (only one type of tumor) and because their target indication is often well-managed by other drugs (unlike HOT which has potential to treat tumor types for which the current standard of care is associated with very poor outcomes). Notably, both Zevalin® and Bexxar® were approved on the basis of objective response rates (shrinking of tumors) without data to support improvement in survival, suggesting that regulatory approval of radiopharmaceuticals may be based on relatively shorter and smaller pivotal clinical trials than is often the case in oncology. We do not believe Zevalin® or Bexxar® would be competing products of HOT in any material respect.

### *COLD*

We believe COLD has the potential to be best-in-class versus other Akt inhibitors in development. We believe COLD has important advantages over competitor agents including:

- Selective uptake and retention by cancer cells/cancer stem cells compared to normal cells/stem cells. This results in significantly greater potency of COLD as an inhibitor of cell proliferation in cancer cells versus normal cells (greater than a10-fold difference), or
- Suitability for intravenous administration, avoiding dose-limiting gastrointestinal toxicity seen with orally administered Akt-inhibiting APCs and potentially enabling greater systemic drug exposure and, hence, Akt-inhibition in cancer cells, resulting in superior efficacy.

Perifosine, an alkylphospholipid that is being developed by Keryx Biopharmaceuticals, which has licensed it in North America from Aeterna Zentaris Inc., is a possible future competitor to COLD.

### **Intellectual Property**

We have established a broad U.S. and international intellectual property rights portfolio around our cancer-targeting alkylphospholipid technology platform including LIGHT, HOT and COLD.

Our proprietary rights include patents and patent applications that are either owned by us or exclusively licensed to us by the University of Michigan (the “Michigan patents”). LIGHT and HOT are covered by the Michigan patents that provide compound (composition of matter) coverage in the US and Canada and expire in 2016. Our patents and applications cover methods of use, composition and method of manufacture related to LIGHT, HOT and COLD. Many of these patents and applications are filed in key commercial markets worldwide. These patents will generally expire between 2025 and 2030 unless extended.

In particular, LIGHT is covered by the Michigan compound patents as well as two of our U.S. patents, one of which is directed to its use for virtual colonoscopy (expiring 2025) and another of which is directed to its use for *in vitro* diagnostics (expiring 2025). LIGHT is also covered by pending U.S. and European patent applications directed to its use for *in vivo* diagnostics and once issued should expire in 2025. Lastly, the use of LIGHT for diagnostics purposes with cancer stem cells is pending in the U.S., Europe, and Japan. Patents resulting from these applications are expected to expire in 2030.

HOT is covered by two additional series of our patents and applications aside from the Michigan patents. The first is directed to a method of use for cancer therapy and has also been filed in Europe and Japan, in addition to the U.S. These are expected to expire in 2025. Secondly, an application directed to cancer stem-cell therapy is pending in the U.S., Europe, and Japan. Patents resulting from these applications are expected to expire in 2030. Some of these resulting patents may be extendable on a country-by-country basis.

COLD is covered by a series of pending applications directed to methods of using COLD for cancer therapy and is expected to be filed/nationalized in foreign countries by 2012. These patents, once issued, would expire in 2030. Some of these resultant patents may be extendable on a country-by-country basis.

Separate from any patent protection and following product approval by regulatory authorities, data exclusivity may be available for HOT and COLD for up to 10 years on a country-by-country basis (e.g., up to 5 years in the U.S.).

The early termination of the University of Michigan license agreement would result in the loss of our rights to use the covered patents, which could severely delay, inhibit or eliminate our ability to develop and commercialize compounds based on the licensed patents.

In addition to the above noted patents/applications directed to LIGHT, HOT and COLD, we own other patents/applications directed to different forms of alkylphospholipids and methods of manufacturing of alkylphospholipids.

We also own all intellectual property rights worldwide (excluding Russia and the other states of the former Soviet Union, the “Russian Territory”) related to our clinical-stage pipeline compound, NOV-002, and other pre-clinical compounds based on oxidized glutathione. Issued composition-of-matter patents cover proprietary formulations of oxidized glutathione that do not expire until 2019, and these patents include methods of manufacture for oxidized glutathione formulated with various metals. In our dispute with ZAO BAM and ZAO BAM Research Laboratories (Russian companies, collectively referred to as “BAM”), one of the remedies BAM is seeking is the revocation of our rights in these compounds (see Part I - Item 3 – Legal Proceedings for discussion regarding our dispute with BAM).

## **Licenses / Collaborations**

In September 2003, Collectar entered into a license agreement with the University of Michigan (“the U. Mich. license”), which granted Collectar exclusive rights to the development, manufacture and marketing of products under several composition of matter patents in North America that expire at varying dates in 2016. The U. Mich. license expires upon the expiration of the last covered patent. We are responsible for an annual license fee of \$10,000 and are required to pay costs associated with the maintenance of the patents covered by the U. Mich. license. Additionally, we are required to make milestone payments of \$50,000 upon the filing of a New Drug Application (NDA) for a licensed product intended for use in a therapeutic or diagnostic application (such milestone fees may be deferred and paid within twelve months of the first commercial sale of such product) and make certain milestone payments within a year following the first commercial sale of any licensed products. The sales milestones range from \$100,000 to \$200,000, dependent upon whether the drug is for use in a diagnostic or therapeutic application, provided that if sales in the first 12 months are less than the amount of the milestone, then we are required to pay 50% of all sales until the milestone is satisfied. The milestone payments may total up to \$400,000. The U. Mich. license provides that we pay a royalty equal to 3% of net sales of any licensed products sold by us or our sublicensees for such licensed products, provided however if the sublicense fee payable to us is between 4% and 5% of net sales, then the royalties payable to U. Mich. shall be equal to 50% of the sublicense fee. Furthermore, the U. Mich. license provides for a reduction in the royalties owed by up to 50% if we are required to pay royalties to any third parties related to the sale of the licensed products. If we receive any revenue in consideration of rights to the licensed technology that is not based on net sales, excluding any funded research and development, we are required to pay U. Mich. 10% of amounts received. During 2003, pursuant to the U. Mich. license, Collectar paid approximately \$54,000 of back patent costs and issued 203,483 shares of common stock to U. Mich. as partial consideration for the rights described above. U. Mich. may terminate the agreement if we cease operations, if we fail to make any required payment under the agreement, or if we otherwise materially breach the agreement, subject to applicable notice and cure periods. To date, we have made all payments as they have become due, there have been no defaults under the U. Mich. license, nor have we ever been notified of a default by U. Mich. We may terminate the agreement with six months’ notice to U. Mich. and the return of licensed product and related data. The U. Mich. license contained milestones that required certain development activities to be completed by specified dates. All such development milestones have been either completed or removed by subsequent amendment to the agreement. U. Mich. has provided no warranties as to validity or otherwise with respect to the licensed technology.

## **Employees**

As of March 2, 2012 we had 18 full time employees. We believe our relationships with our employees are good.

## **Regulation**

The production, distribution, and marketing of products employing our technology, and our development activities, are subject to extensive governmental regulation in the United States and in other countries. In the United States, we are subject to the Federal Food, Drug, and Cosmetic Act, as amended, and the regulations of the FDA, as well as to other federal, state, and local statutes and regulations, including the federal, state and local laws and regulations governing the storage, use and disposal of hazardous materials, including radioactive isotopes. These laws, and similar laws outside the United States, govern the clinical and preclinical testing, manufacture, safety, effectiveness, approval, labeling, distribution, sale, import, export, storage, record-keeping, reporting, advertising, and promotion of drugs. Product development and approval within this regulatory framework, if successful, will take many years and involve the expenditure of substantial resources. Violations of regulatory requirements at any stage may result in various adverse consequences, including the FDA’s and other health authorities’ delay in approving or refusal to approve a product. Violations of regulatory requirements also may result in enforcement actions.

The following paragraphs provide further information on certain legal and regulatory issues with a particular potential to affect our operations or future marketing of products employing our technology.

## **Research, Development, and Product Approval Process**

The research, development, and approval process in the United States and elsewhere is intensive and rigorous and generally takes many years to complete. The typical process required by the FDA before a therapeutic drug may be marketed in the United States includes:

- preclinical laboratory and animal tests performed under the FDA’s Good Laboratory Practices regulations, referred to herein as GLP;
- submission to the FDA of an IND, which must become effective before human clinical trials may commence;
- human clinical studies performed under the FDA’s Good Clinical Practices regulations, to evaluate the drug’s safety and effectiveness for its intended uses;
- FDA review of whether the facility in which the drug is manufactured, processed, packed, or held meets standards designed to assure the product’s continued quality; and
- submission of a marketing application to the FDA, and approval of the application by the FDA.

### *Preclinical Testing*

During preclinical testing, studies are performed with respect to the chemical and physical properties of candidate formulations. These studies are subject to GLP requirements. Biological testing is typically done in animal models to demonstrate the activity of the compound against the targeted disease or condition and to assess the apparent effects of the new product candidate on various organ systems, as well as its relative therapeutic effectiveness and safety. An IND must be submitted to the FDA and become effective before studies in humans may commence.

### *Clinical Trials*

Clinical trial programs in humans generally follow a three-phase process. Typically, Phase 1 studies are conducted in small numbers of healthy volunteers or, on occasion, in patients afflicted with the target disease. Phase 1 studies are conducted to determine the metabolic and pharmacological action of the product candidate in humans and the side effects associated with increasing doses, and, if possible, to gain early evidence of effectiveness. In Phase 2, studies are generally conducted in larger groups of patients having the target disease or condition in order to validate clinical endpoints, and to obtain preliminary data on the effectiveness of the product candidate and optimal dosing. This phase also helps determine further the safety profile of the product candidate. In Phase 3, large-scale clinical trials are generally conducted in patients having the target disease or condition to provide sufficient data for the statistical proof of effectiveness and safety of the product candidate as required by United States regulatory agencies.

In the case of products for certain serious or life-threatening diseases, the initial human testing may be done in patients with the disease rather than in healthy volunteers. Because these patients are already afflicted with the target disease or condition, it is possible that such studies will also provide results traditionally obtained in Phase 2 studies. These studies are often referred to as “Phase 1/2” studies. However, even if patients participate in initial human testing and a Phase 1/2 study carried out, the sponsor is still responsible for obtaining all the data usually obtained in both Phase 1 and Phase 2 studies.

Before proceeding with a study, sponsors may seek a written agreement from the FDA regarding the design, size, and conduct of a clinical trial. This is known as a Special Protocol Assessment (“SPA”). Among other things, SPAs can cover clinical studies for pivotal trials whose data will form the primary basis to establish a product’s efficacy. SPAs help establish upfront agreement with the FDA about the adequacy of a clinical trial design to support a regulatory approval, but the agreement is not binding if new circumstances arise. There is no guarantee that a study will ultimately be adequate to support an approval even if the study is subject to an SPA.

United States law requires that studies conducted to support approval for product marketing be “adequate and well controlled.” In general, this means that either a placebo or a product already approved for the treatment of the disease or condition under study must be used as a reference control. Studies must also be conducted in compliance with good clinical practice requirements, and informed consent must be obtained from all study subjects.

The clinical trial process for a new compound can take ten years or more to complete. The FDA may prevent clinical trials from beginning or may place clinical trials on hold at any point in this process if, among other reasons, it concludes that study subjects are being exposed to an unacceptable health risk. Trials may also be prevented from beginning or may be terminated by institutional review boards, who must review and approve all research involving human subjects. Side effects or adverse events that are reported during clinical trials can delay, impede, or prevent marketing authorization. Similarly, adverse events that are reported after marketing authorization can result in additional limitations being placed on a product’s use and, potentially, withdrawal of the product from the market.

### *Submission of NDA*

Following the completion of clinical trials, the data is analyzed to determine whether the trials successfully demonstrated safety and effectiveness and whether a product approval application may be submitted. In the United States, if the product is regulated as a drug, an NDA must be submitted and approved before commercial marketing may begin. The NDA must include a substantial amount of data and other information concerning the safety and effectiveness of the compound from laboratory, animal, and human clinical testing, as well as data and information on manufacturing, product quality and stability, and proposed product labeling.

Each domestic and foreign manufacturing establishment, including any contract manufacturers we may decide to use, must be listed in the NDA and must be registered with the FDA. The application generally will not be approved until the FDA conducts a manufacturing inspection, approves the applicable manufacturing process and determines that the facility is in compliance with cGMP requirements.

Under the Prescription Drug User Fee Act, as amended, the FDA receives fees for reviewing an NDA and supplements thereto, as well as annual fees for commercial manufacturing establishments and for approved products. These fees can be significant. For fiscal year 2012, the NDA review fee alone is \$1,841,500, although certain limited deferral, waivers, and reductions may be available.

Each NDA submitted for FDA approval is usually reviewed for administrative completeness and reviewability within 45 to 60 days following submission of the application. If deemed complete, the FDA will “file” the NDA, thereby triggering substantive review of the application. The FDA can refuse to file any NDA that it deems incomplete or not properly reviewable. The FDA has established performance goals for the review of NDAs— six months for priority applications and 10 months for standard applications. However, the FDA is not legally required to complete its review within these periods and these performance goals may change over time.

Moreover, the outcome of the review, even if generally favorable, typically is not an actual approval but an “action letter” that describes additional work that must be done before the application can be approved. The FDA’s review of an application may involve review and recommendations by an independent FDA advisory committee. Even if the FDA approves a product, it may limit the approved therapeutic uses for the product as described in the product labeling, require that warning statements be included in the product labeling, require that additional studies be conducted following approval as a condition of the approval, impose restrictions and conditions on product distribution, prescribing, or dispensing in the form of a risk management plan, or otherwise limit the scope of any approval.

### *Post NDA Regulation*

Significant legal and regulatory requirements also apply after FDA approval to market under an NDA. These include, among other things, requirements related to adverse event and other reporting, product advertising and promotion and ongoing adherence to cGMPs, as well as the need to submit appropriate new or supplemental applications and obtain FDA approval for certain changes to the approved product labeling, or manufacturing process. The FDA also enforces the requirements of the Prescription Drug Marketing Act which, among other things, imposes various requirements in connection with the distribution of product samples to physicians.

The regulatory framework applicable to the production, distribution, marketing and/or sale of our product pipeline may change significantly from the current descriptions provided herein in the time that it may take for any of our products to reach a point at which an NDA is approved.

Overall research, development, and approval times depend on a number of factors, including the period of review at FDA, the number of questions posed by the FDA during review, how long it takes to respond to the FDA’s questions, the severity or life-threatening nature of the disease in question, the availability of alternative treatments, the availability of clinical investigators and eligible patients, the rate of enrollment of patients in clinical trials, and the risks and benefits demonstrated in the clinical trials.



## **Other United States Regulatory Requirements**

In the United States, the research, manufacturing, distribution, sale, and promotion of drug and biological products are potentially subject to regulation by various federal, state, and local authorities in addition to the FDA, including the Centers for Medicare and Medicaid Services (formerly the Health Care Financing Administration), other divisions of the United States Department of Health and Human Services (e.g., the Office of Inspector General), the United States Department of Justice and individual United States Attorney offices within the Department of Justice, and state and local governments. For example, sales, marketing, and scientific/educational grant programs must comply with the anti-fraud and abuse provisions of the Social Security Act, the False Claims Act, the privacy provision of the Health Insurance Portability and Accountability Act, and similar state laws, each as amended. Pricing and rebate programs must comply with the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990 and the Veterans Health Care Act of 1992, each as amended. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. All of these activities are also potentially subject to federal and state consumer protection, unfair competition, and other laws.

Our research and development, manufacturing and administration of our drugs involves the controlled use of hazardous materials, including chemicals and radioactive materials, such as radioactive isotopes. Therefore, we are subject to federal, state and local laws and regulations governing the storage, use and disposal of these materials and some waste products and are required to maintain both a manufacturer's license and a radioactive materials license with State of Wisconsin agencies.

Moreover, we are now, and may become subject to, additional federal, state, and local laws, regulations, and policies relating to safe working conditions, laboratory practices, the experimental use of animals, and/or the use, storage, handling, transportation, and disposal of human tissue, waste, and hazardous substances, including radioactive and toxic materials and infectious disease agents used in conjunction with our research work.

## **Foreign Regulatory Requirements**

We and any future collaborative partners may be subject to widely varying foreign regulations, which may be quite different from those of the FDA, governing clinical trials, manufacture, product registration and approval, and pharmaceutical sales. Whether or not FDA approval has been obtained, we or any future collaboration partners must obtain a separate approval for a product by the comparable regulatory authorities of foreign countries prior to the commencement of product marketing in these countries. In certain countries, regulatory authorities also establish pricing and reimbursement criteria. The approval process varies from country to country, and the time may be longer or shorter than that required for FDA approval. In addition, under current United States law, there are restrictions on the export of products not approved by the FDA, depending on the country involved and the status of the product in that country.

## **Reimbursement and Pricing Controls**

In many of the markets where we or any future collaborative partners would commercialize a product following regulatory approval, the prices of pharmaceutical products are subject to direct price controls by law and to drug reimbursement programs with varying price control mechanisms. Public and private health care payers control costs and influence drug pricing through a variety of mechanisms, including through negotiating discounts with the manufacturers and through the use of tiered formularies and other mechanisms that provide preferential access to certain drugs over others within a therapeutic class. Payers also set other criteria to govern the uses of a drug that will be deemed medically appropriate and therefore reimbursed or otherwise covered. In particular, many public and private health care payers limit reimbursement and coverage to the uses of a drug that are either approved by the FDA or that are supported by other appropriate evidence (for example, published medical literature) and appear in a recognized drug compendium. Drug compendia are publications that summarize the available medical evidence for particular drug products and identify which uses of a drug are supported or not supported by the available evidence, whether or not such uses have been approved by the FDA. For example, in the case of Medicare coverage for physician-administered oncology drugs, the Omnibus Budget Reconciliation Act of 1993, with certain exceptions, prohibits Medicare carriers from refusing to cover unapproved uses of an FDA-approved drug if the unapproved use is supported by one or more citations in the American Hospital Formulary Service Drug Information, the American Medical Association Drug Evaluations, or the United States Pharmacopoeia Drug Information. Another commonly cited compendium, for example under Medicaid, is the DRUGDEX Information System.

In recent years, there have been positive developments regarding medical reimbursement for therapeutic radiopharmaceuticals in the United States. The Centers for Medicare and Medicaid Services have proposed that the reimbursement for radiopharmaceuticals shift from a cost-to-charge ratio ("CCR") to an average selling price ("ASP") plus 4% model. There has been support expressed for this proposal by government agencies, key industry members and the industry consortium, The Council on Radionuclides and Radiopharmaceuticals. The historical CCR model resulted in a reimbursement rate that was lower than the cost to purchase the drugs, thus creating a disincentive for hospitals to prescribe radiopharmaceuticals. The current ASP proposal is a solution to this reimbursement problem. Furthermore, there are proposals pending, which, if adopted, would decrease the physician reimbursement for chemotherapy and conventional radiation therapy. The proposed reduction in physician reimbursement for chemotherapy could likely result in the movement of a large volume of cancer care from the physician's office to the hospital environment. The proposed reduction in physician reimbursement for radiation therapy would result in a gap in revenue for radiation oncologists. Both proposed reductions favor an increase in opportunities to prescribe therapeutic radiopharmaceuticals.

**Item 1A. Risk Factors.**

**We will require additional capital in order to continue our operations, and may have difficulty raising additional capital.**

We expect that we will continue to generate significant operating losses for the foreseeable future. At December 31, 2011, our consolidated cash balance was approximately \$5,506,000. We believe our cash on hand is adequate to fund operations into the middle of the third quarter of 2012. We have expended and expect to 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. Our ability to execute our operating plan depends on our ability to obtain additional funding via the sale of equity and/or debt securities, a strategic transaction or otherwise. Although we have not entered into negotiations for a financing or strategic transaction, we plan to actively pursue financing alternatives. However, there can be no assurance that we will obtain the necessary funding or that it will be available on a timely basis or upon terms acceptable to us. If we obtain capital by issuing debt or preferred stock, the holders of such securities would likely obtain rights that are superior to those of holders of our common stock.

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

- the number of potential products and technologies in development;
- continued progress and cost of our research and development programs;
- progress with pre-clinical studies and clinical trials;
- the time and costs involved in obtaining regulatory clearance;
- costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims;
- costs of developing sales, marketing and distribution channels and our ability to sell our drugs;
- costs involved in establishing manufacturing capabilities for clinical trial and commercial quantities of our drugs;
- competing technological and market developments;
- market acceptance of our products;
- costs for recruiting and retaining management, employees and consultants;
- costs for educating physicians regarding the application and use of our products;
- whether or not we obtain listing on a national exchange and, if not, our prospects for obtaining such listing;
- 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 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 we cannot secure adequate financing when needed, we may be required to delay, scale back or eliminate one or more of our research and development programs or to enter into license or other arrangements with third parties to commercialize products or technologies that we would otherwise seek to develop ourselves and commercialize ourselves. In such event, our business, prospects, financial condition, and results of operations may be adversely affected.

**We are a development stage company with a history of losses and can provide no assurance of our future operating results.**

We are a development stage company and have incurred net losses and negative cash flows since inception. We currently have no product revenues, and may not succeed in developing or commercializing any products which will generate product or licensing revenues. We do not expect to have any marketable products on the market for several years. Our primary activity to date has been research and development. In addition, development of our product candidates requires a process of pre-clinical and clinical testing, during which our product candidates could fail. We may not be able to enter into agreements with one or more companies experienced in the manufacturing and marketing of therapeutic drugs and, to the extent that we are unable to do so, we will not be able to market our product candidates. Eventual profitability will depend on our success in developing, manufacturing, and marketing our product candidates. We have experienced net losses and negative cash flows from operating activities since inception and we expect such losses and negative cash flows to continue in the foreseeable future. As of December 31, 2011, we had working capital of \$5,312,346 and stockholders' equity of \$9,481,123, respectively. For the period from Cellectar's inception in November 2002 until the business combination with Novelos on April 8, 2011, and thereafter through December 31, 2011, Cellectar (and, from and after the business combination, Novelos) incurred aggregated net losses of \$31,480,426. Net loss for the year ended December 31, 2011 was \$7,435,422. We may never achieve profitability.

**We and our Chief Executive Officer are defendants in a securities fraud class action lawsuit. We are also defending counterclaims in another lawsuit that we initiated. If we are not successful in defending claims against us, the resulting liability could be substantial.**

A putative class action complaint was filed on March 5, 2010 in the U.S. District Court for the District of Massachusetts by an alleged shareholder on behalf of himself and all others who purchased or otherwise acquired our common stock in the period between December 14, 2009 and February 24, 2010, against us and our President and Chief Executive Officer, Harry S. Palmin. The complaint claimed, among other things, that the defendants violated Section 10(b) of the Securities Exchange Act of 1934, as amended, and Rule 10b-5 promulgated thereunder in connection with alleged misleading disclosures related to the progress of the Phase 3 trial of NOV-002 in advanced non-small cell lung cancer. On June 23, 2011, the case was dismissed without prejudice. On August 5, 2011, the plaintiffs filed a second amended complaint realleging that the defendants violated Section 10(b) of the Exchange Act and Rule 10b-5 in connection with alleged misleading disclosures related to the Phase 3 clinical trial for NOV-002 in non-small cell lung cancer. On September 9, 2011, the defendants filed a motion to dismiss the second amended complaint. The plaintiffs' opposition to the motion was filed on October 14, 2011 and the defendants filed a reply brief on November 4, 2011.

In addition, on June 28, 2010, we received a letter from counsel to ZAO BAM and ZAO BAM Research Laboratories (Russian companies, collectively referred to as “BAM”) alleging that we modified the chemical composition of NOV-002 without prior notice to or approval from BAM, constituting a material breach of a technology and assignment agreement we had entered into with BAM on June 20, 2000 (the “June 2000 Agreement”). On September 24, 2010, we filed a complaint in Suffolk Superior Court seeking a declaratory judgment by the court that the June 2000 Agreement has been replaced by a subsequent agreement between the parties dated April 1, 2005 (the “April 2005 Agreement”), that Novelos’ obligations to BAM are governed solely by the April 2005 Agreement and that the obligations of the June 2000 Agreement have been performed and fully satisfied. BAM answered the complaint, denying the material allegations, and stating its affirmative defenses and certain counterclaims. In June 2011, BAM filed an amended counterclaim alleging additional claims related to Novelos’ acquisition of Collectar. On June 15, 2011 we filed our response to their amended counterclaim. On August 5, 2011, we filed a motion for judgment on the pleadings as to our declaratory judgment count and all counts of BAM’s amended counterclaim. The motion was opposed by BAM and a hearing on the motion was held on September 27, 2011. On October 17, 2011, the court ruled on our behalf for each of our declaratory judgment claims and dismissed all counts of BAM’s counterclaim. Judgment in favor of the Company was entered on October 20, 2011. On November 14, 2011, BAM filed a notice of appeal.

While we intend to continue to vigorously defend ourselves in these actions, the uncertainties of litigation and the uncertainties related to insurance coverage and collection as well as the actual value of claims make it difficult to accurately predict the financial effect these claims may ultimately have on us. We may not be successful in defending such claims, and the resulting liability could be substantial and may not be covered by insurance. At the time the class action complaint was filed, we carried a total of \$10 million in directors and officers liability insurance coverage, consisting of \$5 million in primary coverage (including costs to defend) and \$5 million in excess liability coverage. The BAM dispute is not covered by insurance. In addition, the lawsuits divert management’s attention and resources, whether or not the claims are ultimately successful, and this could adversely affect our business. As a result, there can be no assurance as to the long-term effect litigation will have on our business, prospects, financial condition or results of operations.

**At present, our success depends solely on the successful commercialization of Collectar compounds.**

Prior to the Acquisition, Novelos had for over ten years been developing oxidized glutathione-based compounds for the treatment of cancer, including NOV-002, an injectable small-molecule compound based on a proprietary formulation of oxidized glutathione that Novelos had been developing for use in combination with standard-of-care chemotherapies for the treatment of solid tumors, and NOV-205, a hepatoprotective agent with immunomodulating and anti-inflammatory properties.

Following the Acquisition, development of NOV-002 and NOV-205 has been suspended and we are now focused on the development of novel drugs for the treatment and diagnosis of cancer based on the cancer-targeting technologies of Collectar: I-124-CLR1404 (“LIGHT”, labeled with a shorter-lived radioisotope, iodine-124), I-131-CLR1404 (“HOT”, a radiolabeled compound) and CLR1401 (“COLD”). As a result, the successful commercialization of LIGHT, HOT and COLD is crucial for our success. Our proposed products and their potential applications are in an early stage of clinical and manufacturing/process development and face a variety of risks and uncertainties. Principally, these risks include the following:

- future clinical trial results may show that the cancer-targeting technologies of Collectar are not well tolerated by recipients at its effective doses or are not efficacious;
- future clinical trial results may be inconsistent with Collectar’s previous preliminary testing results and data from Collectar’s earlier studies may be inconsistent with clinical data;
- even if the cancer-targeting technologies of Collectar are shown to be safe and effective for their intended purposes, we may face significant or unforeseen difficulties in obtaining or manufacturing sufficient quantities at reasonable prices or at all;
- our ability to complete the development and commercialization of the cancer-targeting technologies of Collectar for our intended use is substantially dependent upon our ability to obtain and maintain experienced and committed partners to assist us with obtaining clinical and regulatory approvals for, and the manufacturing, marketing and distribution of, our products;
- even if the cancer-targeting technologies of Collectar are successfully developed, commercially produced and receive all necessary regulatory approvals, there is no guarantee that there will be market acceptance of our products; and
- our competitors may develop therapeutics or other treatments which are superior or less costly than our own with the result that our product candidates, even if they are successfully developed, manufactured and approved, may not generate sufficient revenues to offset the development and manufacturing costs of our product candidates.

If we are unsuccessful in dealing with any of these risks, or if we are unable to successfully commercialize the cancer-targeting technologies of Cellestar for some other reason, our business, prospects, financial condition, and results of operations may be adversely affected.

**We have a history of recurring losses and an accumulated deficit which, among other factors, raise substantial doubt about our ability to continue as a going concern, which may hinder our ability to obtain future financing.**

Our financial statements as of December 31, 2011 were prepared under the assumption that we will continue as a going concern. The independent registered public accounting firm that audited our 2011 financial statements, in their report, included an explanatory paragraph referring to our recurring losses since inception and expressing substantial doubt in our ability to continue as a going concern. Our financial statements do not include any adjustments that might result from the outcome of this uncertainty. Our ability to continue as a going concern depends on our ability to obtain additional equity or debt financing, attain further operating efficiencies, reduce expenditures, and, ultimately, to generate revenue.

**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 U.S. and abroad. Before receiving clearance to market our proposed products by the FDA, 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. This includes meeting 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 and other diseases; and
- anticipated expense and time believed to be associated with the development and regulatory approval of treatments for cancer and other diseases.

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

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.

**Clinical trials involve a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.**

In order to receive regulatory approval for the commercialization of our product candidates, we must conduct, at our own expense, extensive clinical trials to demonstrate safety and efficacy of these product candidates. Clinical testing is expensive, it can take many years to complete and its outcome is uncertain. Failure can occur at any time during the clinical trial process. For example, we incurred costs of over \$35 million in clinical trial expenses over a period of 4 years in connection with the Phase 3 trial of NOV-002 for non-small cell lung cancer, and NOV-002 did not ultimately demonstrate efficacy for that indication.

We may experience delays in clinical testing of our product candidates. We do not know whether planned clinical trials will begin on time, will need to be redesigned or will be completed on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including delays in obtaining regulatory approval to commence a trial, in reaching agreement on acceptable clinical trial terms with prospective sites, in obtaining institutional review board approval to conduct a trial at a prospective site, in recruiting patients to participate in a trial or in obtaining sufficient supplies of clinical trial materials. Many factors affect patient enrollment, including the size of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, competing clinical trials and new drugs approved for the conditions we are investigating. Prescribing physicians will also have to decide to use our product candidates over existing drugs that have established safety and efficacy profiles. Any delays in completing our clinical trials will increase our costs, slow down our product development and approval process and delay our ability to generate revenue.

In addition, the results of preclinical studies and early clinical trials of our product candidates do not necessarily predict the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through initial clinical testing. The data collected from clinical trials of our product candidates may not be sufficient to support the submission of a new drug application or to obtain regulatory approval in the United States or elsewhere. Because of the uncertainties associated with drug development and regulatory approval, we cannot determine if or when we will have an approved product for commercialization or achieve sales or profits.

Our clinical trials may not demonstrate sufficient levels of efficacy necessary to obtain the requisite regulatory approvals for our drugs, and our proposed drugs may not be approved for marketing. We suffered significant setbacks in the development of NOV-002 and NOV-205, as some of the promising results of earlier trials were not demonstrated in later stage trials. As a result, following the Acquisition, development of these compounds has been suspended.

**We may be required to suspend or discontinue clinical trials due to unexpected side effects or other safety risks that could preclude approval of our product candidates.**

Our clinical trials may be suspended at any time for a number of reasons. For example, we may voluntarily suspend or terminate our clinical trials if at any time we believe that they present an unacceptable risk to the clinical trial patients. In addition, regulatory agencies may order the temporary or permanent discontinuation of our clinical trials at any time if they believe that the clinical trials are not being conducted in accordance with applicable regulatory requirements or that they present an unacceptable safety risk to the clinical trial patients.

Administering any product candidates to humans may produce undesirable side effects. These side effects could interrupt, delay or halt clinical trials of our product candidates and could result in the FDA or other regulatory authorities denying further development or approval of our product candidates for any or all targeted indications. Ultimately, some or all of our product candidates may prove to be unsafe for human use. Moreover, we could be subject to significant liability if any volunteer or patient suffers, or appears to suffer, adverse health effects as a result of participating in our clinical trials.

**We have limited in-house research and manufacturing capacity and will continue to rely, to some extent, on research and manufacturing facilities at various universities, hospitals, contract research organizations and contract manufacturers for a portion of our research, development, and manufacturing. In the event we exceed our in-house capacity or lose access to those facilities, our ability to gain FDA approval and commercialization of our drug delivery technology and products could be delayed or impaired.**

We remain in the research and development and clinical and pre-clinical trial phase of product commercialization and have limited experience in establishing, supervising and conducting commercial manufacturing. Accordingly, if our products are approved for commercial sale, we will need to establish the capability, or engage a contract manufacturer that has the capability, to commercially manufacture our products in accordance with FDA and other regulatory requirements. There can be no assurance that we would be able to successfully establish any such capability, or identify a suitable manufacturing partner on acceptable terms.

At the present time, we have limited research, development or manufacturing capabilities within our facilities. Our manufacturing facility in Madison, Wisconsin has adequate capacity to supply drug product for Phase 2 studies of HOT, but we will need to expand for larger Phase 3 studies. We are exploring scaling up production capacity of COLD, via contract manufacturers or at our facility, to support an IND filing and clinical trials. LIGHT is currently manufactured by our collaborator, the University of Wisconsin at Madison in small quantities, at no cost to us, for use in investigator-sponsored clinical trials pursuant to a materials transfer agreement expiring in June 2013, but which may be terminated at any time by either party. We rely and expect to continue to rely, to some extent, on contracting with third parties to use their facilities to conduct research, development and manufacturing. The limited 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 may rely on third-party contract research organizations, service providers and suppliers to support development and clinical testing of 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. 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, prospects, financial condition and results of operations.

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 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, prospects, 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:

- receiving regulatory clearance of marketing claims for the uses that we are developing;
- establishing and demonstrating 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. The U. Mich. license does require, and license agreements that we may enter into in the future 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 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, such as ours, that involve licensing agreements, are frequently uncertain and involve complex legal and factual questions. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued or in subsequent legal proceedings. Consequently, our patent applications and any issued and licensed patents may not provide protection against competitive technologies or may be held invalid if challenged or circumvented. To the extent we license patents from third parties, as in the case of the U. Mich. license, the early termination of any such license agreement would result in the loss of our rights to use the covered patents, which could severely delay, inhibit or eliminate our ability to develop and commercialize compounds based on the licensed patents. 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.

**Confidentiality agreements with employees and others may not adequately prevent disclosure of our trade secrets and other proprietary information and may not adequately protect our intellectual property, which could limit our ability to compete.**

We operate in the highly technical field of research and development of small molecule drugs, and rely in part on trade-secret protection in order to protect our proprietary trade secrets and unpatented know-how. However, trade secrets are difficult to protect, and we cannot be certain that our competitors will not develop the same or similar technologies on their own. We have taken steps, including entering into confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors, to protect our trade secrets and unpatented know-how. These agreements generally require that the other party keep confidential and not disclose to third parties all confidential information developed by the party or made known to the party by us during the course of the party's relationship with us. We also typically obtain agreements from these parties which provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, these agreements may not be honored and may not effectively assign intellectual property rights to us. Enforcing a claim that a party has illegally obtained and is using our trade secrets or know-how is difficult, expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States may be less willing to protect trade secrets or know-how. The failure to obtain or maintain trade-secret protection could adversely affect our competitive position.

**We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.**

As is common in the biotechnology and pharmaceutical industry, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that we or these employees have used or disclosed trade secrets or other proprietary information of their former employers, either inadvertently or otherwise. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

**The use of hazardous materials, including radioactive materials, in our research and development imposes certain compliance costs on us and may subject us to liability for claims arising from the use or misuse of these materials.**

Our research and development, manufacturing and administration of our drugs involves the controlled use of hazardous materials, including chemicals and radioactive materials, such as radioactive isotopes. We are subject to federal, state and local laws and regulations governing the storage, use and disposal of these materials and some waste products and are required to maintain both a manufacturer's license and a radioactive materials license with State of Wisconsin agencies. We believe that our safety procedures for the storage, use and disposal of these materials comply with the standards prescribed by federal, state and local regulations. However, we cannot completely eliminate the risk of accidental contamination or injury from these materials. If there were to be an accident, we could be held liable for any damages that result, which could exceed our financial resources. We currently maintain insurance coverage, with limits of up to \$2,500,000 depending on the nature of the claim, for damages resulting from the hazardous materials we use; however, future claims may exceed the amount of our coverage. Also, we do not have insurance coverage for pollution cleanup and removal. Currently the costs of complying with federal, state and local regulations are not significant, and consist primarily of waste disposal expenses and permitting fees. However, they could become expensive, and current or future environmental regulations may impair our research, development, production and commercialization efforts. If we are unable to maintain the required licenses and permits for any reason, it will negatively impact our research and development activities.

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

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

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

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

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

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

If we fail to develop sales, marketing and distribution channels, we would experience delays in product sales and incur increased costs, which would have a material adverse effect on our business, prospects, financial condition, and results of operation.

**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 use of our products in the target market of cancer diagnosis and treatment 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 proposed products. We may be unable to timely educate physicians regarding our intended proposed 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 proposed products. In addition, we may expend significant funds towards physician education before any acceptance or demand for our proposed products is created, if at all.

**The market for our proposed 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.

For example, Perifosine, an alkylphospholipid that is being developed by Keryx Biopharmaceuticals, which has licensed it in North America from Aeterna Zentaris Inc., is a possible future competitor to COLD. We do not know of any current or potential direct competitors for HOT and LIGHT. Marketed drugs Zevalin® (Spectrum Pharmaceuticals) and Bexxar® (Glaxo Smith Kline) provide examples of targeted radiotherapeutics specifically for lymphoma indication. FDG is the current standard for PET imaging for cancer and may be an alternative diagnostic imaging agent to LIGHT.

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 additional healthcare reform measures are adopted, it could hinder or prevent our product candidates' commercial success.**

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

New laws, regulations and judicial decisions, or new interpretations of existing laws, regulations and decisions, that relate to healthcare availability, methods of delivery or payment for healthcare products and services, or sales, marketing or pricing of healthcare products and services, also may limit our potential revenue and may require us to revise our research and development programs. The pricing and reimbursement environment may change in the future and become more challenging for several reasons, including policies advanced by the current or future executive administrations in the U.S., new healthcare legislation or fiscal challenges faced by government health administration authorities. Specifically, in both the U.S. and some foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. In the U.S., changes in federal healthcare policy were enacted in 2010 and remain the subject of continued reconsideration by Congress. Some proposed reforms could result in reduced reimbursement rates for our product candidates, which would adversely affect our business strategy, operations and financial results.

Our ability to commercialize our products will depend in part on the extent to which appropriate reimbursement levels for the cost of our products and related treatment are obtained by governmental authorities, private health insurers and other organizations, such as health maintenance organizations (HMOs). Third-party payers are increasingly challenging the prices charged for medical drugs and services. Also, the trend toward managed healthcare in the U.S. 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 healthcare or change government insurance programs, may all result in lower prices for or rejection of our drugs. The cost containment measures that healthcare payers and providers are instituting and the effect of any healthcare reform could materially harm our ability to operate profitably.

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

Our success will depend to a significant degree on the continued services of our chief executive officer, Harry Palmin, Celectar founder and our chief scientific officer, Jamey Weichert, and our senior vice president of research and development, Christopher Pazoles. There can be no assurance that these individuals will continue to provide services to us. In addition, our success may depend on our ability to attract and retain other highly skilled personnel. We may be unable to recruit such personnel on a timely basis, if at all. Our management and other employees may voluntarily terminate their employment with us at any time. The loss of services of key personnel, or the inability to attract and retain additional qualified personnel, could result in delays in development or approval of our products, loss of sales and diversion of management resources. To date, we have not experienced difficulties attracting and retaining highly qualified personnel, but there can be no assurance we will be successful in doing so in the future.

**Our stock price has experienced price fluctuations.**

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

- announcements or press releases relating to the biopharmaceutical sector or to our own business or prospects;
- regulatory, legislative, or other developments affecting us or the healthcare industry generally;
- sales by holders of restricted securities pursuant to effective registration statements or exemptions from registration; and

- market conditions specific to biopharmaceutical companies, the healthcare industry and the stock market generally.

**Five of our stockholders beneficially own approximately 61% of our outstanding common stock, which limits the influence of other stockholders.**

As of March 2, 2012, 61% of our outstanding common stock is beneficially owned by five stockholders. The interests of these stockholders may differ from those of other stockholders. These stockholders will likely continue to 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; and
- the approval of certain mergers and other significant corporate transactions, including a sale of substantially all of our assets.

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

Our common stock currently does not meet all of the requirements for initial listing on a registered stock exchange. Specifically, our cash on hand is not sufficient to fund operations for twelve months and the bid price of our common stock is less than the minimum bid price required to obtain a listing. Trading in our common stock continues to be conducted on the electronic bulletin board in the over-the-counter market (currently the OTCQX). As a result, an investor may find it difficult to dispose of or to obtain accurate quotations as to the market value of our common stock, and our common stock may be less attractive for margin loans, or for investment by financial institutions, as consideration in future capital raising transactions or other contexts.

**Our common stock has historically been a “penny stock” under SEC rules. It may be more difficult to resell shares of common stock classified as “penny stock”.**

Our common stock has historically been a “penny stock” under applicable SEC rules (generally defined as non-exchange traded stock with a per-share price below \$5.00). These rules impose additional sales practice requirements on broker-dealers that recommend the purchase or sale of penny stocks to persons other than those who qualify as “established customers” or “accredited investors.” For example, broker-dealers must determine the appropriateness for non-qualifying persons of investments in penny stocks. Broker-dealers must also provide, prior to a transaction in a penny stock not otherwise exempt from the rules, a standardized risk disclosure document that provides information about penny stocks and the risks in the penny stock market. The broker-dealer also must provide the customer with current bid and offer quotations for the penny stock, disclose the compensation of the broker-dealer and its salesperson in the transaction, furnish monthly account statements showing the market value of each penny stock held in the customer’s account, provide a special written determination that the penny stock is a suitable investment for the purchaser, and receive the purchaser’s written agreement to the transaction.

Legal remedies available to an investor in "penny stocks" may include the following:

- if a "penny stock" is sold to the investor in violation of the requirements listed above, or other federal or states securities laws, the investor may be able to cancel the purchase and receive a refund of the investment.
- if a “penny stock” is sold to the investor in a fraudulent manner, the investor may be able to sue the persons and firms that committed the fraud for damages.

However, investors who have signed arbitration agreements may have to pursue their claims through arbitration.

These requirements may have the effect of reducing the level of trading activity, if any, in the secondary market for a security that becomes subject to the penny stock rules. The additional burdens imposed upon broker-dealers by such requirements may discourage broker-dealers from effecting transactions in our securities, which could severely limit the market price and liquidity of our securities. These requirements may restrict the ability of broker-dealers to sell our common stock and may affect your ability to resell our common stock.

Many brokerage firms will discourage or refrain from recommending investments in penny stocks. Most institutional investors will not invest in penny stocks. In addition, many individual investors will not invest in penny stocks due, among other reasons, to the increased financial risk generally associated with these investments.

For these reasons, penny stocks may have a limited market and, consequently, limited liquidity. We can give no assurance at what time, if ever, our common stock will not be classified as a “penny stock” in the future.

**If we fail to maintain effective internal controls over financial reporting, the price of our common stock may be adversely affected.**

Our internal control over financial reporting may have weaknesses and conditions that could require correction or remediation, the disclosure of which may have an adverse impact on the price of our common stock. We are required to establish and maintain appropriate internal controls over financial reporting. Failure to establish those controls, or any failure of those controls once established, could adversely affect our public disclosures regarding our business, prospects, financial condition or results of operations. In addition, management’s assessment of internal controls over financial reporting may identify weaknesses and conditions that need to be addressed in our internal controls over financial reporting or other matters that may raise concerns for investors. Any actual or perceived weaknesses and conditions that need to be addressed in our internal control over financial reporting or disclosure of management’s assessment of our internal controls over financial reporting may have an adverse impact on the price of our common stock.

**We are required to comply with certain provisions of Section 404 of the Sarbanes-Oxley Act of 2002 and if we fail to comply in a timely manner, our business could be harmed and our stock price could decline.**

Rules adopted by the SEC pursuant to Section 404 of the Sarbanes-Oxley Act of 2002 require an annual assessment of internal controls over financial reporting, and for certain issuers an attestation of this assessment by the issuer’s independent registered public accounting firm. The standards that must be met for management to assess the internal controls over financial reporting as effective are evolving and complex, and require significant documentation, testing, and possible remediation to meet the detailed standards. We expect to incur significant expenses and to devote resources to Section 404 compliance on an ongoing basis. It is difficult for us to predict how long it will take or costly it will be to complete the assessment of the effectiveness of our internal control over financial reporting for each year and to remediate any deficiencies in our internal control over financial reporting. As a result, we may not be able to complete the assessment and remediation process on a timely basis. In addition, although attestation requirements by our independent registered public accounting firm are not presently applicable to us we could become subject to these requirements in the future and we may encounter problems or delays in completing the implementation of any resulting changes to internal controls over financial reporting. In the event that our Chief Executive Officer or Chief Financial Officer determine that our internal control over financial reporting is not effective as defined under Section 404, we cannot predict how regulators will react or how the market prices of our shares will be affected; however, we believe that there is a risk that investor confidence and share value may be negatively affected.

**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 notes) 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 exercise of certain 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 exercise prices of outstanding warrants (resulting in these securities becoming 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.

**Shares eligible for future sale may adversely affect the market.**

From time to time, certain of our stockholders may be eligible to sell all or some of their shares of common stock by means of ordinary brokerage transactions in the open market pursuant to Rule 144 promulgated under the Securities Act, subject to certain limitations. In general, pursuant to amended Rule 144, non-affiliate stockholders may sell freely after six months subject only to the current public information requirement. Affiliates may sell after six months subject to the Rule 144 volume, manner of sale (for equity securities), current public information and notice requirements. Of the approximately 37 million shares of our common stock outstanding as of March 2, 2012, approximately 11.8 million shares are tradable without restriction. On October 8, 2011, 23,848,133 shares that had been issued in unregistered transactions became tradable pursuant to Rule 144. Any substantial sales of our common stock pursuant to Rule 144 may have a material adverse effect on the market price of our common stock.

**Provisions of our charter, bylaws, and Delaware law may make an acquisition of us or a change in our management more difficult.**

Certain provisions of our amended restated certificate of incorporation and bylaws could discourage, delay or prevent a merger, acquisition or other change in control that stockholders may consider favorable, including transactions in which an investor might otherwise receive a premium for their shares. These provisions also could limit the price that investors might be willing to pay in the future for shares of our common stock or warrants, thereby depressing the market price of our common stock. Stockholders who wish to participate in these transactions may not have the opportunity to do so.

Furthermore, these provisions could prevent or frustrate attempts by our stockholders to replace or remove our management. These provisions:

- provide for the division of our board into three classes as nearly equal in size as possible with staggered three-year terms and further limit the removal of directors and the filling of vacancies;
- authorize our board of directors to issue without stockholder approval blank-check preferred stock that, if issued, could operate as a "poison pill" to dilute the stock ownership of a potential hostile acquirer to prevent an acquisition that is not approved by our board of directors;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit stockholder action by written consent;
- establish advance notice requirements for stockholder nominations to our board of directors or for stockholder proposals that can be acted on at stockholder meetings;
- limit who may call stockholder meetings; and
- require the approval of the holders of 75% of the outstanding shares of our capital stock entitled to vote in order to amend certain provisions of our restated certificate of incorporation and restated bylaws.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which may, unless certain criteria are met, prohibit large stockholders, in particular those owning 15% or more of our outstanding voting stock, from merging or combining with us for a prescribed period of time.

**We have not paid dividends in the past and do not expect to pay dividends for the foreseeable future. Any return on investment may be limited to the value of our common stock.**

No cash dividends have been paid on Novelos common stock. We do not expect to pay cash dividends in the near future. Payment of dividends would depend upon our profitability at the time, cash available for those dividends, and other factors as our board of directors may consider relevant. If we do not pay dividends, our common stock may be less valuable because a return on an investor's investment will only occur if our stock price appreciates.

## **Item 2. Properties.**

We lease our executive office in Newton, Massachusetts. Our office consists of approximately 2,000 square feet and is rented for approximately \$5,300 per month. This lease may be terminated by either party with one month's notice.

We lease office, laboratory and manufacturing space in Madison, Wisconsin. The space consists of approximately 19,500 square feet and is rented for approximately \$12,600 per month and expires on September 14, 2014. The lease may be renewed for two-year periods through 2024 with an increase of 3% in annual rent.

We believe that our present facilities are adequate to meet our current needs. If new or additional space is required, we believe that adequate facilities are available at competitive prices.

## **Item 3. Legal Proceedings.**

A putative federal securities class action complaint was filed on March 5, 2010 in the United States District Court for the District of Massachusetts by an alleged shareholder of Novelos, on behalf of himself and all others who purchased or otherwise acquired our common stock in the period between December 14, 2009 and February 24, 2010, against Novelos and our President and Chief Executive Officer, Harry S. Palmin. On October 1, 2010, the court appointed lead plaintiffs (Boris Urman and Ramona McDonald) and appointed lead plaintiffs' counsel. On October 22, 2010, an amended complaint was filed. The amended complaint claims, among other things, that the defendants violated Section 10(b) of the Securities Exchange Act of 1934, as amended, and Rule 10b-5 promulgated thereunder in connection with alleged misleading disclosures related to the progress of the Phase 3 clinical trial of NOV-002 for non-small cell lung cancer. On December 6, 2010, we filed a motion to dismiss the complaint with prejudice. On January 20, 2011, the plaintiffs filed their opposition to our motion and on March 3, 2011, we filed our response to their opposition. On June 23, 2011, the motion to dismiss was granted and the case was dismissed without prejudice. On August 5, 2011, the plaintiffs filed a second amended complaint realleging that the defendants violated Section 10(b) of the Exchange Act and Rule 10b-5 in connection with alleged misleading disclosures related to the Phase 3 clinical trial for NOV-002 in non-small cell lung cancer. On September 9, 2011, the defendants filed a motion to dismiss the second amended complaint. The plaintiffs' opposition to the motion was filed on October 14, 2011 and the defendants filed a reply brief on November 4, 2011. The Company and Mr. Palmin believe the allegations are without merit and intend to continue to vigorously defend against them.

On June 28, 2010, we received a letter from counsel to ZAO BAM and ZAO BAM Research Laboratories (Russian companies, collectively referred to as "BAM") alleging that we modified the chemical composition of NOV-002 without prior notice to or approval from BAM, constituting a material breach of a technology and assignment agreement we had entered into with BAM on June 20, 2000 (the "June 2000 Agreement"). The letter references our amendment, submitted to the FDA on August 30, 2005, to our investigational new drug application dated August 1999 as the basis for BAM's claims and demands the transfer of all intellectual property rights concerning NOV-002 to BAM. Mark Balazovsky, a director of Novelos from June 1996 until November 2006 and a shareholder of Novelos through at least June 25, 2010, is, to our knowledge, still the general director and principal shareholder of ZAO BAM. On September 24, 2010, we filed a complaint in Suffolk Superior Court seeking a declaratory judgment by the court that the June 2000 Agreement has been replaced by a subsequent agreement between the parties dated April 1, 2005 (the "April 2005 Agreement"), that Novelos' obligations to BAM are governed solely by the April 2005 Agreement and that the obligations of the June 2000 agreement have been performed and fully satisfied. On November 29, 2010, BAM answered the complaint, denying the material allegations, and stating its affirmative defenses and certain counterclaims. On January 14, 2011, we responded to the counterclaims, denying BAM's material allegations and stating our affirmative defenses. On June 9, 2011, BAM filed an amended counterclaim alleging additional claims related to Novelos' acquisition of Cellectar. In that amended counterclaim, BAM alleges that the acquisition evidences Novelos' abandonment of the technology assigned to it by BAM constituting a breach of the June 2000 Agreement or, if that agreement is determined to no longer be in effect, a breach of the April 2005 Agreement and/or a breach of the implied duty of good faith and fair dealing with respect to the April 2005 Agreement. On June 15, 2011 we filed our response to their amended counterclaim. On August 5, 2011, we filed a motion for judgment on the pleadings as to our declaratory judgment count and all counts of BAM's amended counterclaim. The motion was opposed by BAM and a hearing on the motion was held on September 27, 2011. On October 17, 2011, the court ruled on our behalf for each of our declaratory judgment claims and dismissed all counts of BAM's counterclaim. Judgment in favor of the Company was entered on October 20, 2011. On November 14, 2011, BAM filed a notice of appeal.

We do not anticipate that these litigation contingencies will have a material adverse effect on the Company's future financial position, results of operations or cash flows.



## PART II

### Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

#### MARKET FOR COMMON EQUITY

##### Market Information

Our common stock was quoted on the OTC Bulletin Board under the symbol "NVLT" beginning on June 14, 2005 until February 16, 2012, after which time it has been quoted on the OTCQX platform. 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 2010</b>	<b>High</b>	<b>Low</b>
First Quarter	\$ 466.36	\$ 26.16
Second Quarter	42.66	14.67
Third Quarter	23.08	6.17
Fourth Quarter	9.17	2.82

  

<b>Fiscal Year 2011</b>	<b>High</b>	<b>Low</b>
First Quarter	\$ 8.10	\$ 1.52
Second Quarter	3.82	0.95
Third Quarter	1.55	1.13
Fourth Quarter	1.39	0.33

The above share prices have been adjusted to give effect to a 1-for-153 reverse split of our common stock completed April 8, 2011 in connection with the Acquisition.

On March 2, 2012 there were 360 holders of record of our common stock. This number does not include stockholders for whom shares were held in a "nominee" or "street" name.

We have not declared or paid any cash dividends on our common stock and do not anticipate declaring or paying any cash dividends in the foreseeable future. We currently expect to retain future earnings, if any, for the development of our business.

##### Equity compensation plans

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

The following table provides information as of December 31, 2011 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. During 2004 and 2005, we also issued options to our directors and consultants that were not approved by our stockholders and during 2011 we issued options to certain 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	4,717,500	\$ 1.63	2,281,112
Equity compensation plans not approved by stockholders	110,138	\$ 10.16	0
<b>Total</b>	<b>4,827,638</b>	<b>\$ 1.82</b>	<b>2,281,112</b>

#### Item 6. Selected Financial Data.

Not applicable.

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

##### Forward-Looking Statements

This annual report on Form 10-K includes forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, which we refer to as the Exchange Act. For this purpose, any statements contained herein regarding our strategy, future operations, financial position, future revenues, projected costs, prospects, plans and objectives of management, other than statements of historical facts, are forward-looking statements. The words "anticipates," "believes," "estimates," "expects," "intends," "may," "plans," "projects," "will," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We cannot guarantee that we actually will achieve the plans, intentions or expectations disclosed in our forward-looking statements. There are a number of important factors that could cause actual results or events to differ materially from those disclosed in the forward-looking statements we make. These important factors include our significant accounting estimates and the risk factors set forth above under the caption "Risk Factors". Although we may elect to update forward-looking statements in the future, we specifically disclaim any obligation to do so, even if our estimates change, and readers should not rely on those forward-looking statements as representing our views as of any date subsequent to the date of this annual report.

## Acquisition

On April 8, 2011, we completed the Acquisition. Immediately prior to the Acquisition, we completed a 1-for-153 reverse split of our common stock. We then issued 17,001,596 shares of our common stock to the former shareholders of Collectar as consideration for the Acquisition, constituting approximately 85% of our outstanding common stock after giving effect to the Acquisition. Upon the closing of the Acquisition, we completed the private placement of 6,846,537 shares of our common stock and warrants to purchase an additional 6,846,537 shares of our common stock. The Acquisition was accounted for as a reverse acquisition whereby Collectar, Inc. was treated as the acquirer for accounting and financial reporting purposes. As such, references to the results of operations for the twelve months ended December 31, 2010 represent the historical results of Collectar. References to the results of operations for the twelve months ended December 31, 2011 include the historical results of Collectar from January 1, 2011 through April 8, 2011 and include the consolidated results of the combined company from April 9, 2011 through December 31, 2011.

As a result of the Acquisition, we have been implementing a revised business plan focused on the development of the Collectar compounds. We conduct our operations from Collectar's headquarters in Madison, Wisconsin and our executive offices are in Newton, Massachusetts. Further development of our other compounds (NOV-002 and NOV-205) has been suspended.

On April 8, 2011, immediately prior to the Acquisition, Collectar paid approximately \$627,000 in full settlement of a note payable to a bank. The payment was made in order to avoid an event of default that would have occurred as a result of the change of control that occurred at the time of the Acquisition. On April 8, 2011, the holders of Collectar convertible notes converted outstanding principal of \$2,720,985 and unpaid interest thereon into a total of 4,181,535 shares of common stock.

## Overview

We are a pharmaceutical company developing novel drugs for the treatment and diagnosis of cancer. We believe our three cancer-targeted compounds are selectively taken up and retained in cancer cells, including cancer stem cells, versus normal cells. Thus, our therapeutic compounds appear to directly kill cancer cells while minimizing harm to normal cells. This offers the potential for a paradigm shift in cancer therapy by providing efficacy versus all three major drivers of mortality in cancer: primary tumors, metastases and stem cell-based relapse. LIGHT is a small-molecule cancer-targeted PET imaging agent. We believe LIGHT has first-in-class potential and Phase 1-2 clinical trials are ongoing. HOT is a small-molecule, broad-spectrum, cancer-targeted molecular radiotherapeutic that delivers cytotoxic radiation directly and selectively to cancer cells and cancer stem cells. We believe HOT also has first-in-class potential. HOT Phase 1b dose-escalation trial is ongoing and we expect HOT to enter Phase 2 trials in the first quarter of 2013, as a monotherapy for solid tumors with significant unmet medical need, subject to additional funding. COLD, a cancer-targeted non-radioactive chemotherapy, works primarily through Akt inhibition. We plan to file an IND for COLD in the first quarter of 2013, subject to additional funding. Together, we believe our compounds are able to "find, treat and follow" cancer anywhere in the body in a novel, effective and highly selective way.

LIGHT is a small-molecule imaging agent that we believe has first-in-class potential for selective detection of tumors and metastases in a broad range of cancers. LIGHT is comprised of a small, non-pharmacological quantity of CLR1404 (COLD, acting as a cancer-targeted delivery and retention vehicle) labeled with the short-lived radioisotope, iodine-124, a new positron emission tomography (PET) imaging isotope. PET imaging used in conjunction with CT scanning has now become the imaging method of choice in oncology. In studies to date, LIGHT selectively illuminated malignant tumors in 52 of 54 animal models of cancer, demonstrating evidence of broad-spectrum, cancer-selective uptake and retention. Investigator-sponsored Phase 1-2 trials of LIGHT as a PET imaging agent are ongoing at the University of Wisconsin. The trials include lung cancer and brain metastases and starting in the second quarter of 2012, other solid tumors. These human trials, if successful, will serve two important purposes. First, they would provide proof-of-concept for LIGHT itself as a PET imaging agent with the potential to supplant the current "gold standard" agent, 18-fluoro-deoxyglucose (FDG), due to what we believe to be LIGHT's superior cancer-specificity and more favorable logistics of clinical use. Second, favorable results would accelerate clinical development of HOT by predicting efficacy and enabling calculation of efficacious doses of HOT for Phase 2 trials.

HOT (iodine-131 radiolabeled CLR1404) is a small-molecule, broad-spectrum, cancer-targeted molecular radiotherapeutic that we believe has first-in-class potential. HOT is comprised of a small, non-pharmacological quantity of CLR1404 (COLD) acting as a cancer-targeted delivery and retention vehicle and incorporating a cytotoxic (cell-killing) dose of radiotherapy (in the form of iodine-131, a radioisotope that is already in common use to treat thyroid and other cancer types). It is this “intracellular radiation” mechanism of cancer cell killing, coupled with selective delivery to a wide range of malignant tumor types that we believe imbues HOT with broad-spectrum anti-cancer activity. Selective uptake and retention has also been demonstrated in cancer stem cells compared with normal stem cells, offering the prospect of longer lasting cancer remission. In 2009 we filed an IND with the FDA to study HOT in humans. In early 2010 we successfully completed a Phase 1a dosimetry trial demonstrating initial safety, tumor imaging and pharmacokinetic consistency and establishing a starting dose for a Phase 1b dose-escalation trial. Radiation dosimetry measures how much radiation is absorbed by tumors and body organs in order to optimize delivery of radiation therapy. The ongoing Phase 1b dose-escalation trial is aimed at determining the Maximum Tolerated Dose of HOT. We expect to initiate HOT Phase 2 efficacy trials as a monotherapy for solid tumors with significant unmet medical need as soon as a minimal efficacious dose is established, in the event that we obtain the additional funding necessary for that purpose. We may determine such an effective dose upon seeing a tumor response in the Phase 1b trial or calculating it from ongoing PET imaging trials in cancer patients with LIGHT (since PET imaging is quantitative, enabling determination of tumor radiation exposure at a given dose level). Preclinical *in vitro* (in cell culture) and *in vivo* (in animals) experiments have demonstrated selective killing of cancer cells along with a benign safety profile. HOT’s anti-tumor/survival-prolonging activities have been demonstrated in more than a dozen xenograft models (human tumor cells implanted into animals) including breast, prostate, lung, glioma (brain), pancreatic, ovarian, uterine, renal and colorectal cancers and melanoma. In all but two models, a single administration of a well-tolerated dose of HOT was sufficient to demonstrate efficacy. In view of HOT’s selective uptake and retention in a wide range of solid tumors and in cancer stem cells, its single-agent efficacy in xenograft models and its non-specific mechanism of cancer-killing (radiation), we expect first to develop HOT as a monotherapy, initially for solid tumors.

COLD is a cancer-targeted chemotherapy that, in pre-clinical experiments, has been observed to inhibit the phosphatidylinositol 3-kinase (PI3K)/Akt survival pathway, which is overexpressed in many types of cancer. As a result, in such pre-clinical experiments COLD has been observed to selectively inhibit Akt activity, induce apoptosis through caspase activation and inhibit cell proliferation in cancer cells versus normal cells. COLD also exhibits significant *in vivo* efficacy in mouse xenograft tumor models, including non-small cell lung cancer and triple-negative breast cancers, producing long-lasting tumor growth suppression and significantly increased survival. We believe COLD has the potential to be best-in-class versus other Akt inhibitors in development due to (a) cancer cell/cancer stem cell targeting, resulting in cancer-selective inhibition of Akt and cell proliferation or (b) suitability for intravenous administration that we believe offers the prospect of greater systemic exposure and hence Akt inhibition in cancer cells, which we believe would result in superior efficacy. We plan to submit an IND application to the FDA in the first quarter of 2013, in the event we obtain the additional funding necessary for that purpose.

Prior to the Acquisition, for more than 10 years, Novelos had been developing oxidized glutathione-based compounds for the treatment of cancer, including NOV-002, an injectable small-molecule compound based on a proprietary formulation of oxidized glutathione that Novelos had been developing for use in combination with standard of care chemotherapies for the treatment of solid tumors. From 2005 through 2010 Novelos raised approximately \$67 million in capital for the development of our compounds. From November 2006 through January 2010, Novelos conducted a Phase 3 trial of NOV-002 plus first-line chemotherapy in advanced non-small cell lung cancer which, when completed in February 2010, did not meet its primary and secondary efficacy endpoints. Following the completion of the Phase 3 trial during 2010, Novelos continued clinical development of NOV-002 in breast cancer and NOV-205 in hepatitis C, although further development of those compounds has been suspended. Novelos also explored strategic alternatives which resulted in the completion of the Acquisition in April 2011.

## Results of Operations

**Executive summary.** In March 2010, Collectar completed a Phase 1a dosimetry trial of HOT in humans (the “Phase 1a Trial”), demonstrating initial safety and establishing dosing parameters for a Phase 1b dose-escalation trial. Following the completion of the Phase 1a Trial and as a result of limited funding, Collectar suspended research and manufacturing activities, terminated certain non-key personnel and implemented salary reductions in an effort to contain costs while Collectar concentrated on its fundraising efforts. The increases in research and development costs for the year ended December 31, 2011 compared to the year ended December 31, 2010 are primarily attributable to the cost reduction efforts implemented in mid-2010 as well as the increases associated with the recommencement of research activities following the Acquisition. Following the Acquisition, we have resumed development activities including the commencement of clinical trials in HOT and LIGHT.

**Research and development expense.** Research and development expense consists of costs incurred in identifying, developing and testing, and manufacturing product candidates, which primarily include salaries and related expenses for personnel, costs of our research and manufacturing facility, cost of manufacturing materials, fees paid to professional service providers for independent monitoring and analysis of our clinical trials, and costs to secure intellectual property. The Company analyzes its research and development expenses based on four categories as follows: clinical projects, preclinical projects, chemistry and manufacturing costs, and general fixed and overhead costs that are not allocated to the functional project costs, including personnel costs, manufacturing facility costs, related overhead costs and patent costs.

**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 insurance, costs for public and investor relations, directors’ fees and professional fees for legal and accounting services.

### *Twelve Months Ended December 31, 2011 and 2010*

**Research and Development.** Research and development expense for the year ended December 31, 2011 was approximately \$3,599,000 (comprised of approximately \$166,000 in clinical project costs, \$207,000 of preclinical project costs, \$205,000 of manufacturing and related costs and \$3,021,000 in general unallocated research and development costs) compared to approximately \$2,984,000 (comprised of \$200,000 in clinical project costs, \$459,000 of preclinical project costs, \$58,000 of manufacturing and related costs and \$2,267,000 in general unallocated research and development costs) for 2010. The approximately \$615,000, or 20.6%, increase in research and development resulted from increases in manufacturing and general unallocated research costs partially offset by decreases in clinical and preclinical costs. The \$34,000 decrease in clinical projects in the year ended December 31, 2011 versus 2010 was related to a \$200,000 decrease in costs related to the completion of the Phase 1a trial in March 2010 partially offset by clinical costs incurred in 2011 related to the Company’s Phase 1b trial for HOT. The \$252,000 decrease in preclinical projects, for the year ended December 31, 2011 versus 2010 was primarily related to a \$210,000 decrease in subcontracted preclinical research as those activities had increased in the first half of 2010 in preparation for future clinical trials. These decreases were offset by an increase of approximately \$754,000 in general unallocated research and development costs primarily due to an approximately \$215,000 increase in salary and related costs as a result of increases in personnel following the Acquisition, an approximately \$165,000 increase in stock-based compensation resulting from stock options granted in May 2011 and December 2011 following the Acquisition, an approximately \$87,000 increase in patent costs as well as increases in subcontracted services, facilities and equipment maintenance costs incurred as we resumed manufacturing and research activities following the Acquisition.

**General and Administrative.** General and administrative expense for the year ended December 31, 2011 was approximately \$2,692,000 compared to approximately \$1,157,000 in 2010. The \$1,535,000, or 132.7%, increase in general and administrative costs were primarily related to the following items: Salary increased approximately \$582,000 resulting from the addition of employees in connection with the Acquisition and the removal of salary reductions that had been in place in order to conserve cash; stock-based compensation increased by \$390,000 associated with stock option grants made in May and December 2011; the cost of subcontracted services increased by approximately \$331,000 as a result of increased investor relations activities, directors’ fees and costs associated with public company reporting. Insurance costs increased approximately \$67,000, rent increased approximately \$49,000 associated with the addition of the Massachusetts location following the Acquisition and travel costs increased approximately \$53,000 due principally to an increase in travel between our Massachusetts and Wisconsin offices.

*Merger Costs.* Merger costs during the year ended December 31, 2011 consisted of \$450,000 in investment banking fees, approximately \$286,000 in legal fees and approximately \$10,000 in insurance costs compared to approximately \$53,000 of merger costs in 2010, primarily related to legal fees.

*Grant income.* Qualifying therapeutic discovery projects, among others, include those designed to treat or prevent diseases or conditions by conducting pre-clinical or clinical activities for the purpose of securing FDA approval of a product. The Company received payments of approximately \$44,000 in the year ended December 31, 2011 compared to \$200,000 for 2010 under a cash grant from the U.S. Internal Revenue Service as a qualifying therapeutic discovery project credit pursuant to Patient Protection and Affordable Care Act. The payments have been recorded as a component of other income.

*Loss on Derivative Warrants.* We recorded a loss on derivative warrants of approximately \$12,000 in the year ended December 31, 2011. This amount represents the change in fair value, during the respective period, of outstanding warrants that contain “down-round” anti-dilution provisions whereby the number of shares for which the warrants are exercisable and/or the exercise price of the warrants is subject to change in the event of certain issuances of stock at prices below the then-effective exercise prices of the warrants.

*Interest expense, net.* Interest expense, net, for the years ended December 31, 2011 and 2010 consists approximately of the following:

	<b>Year Ended December 31,</b>	
	<b>2011</b>	<b>2010</b>
Interest expense, convertible notes	\$ (159,000)	\$ (305,000)
Beneficial conversion feature, convertible notes	(258,000)	(214,000)
Interest expense, bank note	(6,500)	(55,000)
Interest expense, other	(11,000)	(7,000)
Interest income	4,500	15,000
	<u>\$ (430,000)</u>	<u>\$ (566,000)</u>

Since the convertible notes were converted based on revised conversion terms that resulted in the issuance of an additional 343,963 shares of common stock than would have been issued if the convertible notes had been converted in accordance with their original terms, the value of these additional shares of approximately \$258,000 was recorded as a component of interest expense at the date of conversion in 2011. Since the convertible notes were convertible into common stock at the date of issuance at a price per share which is less than the estimated fair value of our common stock at that date, the estimated intrinsic value of the beneficial conversion feature of approximately \$214,000 was recorded as a component of interest expense on the date of issuance in 2010. The decrease in interest expense on the convertible notes and bank note was a result of the settlement of those obligations in connection with the Acquisition. The increase in other interest expense is principally a result of the issuance of notes payable to the Wisconsin Department of Commerce in September 2010. The reduction of interest income was a result of a decrease in average cash balances and interest rates.

## **Liquidity and Capital Resources**

We have financed our operations since inception primarily through the sale of equity securities and securities convertible into equity securities. To date, Collectar and Novelos have raised capital aggregating approximately \$110 million. Novelos has raised capital aggregating approximately \$83 million, including proceeds from the April 2011 private placement and the December 2011 underwritten offering. Since its inception and prior to the Acquisition, Collectar had raised capital aggregating approximately \$27 million. As of December 31, 2011, we had approximately \$5,506,000 in cash and cash equivalents.

During the twelve months ended December 31, 2011, approximately \$5,970,000 in cash was used in operations. During this period we reported a net loss of approximately \$7,435,000. However, this loss included the following non-cash items: an approximately \$12,000 loss on derivative warrants, an approximately \$6,000 loss on the disposal of fixed assets, an approximately \$907,000 in stock-based compensation, an approximately \$585,000 in depreciation and amortization expense and an approximately \$258,000 of interest expense attributed to the estimated intrinsic value of the beneficial conversion feature associated with convertible notes. After adjustment for these non-cash items, we used approximately \$295,000 in cash for the payment of accounts payable and accrued liabilities resulting from the payment of vendor liabilities that had accumulated leading up to the Acquisition and private placement. The Company utilized approximately \$176,000 in cash for the prepayment of certain items, including an annual renewal of its directors' and officers' insurance and general business insurance and payments for legal defense costs which are reimbursable by our insurance carrier. Other changes in working capital provided cash of \$9,000. We incurred \$159,000 of accrued interest associated with notes payable that were converted to common stock on April 8, 2011.

During the twelve months ended December 31, 2011, we purchased approximately \$118,000 in fixed assets. As described above, on April 8, 2011, we completed the Acquisition. In connection with the Acquisition, we acquired cash of approximately \$906,000.

During the twelve months ended December 31, 2011, we repaid \$676,000 in long-term obligations, including the payment, immediately prior to the Acquisition, of approximately \$627,000 in full settlement of a Collectar note payable to a bank. In connection with that repayment, restrictions were released on \$500,000 of cash equivalents. On April 8, 2011, the holders of Collectar convertible notes converted outstanding principal of \$2,720,985 and unpaid interest thereon into a total of 4,181,535 shares of common stock.

Upon the closing of the Acquisition, we completed the private placement of our common stock and warrants for net proceeds of approximately \$4,866,000. In December 2011 we completed an underwritten offering of our common stock and warrants for net proceeds of approximately \$5,298,000.

The accompanying consolidated financial statements have been prepared on a basis that assumes that we will continue as a going concern and that contemplates the continuity of operations, realization of assets and the satisfaction of liabilities and commitments in the normal course of business. We have incurred losses since inception in devoting substantially all of our efforts toward research and development and have an accumulated deficit of \$31,480,426 at December 31, 2011. During the year ended December 31, 2011, we generated a net loss of \$7,435,422 and we expect that we will continue to generate operating losses for the foreseeable future. At December 31, 2011, our cash balance was approximately \$5,506,000. We believe our cash on hand is adequate to fund operations into the middle of the third quarter of 2012. Our ability to execute our operating plan beyond that time depends on our ability to obtain additional funding via the sale of equity and/or debt securities, a strategic transaction or otherwise. We plan to actively pursue financing alternatives; however, we have not entered into negotiations for any such transactions. There can be no assurance that we will obtain the necessary funding. Other than the uncertainties regarding our ability to obtain additional funding, there are currently no known trends, demands, commitments, events or uncertainties that are likely to materially affect our liquidity.

## Critical Accounting Policies and Estimates

The preparation of financial statements and related disclosures in conformity with accounting principles generally accepted in the United States, or GAAP, requires management to make certain estimates, judgments and assumptions that affect the reported amounts of assets and liabilities as of the date of the financial statements, as well as the reported amounts of revenues and expenses during the periods presented. Management bases its estimates and judgments on historical experience, knowledge of current conditions and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. 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 vendors in conjunction with the manufacturing of clinical materials; and professional service fees, such as for lawyers and accountants. In connection with such service fees, our estimates are most affected by our understanding of the status and timing of services provided relative to the actual levels of services incurred by such service providers. The majority of our service providers invoice us monthly in arrears for services performed. In the event that we do not identify certain costs that have begun to be incurred, or we over- or underestimate the level of services performed or the costs of such services, our reported expenses for such period would be too high or too low. The date on which certain services commence, the level of services performed on or before a given date and the cost of such services are often determined based on subjective judgments. We make these judgments based on the facts and circumstances known to us, in accordance with GAAP.

*Goodwill and Other Intangible Assets.* As of December 31, 2011 there was approximately \$1,675,000 of goodwill recorded in connection with the Acquisition. We are required to evaluate goodwill for impairment annually or whenever events or changes in circumstances suggest that the carrying value of an asset may not be recoverable. The Company evaluates goodwill for impairment annually in the fourth fiscal quarter and additionally on an interim basis if an event occurs or circumstances change such as a decline in the Company's stock price, or a material adverse change in the business climate, which would more likely than not reduce the fair value of the reporting unit below its carrying amount.

*Stock-based Compensation.* We account for stock-based compensation by measuring the cost of employee services received in exchange for an award of equity instruments based on the grant-date fair value of the award, using the Black-Scholes option-pricing model. The cost of non-performance based awards 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). For stock options with performance-based vesting provisions, recognition of compensation expense commences if and when the achievement of the performance criteria is deemed probable and is recognized over the relevant performance 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 (using the Black-Scholes option-pricing model) whichever is more reliably measured. The measurement of stock-based compensation for non-employees is subject to periodic adjustments as the options vest, and the expense is recognized over the period during which a non-employee is required to provide services for the award (usually the vesting period).



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

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

The fair value of the outstanding derivative warrants is estimated as of a reporting date. The Company uses valuation methods and assumptions that consider among others the fair value of the underlying stock, risk-free interest rate, volatility, expected life and dividend rates in estimating fair value for the warrants considered to be derivative instruments. We estimate volatility based on an average of our historical volatility and volatility estimates of publicly held drug development companies with similar market capitalizations. If our estimates of the fair value of these derivative warrants are too high or too low, our expenses may be over- or understated.

*Fair value measurements.* We account for certain financial assets at fair value, defined as the price that would be received to sell an asset or pay to transfer a liability (i.e., exit price) in the principal, most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. As such, fair value is a market-based measurement that is determined based on assumptions that market participant would use in pricing a asset or liability. If management made different assumptions or judgments, material differences in measurements of fair value could occur.

*Contingencies.* From time to time, we may become involved in legal disputes regarding our products in development, intellectual property rights, stockholder claims or other matters. We are currently involved in two such matters (see Part I – Item 3 – Legal Proceedings) that are ongoing. We assess each matter to determine if a contingent liability should be recorded. In making this assessment, we may consult, depending on the nature of the matter, with external legal counsel and technical experts. Based on the information we obtain, combined with our judgment regarding all the facts and circumstances of each matter, we determine whether it is probable that a contingent loss may be incurred and whether the amount of such loss can be reasonably estimated. Should a loss be probable and reasonably estimable we record a loss. In determining the amount of the loss, we consider advice received from experts in the specific matter, current status of legal proceedings, if any, prior case history and other factors. Should the judgments and estimates made by us be incorrect, we may need to record additional contingent losses that could materially adversely impact the results of operations and financial conditions.

**Item 7A. Quantitative and Qualitative Disclosures About Market Risk.**

Not applicable.

**Item 8. Financial Statements.**

**FINANCIAL STATEMENTS**

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(a Development Stage Company)**

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## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders  
Novelos Therapeutics, Inc.

We have audited the accompanying consolidated balance sheets of Novelos Therapeutics, Inc. and Subsidiary (a Development Stage Company) (a Delaware corporation) (the "Company") as of December 31, 2011 and 2010, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2011 and the period from November 7, 2002 (date of inception) through December 31, 2011. 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 audit 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 consolidated financial statements referred to above present fairly, in all material respects, the financial position of Novelos Therapeutics, Inc. and Subsidiary, as of December 31, 2011 and 2010, and the results of their operations and their cash flows for each of the two years in the period ended December 31, 2011 and the period from November 7, 2002 (date of inception) through December 31, 2011, in conformity with accounting principles generally accepted in the United States of America.

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 losses since its inception and, as of December 31, 2011, had an accumulated deficit of \$31,480,426. These conditions, along with other matters as set forth in Note 1, raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ Grant Thornton LLP

Boston, Massachusetts  
March 9, 2012

**NOVELOS THERAPEUTICS, INC.**  
**(a Development Stage Company)**  
**CONSOLIDATED BALANCE SHEETS**

	<u>December 31,</u> <u>2011</u>	<u>December 31,</u> <u>2010</u>
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 5,505,960	\$ 673,739
Restricted cash	55,000	555,000
Prepaid expenses and other current assets	254,967	51,042
Total current assets	5,815,927	1,279,781
<b>FIXED ASSETS, NET</b>	<b>3,044,565</b>	<b>3,510,489</b>
<b>GOODWILL</b>	<b>1,675,462</b>	<b>—</b>
<b>OTHER ASSETS</b>	<b>27,222</b>	<b>11,872</b>
<b>TOTAL ASSETS</b>	<b><u>\$ 10,563,176</u></b>	<b><u>\$ 4,802,142</u></b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable and accrued liabilities	\$ 478,041	\$ 392,881
Accrued interest	—	305,049
Derivative liability	23,305	—
Notes payable, current portion	—	204,802
Capital lease obligations, current portion	2,235	2,085
Total current liabilities	503,581	904,817
<b>LONG-TERM LIABILITIES:</b>		
Convertible debt	—	2,720,985
Notes payable, net of current portion	450,000	920,941
Deferred rent	124,381	115,311
Capital lease obligations, net of current portion	4,091	6,326
Total long-term liabilities	578,472	3,763,563
<b>COMMITMENTS AND CONTINGENCIES (Notes 13 and 14)</b>		
<b>STOCKHOLDERS' EQUITY:</b>		
Preferred stock, \$0.00001 par value; 7,000 shares authorized; none issued and outstanding as of December 31, 2011 and 2010	—	—
Common stock, \$0.00001 par value; 150,000,000 shares authorized; 36,907,824 and 12,820,102 shares issued and outstanding at December 31, 2011 and 2010, respectively	369	128
Additional paid-in capital	40,961,180	24,178,638
Deficit accumulated during the development stage	(31,480,426)	(24,045,004)
Total stockholders' equity	9,481,123	133,762
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<b><u>\$ 10,563,176</u></b>	<b><u>\$ 4,802,142</u></b>

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

**NOVELOS THERAPEUTICS, INC.**  
**(a Development Stage Company)**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**

	<u>Year Ended December, 31</u>		<u>Cumulative</u>
	<u>2011</u>	<u>2010</u>	<u>Development-Stage</u> <u>Period from</u> <u>November 7, 2002</u> <u>(date of inception)</u> <u>through December 31,</u> <u>2011</u>
Research and development	\$ 3,599,080	\$ 2,984,207	\$ 20,805,039
General and administrative	2,692,433	1,156,549	9,662,611
Merger costs	746,207	52,925	799,133
Total costs and expenses	<u>7,037,720</u>	<u>4,193,681</u>	<u>31,266,783</u>
LOSS FROM OPERATIONS	<u>(7,037,720)</u>	<u>(4,193,681)</u>	<u>(31,266,783)</u>
OTHER INCOME (EXPENSE):			
Grant income	44,479	200,000	244,479
Loss on derivative warrants	(12,158)	—	(12,158)
Interest expense, net	(430,023)	(566,156)	(447,125)
Other income (expense)	—	(426)	1,161
Total other expense, net	<u>(397,702)</u>	<u>(366,582)</u>	<u>(213,643)</u>
NET LOSS	<u>\$ (7,435,422)</u>	<u>\$ (4,560,263)</u>	<u>\$ (31,480,426)</u>
BASIC AND DILUTED NET LOSS PER COMMON SHARE	<u>\$ (0.31)</u>	<u>\$ (0.36)</u>	<u>\$ (2.84)</u>
SHARES USED IN COMPUTING BASIC AND DILUTED NET LOSS PER COMMON SHARE	<u>23,959,008</u>	<u>12,820,102</u>	<u>11,090,838</u>

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

**NOVELOS THERAPEUTICS, INC.**  
**(a Development Stage Company)**  
**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY**

	Common Stock		Additional Paid-in Capital	Deficit Accumulated During the Development Stage	Total Stockholders' Equity
	Shares	Par Amount			
	—	\$ —			
BALANCE AT NOVEMBER 7, 2002	—	\$ —	\$ —	\$ —	\$ —
Issuance of common stock for cash	6,440,123	64	590,205	—	590,269
Issuance of common stock in exchange for professional services	101,220	1	9,107	—	9,108
Net loss	—	—	—	—	—
BALANCE AT DECEMBER 31, 2002	6,541,343	65	599,312	—	599,377
Issuance of common stock for cash, net of issuance costs	37,958	—	4,937	—	4,937
Issuance of common stock in exchange for licensed technology	203,483	2	80,410	—	80,412
Net loss	—	—	—	(295,790)	(295,790)
BALANCE AT DECEMBER 31, 2003	6,782,784	67	684,659	(295,790)	388,936
Net loss	—	—	—	(342,761)	(342,761)
BALANCE AT DECEMBER 31, 2004	6,782,784	67	684,659	(638,551)	46,175
Issuance of common stock for cash, net of issuance costs	610,664	6	835,862	—	835,868
Net loss	—	—	—	(481,837)	(481,837)
BALANCE AT DECEMBER 31, 2005	7,393,448	73	1,520,521	(1,120,388)	400,206
Issuance of common stock for cash, net of issuance costs	2,202,179	22	7,097,050	—	7,097,072
Common stock repurchased	(43,819)	—	(31,667)	—	(31,667)
Stock-based compensation	—	—	43,994	—	43,994
Net loss	—	—	—	(963,440)	(963,440)
BALANCE AT DECEMBER 31, 2006	9,551,808	95	8,629,898	(2,083,828)	6,546,165
Issuance of common stock for cash, net of issuance costs	60,250	1	249,999	—	250,000
Exercise of warrant to purchase common stock	75,045	1	249,999	—	250,000
Stock-based compensation	—	—	570,392	—	570,392
Net loss	—	—	—	(5,090,325)	(5,090,325)
BALANCE AT DECEMBER 31, 2007	9,687,103	97	9,700,288	(7,174,153)	2,526,232
Issuance of common stock for cash, net of issuance costs	3,132,999	31	12,931,531	—	12,931,562
Stock-based compensation	—	—	477,488	—	477,488
Net loss	—	—	—	(6,090,715)	(6,090,715)
BALANCE AT DECEMBER 31, 2008	12,820,102	128	23,109,307	(13,264,868)	9,844,567
Stock-based compensation	—	—	502,199	—	502,199
Net loss	—	—	—	(6,219,873)	(6,219,873)
BALANCE AT DECEMBER 31, 2009	12,820,102	128	23,611,506	(19,484,741)	4,126,893
Stock-based compensation	—	—	353,340	—	353,340
Intrinsic value of beneficial conversion feature associated with convertible debt issued in exchange for cash	—	—	213,792	—	213,792
Net loss	—	—	—	(4,560,263)	(4,560,263)
BALANCE AT DECEMBER 31, 2010	12,820,102	128	24,178,638	(24,045,004)	133,762
Issuance of common stock upon conversion of convertible notes	4,181,535	42	3,184,665	—	3,184,707
Issuance of common stock in a business combination	2,959,871	30	2,219,873	—	2,219,903
Cash paid in lieu of fractional shares in a business combination	(41)	—	(145)	—	(145)
Issuance of common stock and warrants, net of issuance costs	16,928,204	169	10,164,377	—	10,164,546
Intrinsic value of beneficial conversion feature associated with the conversion of convertible debt	—	—	257,973	—	257,973
Issuance of common stock upon the cashless exercise of warrants and reclassification of derivative liability to additional paid-in-capital	18,153	—	48,339	—	48,339
Stock-based compensation	—	—	907,460	—	907,460
Net loss	—	—	—	(7,435,422)	(7,435,422)

BALANCE AT DECEMBER 31, 2011                      36,907,824    \$ 369    \$ 40,961,180    \$ (31,480,426)    \$ 9,481,123

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

**NOVELOS THERAPEUTICS, INC.**  
**(a Development Stage Company)**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**

	Year Ended December 31,		Cumulative Development-Stage Period from November 7, 2002 through December 31,
	2011	2010	2011
Net loss	\$ (7,435,422)	\$ (4,560,263)	\$ (31,480,426)
Adjustments to reconcile net loss to cash used in operating activities:			
Depreciation and amortization	584,841	580,114	2,416,038
Stock-based compensation	907,460	353,340	2,854,873
Intrinsic value of beneficial conversion feature associated with convertible debt	257,973	213,792	471,765
Issuance of stock for technology and services	—	—	89,520
Impairment of intangible assets	—	19,671	19,671
Loss on disposal of fixed assets	6,009	—	36,477
Loss on derivative warrants	12,158	—	12,158
Changes in:			
Prepaid expenses and other current assets	(175,883)	18,584	(238,797)
Accounts payable and accrued liabilities	(294,969)	(322,707)	97,912
Accrued interest	158,673	305,049	463,722
Deferred rent	9,070	9,973	124,381
Cash used in operating activities	<u>(5,970,090)</u>	<u>(3,382,447)</u>	<u>(25,132,706)</u>
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>			
Cash acquired in a business combination	905,649	—	905,649
Purchases of fixed assets	(118,411)	(1,652)	(5,486,592)
Proceeds from sale of fixed assets	—	—	7,000
Purchases of short-term certificates of deposit	—	—	(5,500,730)
Proceeds from short-term certificates of deposit	—	—	5,500,730
Change in restricted cash	500,000	—	(55,000)
Payment for intangible assets	—	—	(19,671)
Cash provided by (used) in investing activities	<u>1,287,238</u>	<u>(1,652)</u>	<u>(4,648,614)</u>
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>			
Proceeds from issuance of convertible notes	—	2,720,985	2,720,985
Proceeds from long-term obligations	—	450,000	1,677,945
Payments on long-term obligations	(675,743)	(190,789)	(1,227,944)
Payments on capital lease obligations	(2,085)	(1,944)	(4,648)
Proceeds from issuance of common stock and warrants, net of issuance costs	10,164,546	—	31,874,254
Proceeds from exercise of warrant	—	—	250,000
Repurchase of common stock	—	—	(31,667)
Cash in lieu of fractional shares in a business combination	(145)	—	(145)
Change in deferred issuance costs	28,500	99,461	28,500
Cash provided by financing activities	<u>9,515,073</u>	<u>3,077,713</u>	<u>35,287,280</u>
<b>INCREASE (DECREASE) IN CASH AND EQUIVALENTS</b>	<b>4,832,221</b>	<b>(306,386)</b>	<b>5,505,960</b>
<b>CASH AND EQUIVALENTS AT BEGINNING OF PERIOD</b>	<b>673,739</b>	<b>980,125</b>	<b>—</b>
<b>CASH AND EQUIVALENTS AT END OF PERIOD</b>	<b><u>\$ 5,505,960</u></b>	<b><u>\$ 673,739</u></b>	<b><u>\$ 5,505,960</u></b>
<b>SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION</b>			
Interest paid	<u>\$ 13,716</u>	<u>\$ 54,454</u>	<u>\$ 208,689</u>
Fair value of derivative warrants reclassified to additional paid-in capital upon cashless exercise	<u>\$ 48,339</u>	<u>\$ —</u>	<u>\$ 48,339</u>
Issuance of common stock in connection with the conversion of notes payable and accrued interest	<u>\$ 3,184,707</u>	<u>\$ —</u>	<u>\$ 3,184,707</u>
Fair value of assets acquired in exchange for securities in a business combination	<u>\$ 78,407</u>	<u>\$ —</u>	<u>\$ 78,407</u>
Fair value of liabilities assumed in exchange for securities in a business combination	<u>\$ (439,615)</u>	<u>\$ —</u>	<u>\$ (439,615)</u>
Goodwill resulting from a business combination	<u>\$ 1,675,462</u>	<u>\$ —</u>	<u>\$ 1,675,462</u>

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



**NOVELOS THERAPEUTICS, INC.**  
**(a Development Stage Company)**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

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

Novelos Therapeutics, Inc. (“Novelos” or the “Company”) is a pharmaceutical company developing compounds for the treatment of cancer. On April 8, 2011, Novelos completed a business combination with Cellectar, Inc. (“Cellectar”), a privately held Wisconsin corporation that designed and developed products to detect, treat and monitor a wide variety of human cancers, and Cell Acquisition Corp. (the “Merger Subsidiary”), a Wisconsin corporation and a wholly owned subsidiary of Novelos. Pursuant to the transaction Cellectar was merged into the Merger Subsidiary (the “Acquisition”, see Note 4). References in these financial statements and notes to “Cellectar” relate to the activities and financial information of Cellectar prior to the Acquisition, references to “Novelos” relate to the activities and financial information of Novelos prior to the Acquisition and references to “the Company” or “we” or “us” or “our” relate to the activities and obligations of the combined Company following the Acquisition.

Immediately prior to the Acquisition, Novelos completed a 1-for-153 reverse split of its common stock. Novelos then issued to the shareholders of Cellectar at that date 17,001,596 shares of its common stock as consideration for the Acquisition, representing a ratio of 0.8435 shares of Novelos common stock in exchange for one share of Cellectar common stock (the “Exchange Ratio”) as set forth in the Agreement and Plan of Merger (the “Merger Agreement”) dated April 8, 2011. The shares issued to Cellectar shareholders in the Acquisition constituted approximately 85% of Novelos’ outstanding common stock after giving effect to the Acquisition. Upon the closing of the Acquisition, the Company completed the private placement of 6,846,537 shares of its common stock and warrants to purchase an additional 6,846,537 shares of its common stock for gross proceeds of approximately \$5,135,000.

Accounting principles generally accepted in the United States require that a company whose security holders retain the majority voting interest in the combined business be treated as the acquirer for financial reporting purposes. Accordingly, the Acquisition was accounted for as a reverse acquisition whereby Cellectar, Inc. was treated as the acquirer for accounting and financial reporting purposes. The financial statements presented herein as of and for the twelve months ended December 31, 2010 represent the historical financial information of Cellectar, except for the capital structure which represents the historical amounts of Cellectar, retroactively adjusted to reflect the legal capital structure of Novelos by applying the Exchange Ratio. On April 8, 2011, Cellectar was merged into the Merger Subsidiary a wholly owned subsidiary of Novelos; as such, the financial statements presented herein as of and for the twelve months ended December 31, 2011 include the historical results of Cellectar from January 1, 2011 through April 8, 2011, except for the capital structure which represents the historical amounts of Cellectar, retroactively adjusted to reflect the legal capital structure of Novelos by applying the Exchange Ratio, and include the consolidated results of the combined company from April 9, 2011 through December 31, 2011. All per-share amounts and outstanding shares, including all common stock equivalents, and stock options, have been retroactively restated in these financial statements and notes for all periods presented to reflect the capital structure of Novelos by applying the Exchange Ratio. The cumulative capital activity from the date of inception (November 7, 2002) up to the closing of the Acquisition, as presented in the accompanying statement of stockholders’ equity, equals 17,001,596 shares of common stock, which represents the equity interests the legal parent (Novelos) issued to effect the Acquisition. The number of authorized shares of common stock disclosed on the balance sheet (150,000,000) represents the number of authorized shares of Novelos common stock following the Acquisition. Additionally, on the accompanying balance sheet as of December 31, 2010 and statements of stockholders’ equity for the period from inception (November 7, 2002) to December 31, 2010 the aggregate par value of the issued common stock was reduced to reflect the \$0.00001 par value of Novelos common stock associated with the shares of Cellectar common stock adjusted for the Exchange Ratio and the difference was reclassified to additional paid-in capital.

As a result of the Acquisition, the Company has implemented a revised business plan focused on the development of the Cellectar compounds. Development of Novelos’ other compounds (NOV-002 and NOV-205) has been suspended. The Company is conducting its operations from Cellectar’s headquarters in Madison, Wisconsin and the Company’s executive offices are in Newton, Massachusetts.

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

The accompanying financial statements have been prepared on a basis that assumes that the Company will continue as a going concern and that contemplates the continuity of operations, realization of assets and the satisfaction of liabilities and commitments in the normal course of business. The Company has incurred losses since inception in devoting substantially all of its efforts toward research and development and has an accumulated deficit of \$31,480,426 at December 31, 2011. During the year ended December 31, 2011, the Company generated a net loss of \$7,435,422 and the Company expects that it will continue to generate operating losses for the foreseeable future. The Company believes that its cash on hand is adequate to fund operations into the middle of the third quarter of 2012. The Company's ability to execute its operating plan beyond that time depends on its ability to obtain additional funding via the sale of equity and/or debt securities, a strategic transaction or otherwise. The Company plans to continue to actively pursue financing alternatives, but there can be no assurance that it will obtain the necessary funding. The accompanying financial statements do not include any adjustments that might result from the outcome of this uncertainty.

## **2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

The accompanying consolidated financial statements reflect the application of certain accounting policies, as described in this note and elsewhere in the accompanying notes to the consolidated financial statements. The consolidated financial statements as of and for the twelve months ended December 31, 2011 are presented on a consolidated basis to reflect the Acquisition described in Note 4.

**Principles of Consolidation** — The consolidated financial statements include the accounts of the Company and the accounts of its wholly-owned subsidiary. All intercompany accounts and transactions have been eliminated in consolidation.

**Development Stage Company** — The Company has been in the development stage since its inception. The primary activities since inception have been organizational activities, research and development and raising capital. No significant revenues have been generated from planned operations. As of December 31, 2011 and 2010, the Company remained in the development stage.

**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 judgments that may affect the reported amounts of assets, liabilities, revenue and expenses and disclosure of contingent assets and liabilities. On an on-going basis, management evaluates its estimates including those related to unbilled vendor amounts and share-based compensation. Management bases its estimates on historical experience and on various other assumptions that are believed to be reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results may differ from those estimates under different assumptions or conditions. Changes in estimates are reflected in reported results in the period in which they become known.

**Cash and Cash Equivalents** — All short-term investments purchased with maturities of three months or less are considered to be cash equivalents.

**Restricted Cash** — Restricted cash at December 31, 2011 consists of a certificate of deposit required under the Company's lease agreement for its Madison, Wisconsin facility (see Note 13). Restricted cash at December 31, 2010 consists of a certificate of deposit required for collateral for a promissory note with a bank (see Note 8) and a certificate of deposit required under the Company's lease agreement for its Madison, Wisconsin facility (see Note 13).

**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 (5 years). Due to the significant value of leasehold improvements purchased during the initial 3-year lease term and the economic penalty for not extending the building lease, leasehold improvements are depreciated over 17 years (their estimated useful life), which represents the full term of the lease, including all extensions (Note 13).

**Goodwill** — Intangible assets at December 31, 2011 consist of goodwill recorded in connection with the Acquisition. Goodwill is not amortized, but is required to be evaluated for impairment annually or whenever events or changes in circumstances suggest that the carrying value of an asset may not be recoverable. The Company evaluates goodwill for impairment annually in the fourth fiscal quarter and additionally on an interim basis if an event occurs or there is a change in circumstances, such as a decline in the Company's stock price or a material adverse change in the business climate, which would more likely than not reduce the fair value of the reporting unit below its carrying amount.

**Impairment of Long-Lived Assets** — Long-lived assets other than intangible assets consist of fixed assets, which we periodically evaluate for potential impairment. Whenever events or circumstances change, an assessment is made as to 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. During 2010, following a reduction in staff and suspension of research and manufacturing activities in order to reduce operating costs, it was determined that the trademarks previously capitalized as intangible assets had been impaired and the carrying value was reduced to zero.

**Stock-Based Compensation** — The Company uses the Black-Scholes option-pricing model to calculate the grant-date fair value of stock option awards. The resulting compensation expense, net of expected forfeitures, for awards that are not performance-based is recognized on a straight-line basis over the service period of the award, which is generally three years for stock options. For stock options with performance-based vesting provisions, recognition of compensation expense, net of expected forfeitures, commences if and when the achievement of the performance criteria is deemed probable. The compensation expense, net of expected forfeitures, for performance-based stock options is recognized over the relevant performance period. Non-employee stock-based compensation is accounted for in accordance with the guidance of FASB ASC Topic 505, *Equity*. As such, the Company recognizes 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 and deemed completed by such non-employees.

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

**Income Taxes** — Income taxes are accounted for using the liability method of accounting. Under this method, deferred tax assets and liabilities are determined based on temporary differences between the financial statement basis 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. Management has provided a full valuation allowance against the Company's gross deferred tax asset. Tax positions taken or expected to be taken in the course of preparing tax returns are required to be evaluated to determine whether the tax positions are "more likely than not" to be sustained by the applicable tax authority. Tax positions deemed not to meet a more-likely-than-not threshold would be recorded as tax expense in the current year. There were no uncertain tax positions that require accrual to or disclosure in the financial statements as of December 31, 2011 and 2010.

**Comprehensive Loss** — There were no components of comprehensive loss other than net loss in all of the periods presented.

**Grant Income** — Cellectar received a cash grant of approximately \$44,000 and \$200,000 for the years ended December 31, 2011 and 2010, respectively, from the U.S. Internal Revenue Service as a qualifying therapeutic discovery project credit pursuant to the Patient Protection and Affordable Care Act. This grant has been recorded as a component of other income.

**Fair Value of Financial Instruments** — The guidance under FASB ASC Topic 825, *Financial Instruments*, requires disclosure of the fair value of certain financial instruments. Financial instruments in the accompanying financial statements consist of cash equivalents, accounts payable, convertible debt and long-term obligations. The carrying amount of cash equivalents, investments and accounts payable approximate their fair value due to their short-term nature. The estimated fair value of the convertible debt, determined on an as-converted basis including conversion of accumulated unpaid interest, was approximately \$0 and \$3,264,000 at December 31, 2011 and 2010, respectively. The carrying value of long-term obligations, including the current portion, approximates fair value because the fixed interest rate approximates current market rates of interest available in the market.

**Derivative Instruments** — The Company generally does not use derivative instruments to hedge exposures to cash flow or market risks. However, certain warrants to purchase common stock that do not meet the requirements for classification as equity, in accordance with the Derivatives and Hedging Topic of the Financial Accounting Standards Board Accounting Standards Codification (“FASB ASC”), are classified as liabilities. In such instances, net-cash settlement is assumed for financial reporting purposes, even when the terms of the underlying contracts do not provide for a net-cash settlement. These warrants are considered derivative instruments because the agreements contain “down-round” provisions whereby the number of shares for which the warrants are exercisable and/or the exercise price of the warrants are subject to change in the event of certain issuances of stock at prices below the then-effective exercise price of the warrants. The number of shares issuable under such warrants was 77,729 at December 31, 2011. The primary underlying risk exposure pertaining to the warrants is the change in fair value of the underlying common stock. Such financial instruments are initially recorded at fair value with subsequent changes in fair value recorded as a component of gain or loss on derivatives on the consolidated statements of operations in each reporting period. If these instruments subsequently meet the requirements for equity classification, the Company reclassifies the fair value to equity. At December 31, 2011, these warrants represented the only outstanding derivative instruments issued or held by the Company. There were no outstanding derivative instruments at December 31, 2010.

**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 as of December 31, 2011 is on deposit in a non-interest-bearing transaction account that is fully covered by FDIC deposit insurance.

**New Accounting Pronouncements** — In January 2010, the FASB issued ASU No. 2010-06, *Improving Disclosures about Fair Value Measurements*, which requires additional disclosures about the amounts of and reasons for significant transfers in and out of Level 1 and Level 2 fair value measurements. This standard also clarifies existing disclosure requirements related to the level of disaggregation of fair value measurements for each class of assets and liabilities and disclosures about inputs and valuation techniques used to measure fair value for both recurring and non-recurring Level 2 and Level 3 measurements. Since this new accounting standard only required additional disclosure, the adoption of the standard in the first quarter of 2010 did not impact the accompanying financial statements. Additionally, effective for interim and annual periods beginning after December 15, 2010, this standard will require additional disclosure and require an entity to present disaggregated information about activity in Level 3 fair value measurements on a gross basis, rather than one net amount. The adoption of this accounting standard did not impact the accompanying financial statements.

In December 2010, the FASB issued ASU No. 2010-29, *Disclosures of Supplementary Pro Forma Information for Business Combinations*, which, if comparative financial statements are presented, requires the supplemental pro forma disclosure of revenue and earnings to be presented as if the business combination had occurred at the beginning of the comparable prior annual reporting period only. This standard also expands the supplemental pro forma disclosures required under FASB ASC Topic 850, *Business Combinations*, to include a description of the nature and amount of material nonrecurring pro forma adjustments directly attributable to the business combination in the reported pro forma revenue and earnings. This standard is effective for the Company for any business combinations completed after January 1, 2011. The Company adopted the provisions of this standard during the first quarter of 2011.

In May 2011, the FASB issued ASU No. 2011-04, *Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. Generally Accepted Accounting Principles ("GAAP") and International Financial Reporting Standards ("IFRSs")*. This standard updates accounting guidance to clarify the measurement of fair value to align the guidance and improve the comparability surrounding fair value measurement within GAAP and IFRSs. The standard also updates requirements for measuring fair value and expands the required disclosures. The standard does not require additional fair value measurements and was not intended to establish valuation standards or affect valuation practices outside of financial reporting. This standard will become effective for the Company on January 1, 2012. The Company does not expect that the adoption of this standard will have a material impact when applied prospectively on the Company's financial statements or required disclosures.

In June 2011, the FASB issued ASU No. 2011-05, *Presentation of Comprehensive Income*. This standard eliminates the current option to report other comprehensive income and its components in the statement of changes in equity. The standard is intended to enhance comparability between entities that report under US GAAP and those that report under IFRS, and to provide a more consistent method of presenting non-owner transactions that affect an entity's equity. Under the ASU, an entity can elect to present items of net income and other comprehensive income in one continuous statement, referred to as the statement of comprehensive income, or in two separate, but consecutive, statements. Each component of net income and each component of other comprehensive income, together with totals for comprehensive income and its two parts, net income and other comprehensive income, would need to be displayed under either alternative. The statement(s) would need to be presented with equal prominence as the other primary financial statements. The ASU does not change items that constitute net income and other comprehensive income, when an item of other comprehensive income must be reclassified to net income or the earnings-per-share computation (which will continue to be based on net income). The new US GAAP requirements are effective for public entities as of the beginning of a fiscal year that begins after December 15, 2011 and interim and annual periods thereafter. Early adoption is permitted, but full retrospective application is required under the accounting standard. The Company does not expect that the adoption of this standard will have a material impact on our results of operations, cash flows, and financial position.

In September 2011, the FASB issued ASU No. 2011-08, *Intangibles – Goodwill and Other (Topic 350) Testing Goodwill for Impairment*. This standard simplifies how an entity tests goodwill for impairment and allows an entity to first assess qualitative factors in determining whether it is more likely than not that the fair value of a reporting unit is less than its carrying amount as a basis for determining whether it is necessary to perform the two-step goodwill impairment test. This standard is effective for entities as of the beginning of a fiscal year that begins after December 15, 2011 and interim and annual periods thereafter. Early adoption is permitted. The Company does not expect that the adoption of this standard will have a material impact on the Company's financial statements or required disclosures.

In December 2011, the FASB issued ASU No. 2011-12, *Deferral of Effective Date for Amendments to the Presentation of Reclassifications of Items Out of Accumulated Other Comprehensive Income in ASU 2011-05*, which defers the requirement in ASU No. 2011-05 that companies present reclassification adjustments for each component of accumulated other comprehensive income. All other requirements of ASU No. 2011-05 remain unchanged.

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

### 3. FAIR VALUE

In accordance with Fair Value Measurements and Disclosures Topic of the FASB ASC 820, the Company groups its financial assets and financial liabilities generally measured at fair value in three levels, based on the markets in which the assets and liabilities are traded and the reliability of the assumptions used to determine fair value.

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

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

	December 31, 2011			Fair Value
	Level 1	Level 2	Level 3	
<b>Liabilities:</b>				
Warrants	\$ -	\$ 23,305	\$ -	\$ 23,305

  

	December 31, 2010			Fair Value
	Level 1	Level 2	Level 3	
<b>Liabilities:</b>				
Warrants	\$ -	\$ -	\$ -	\$ -

The Company uses the Black-Scholes option pricing model and assumptions that consider, among other variables, the fair value of the underlying stock, risk-free interest rate, volatility, expected life and dividend rates in estimating fair value for the warrants considered to be derivative instruments. Assumptions used are generally consistent with those disclosed for stock-based compensation (see Note 10).

#### 4. ACQUISITION

##### *Merger Agreement*

On April 8, 2011, Novelos acquired Collectar through a merger with and into the Merger Subsidiary, pursuant to the Merger Agreement entered into on that date. As a result of the Acquisition, the Merger Subsidiary, which was renamed Collectar, Inc., owns all assets of and operates the business previously owned and operated by Collectar.

In the Acquisition, the former stockholders of Collectar received an aggregate number of shares of Novelos common stock constituting approximately 85% of the outstanding shares of Novelos common stock, after giving effect to the Acquisition but before giving effect to the concurrent private placement of Novelos securities described below. Prior to the Acquisition, Novelos amended and restated its certificate of incorporation and in connection therewith, among other things, effected a 1-for-153 reverse split of its common stock resulting in 2,959,871 shares of Novelos common stock outstanding. Novelos then issued 17,001,596 shares of Novelos common stock to the stockholders of Collectar upon the effective date of the Acquisition. Warrants and options to purchase Novelos common stock that were outstanding prior to the Acquisition remained outstanding following the Acquisition. These consist of warrants to purchase a total of 315,164 shares of Novelos common stock with prices ranging from \$16.07 to \$191.25 and options to purchase a total of 49,159 shares of Novelos common stock with prices ranging from \$1.53 to \$1,072.53.

XMS Capital Partners, the financial advisor to Collectar in connection with the Acquisition, received a cash fee of \$200,000 upon the completion of the Acquisition in consideration of their services. Rodman & Renshaw, LLC ("Rodman"), financial advisor to Novelos in connection with the Acquisition, received a cash fee of \$250,000 upon the completion of the Acquisition in consideration of their services. These amounts were recorded as merger costs and expensed as incurred on the date of the Acquisition. In addition to the investment banking fees, the Company also incurred an additional \$296,207 of merger-related legal and other costs during the year ended December 31, 2011 and \$52,925 during the year ended December 31, 2010 which were included as a component of expense in the respective period.

The Acquisition was completed principally to leverage synergies between Novelos' strategic focus and experience in developing and funding the development of cancer drugs and Collectar's portfolio of cancer-targeted compounds.

### **Purchase Accounting**

The Acquisition was accounted for using the purchase method of accounting as a reverse acquisition. In a reverse acquisition, the post-acquisition net assets of the surviving combined company includes the historical cost basis of the net assets of the accounting acquirer (Cellestar) plus the fair value of the net assets of the accounting acquiree (Novelos). Further, under the purchase method, the purchase price is allocated to the assets acquired and liabilities assumed based on their estimated fair values and the excess of the purchase price over the estimated fair value of the identifiable net assets is allocated to any intangible assets with the remaining excess purchase price over net assets acquired allocated to goodwill.

The fair value of the consideration transferred in the Acquisition was \$2,219,903 and was calculated as the number of shares of common stock that Cellestar would have had to issue (adjusted for the Exchange Ratio) in order for Novelos shareholders to hold a 15% equity interest in the combined Company post-acquisition (but prior to the concurrent private placement), multiplied by the estimated fair value of the Company's common stock on the acquisition date. The estimated fair value of the Company's common stock was based on the offering price of the common stock sold in the private placement which was both completed concurrently with and conditioned upon the closing of the Acquisition. This price was determined to be the best indication of fair value on that date since the price was based on an arm's length negotiation with a group consisting of both new and existing investors that had been advised of the pending Acquisition and assumed similar liquidity risk as those investors holding the majority of shares being valued as purchase consideration.

The following table summarizes the Company's determination of fair values of the assets acquired and the liabilities as of the date of acquisition.

Consideration - issuance of securities	<u>\$ 2,219,903</u>
Prepaid expenses and other assets	\$ 71,892
Fixed assets	6,515
Accrued liabilities	(380,130)
Derivative liability	(59,485)
Goodwill	<u>1,675,462</u>
Total purchase price – net of cash acquired of \$905,649	<u>\$ 1,314,254</u>

The Company determined that the acquired technology had no value as of the date of the acquisition.

### **Goodwill**

Of the total purchase price of \$2,219,903, \$1,675,462 was allocated to goodwill. Goodwill represents the excess of the purchase price of an acquired business over the fair value of the underlying net tangible and intangible assets. The goodwill includes the value of the Novelos work force. None of the goodwill associated with the Acquisition is deductible for income tax purposes.

There were no changes in goodwill during the year ended December 31, 2011, after the initial purchase accounting.

The Company is required to perform an annual impairment test related to goodwill which is performed in the fourth quarter of each year, or sooner if changes in circumstances suggest that the carrying value of an asset may not be recoverable. During the fourth quarter of 2011, the annual test was performed and it was determined that there had been no impairment to goodwill.

## 5. FIXED ASSETS

Fixed assets consisted of the following at December 31:

	<u>2011</u>	<u>2010</u>
Office and laboratory equipment	\$ 3,069,889	\$ 2,984,375
Computer software	4,000	—
Leasehold improvements	<u>2,324,672</u>	<u>2,317,597</u>
Total fixed assets	5,398,561	5,301,972
Less accumulated depreciation and amortization	<u>(2,353,996)</u>	<u>(1,791,483)</u>
Fixed assets, net	<u>\$ 3,044,565</u>	<u>\$ 3,510,489</u>

For the years ended December 31, 2011 and 2010, the Company incurred approximately \$585,000 and \$580,000 of depreciation expense, respectively.

## 6. LICENSE AGREEMENTS

### *2003 License Agreement with the University of Michigan*

In September 2003, Collectar entered into an exclusive license agreement (the “U. Mich. Agreement”) with the Regents of the University of Michigan, (“U. Mich.”) for the development, manufacture and marketing of products under several composition-of-matter patents in North America that expire at varying dates in 2016. The U. Mich. Agreement expires upon the expiration of the last covered patent. The Company is responsible for an annual license fee of \$10,000 and is required to pay costs associated with the maintenance of the patents covered by the U. Mich. Agreement. Additionally, the Company is required to make milestone payments of \$50,000 upon the filing of a New Drug Application (“NDA”) for a licensed product intended for use in a therapeutic or diagnostic application (such milestone fees may be deferred and paid within 12 months of the first commercial sale of such products) and make certain milestone payments within a year following the first commercial sale of any licensed products. The sales milestones range from \$100,000 to \$200,000, dependent upon whether the drug is for use in a diagnostic or therapeutic application, provided that if sales in the first 12 months are less than the amount of the milestone, then we are required to pay 50% of all sales until the milestone is satisfied. The milestone payments may total up to \$400,000. The U. Mich. Agreement provides that the Company pay a royalty equal to 3% of net sales of any licensed products sold by the Company or its sublicensees for such licensed products, provided however if the sublicense fee payable to the Company is between 4% and 5% of net sales, then the royalties payable to U. Mich. shall be equal to 50% of the sublicense fee. Furthermore, the U. Mich. Agreement provides for a reduction in the royalties owed by up to 50% if the Company is required to pay royalties to any third parties related to the sale of the licensed products. If the Company receives any revenue in consideration of rights to the licensed technology that is not based on net sales, excluding any funded research and development, the Company is required to pay U. Mich. 10% of amounts received. U. Mich. may terminate the agreement if the Company ceases operations, if the Company fails to make any required payment under the agreement, or if the Company otherwise materially breaches the agreement, subject to the applicable notice and cure periods. To date, the Company has made all payments as they have become due, there have been no defaults under the U. Mich. Agreement, nor has the Company been notified of a default by U. Mich. The Company may terminate the agreement with six months’ notice to U. Mich. and the return of licensed product and related data. The U. Mich. Agreement contained milestones that required certain development activities to be completed by specified dates. All such development milestones have either been completed or have been removed by subsequent amendment to the agreement. U. Mich. has provided no warranties as to validity or otherwise with respect to the licensed technology.

The Company paid approximately \$600 and \$300 to U. Mich. for the reimbursement of patent maintenance fees during the years ended December 31, 2011 and 2010, respectively. As of December 31, 2011 and 2010, all annual license fees have been paid in a timely manner.



In connection with the U. Mich. Agreement, during 2003 Collectar paid approximately \$54,000 of back patent costs and issued 203,483 shares of common stock to U. Michigan as partial consideration for the rights described above. The estimated fair-market value of the issuance was \$80,412 and was recorded as a license cost and is included as a component of stockholders equity in the accompanying balance sheets.

#### ***License Agreement with Wisconsin Alumni Research Foundation***

In January 2006, Collectar entered into a license agreement (the "WARF Agreement") with the Wisconsin Alumni Research Foundation ("WARF") under which Collectar received a license, with a right to grant sublicenses, to develop, manufacture, and market products with respect to certain patents. The WARF Agreement required an initial license fee of \$8,800 and provided that Collectar pay royalties equal to 0.3% of sales of any licensed products. Collectar was also required to reimburse WARF for patent filing fees and related costs. During the year ended December 31, 2010 there were no costs related to the patents under the WARF Agreement. During 2010, the WARF Agreement was terminated.

#### ***Novelos License Agreements***

During 2007, Novelos entered into a Collaboration Agreement with Lee's Pharmaceutical (HK) Ltd. ("Lee's Pharm") whereby Lee's Pharm obtained an exclusive license to develop, manufacture and commercialize NOV-002 and NOV-205 in China, Hong Kong, Taiwan and Macau (the "Chinese Territory"). Under the terms of the agreement the Company is entitled to receive up to \$1,700,000 in future milestone payments upon the completion of development and marketing milestones by Lee's Pharm and to receive royalty payments of between 12-25% of net sales of NOV-205 and NOV-002, as applicable, in the Chinese Territory and receive royalty payments of 12-15% of net sales of NOV-205 in the Chinese Territory. 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.

During 2009, Novelos entered into a collaboration agreement (the "Collaboration Agreement") with Mundipharma International Corporation Limited ("Mundipharma") to develop, manufacture and commercialize, on an exclusive basis, Licensed Products (as defined in the Collaboration Agreement), including NOV-002, in Europe (other than the Russian Territory), Asia (other than the Chinese Territory) and Australia (collectively referred to as the "Mundipharma Territory"). Mundipharma is an independent associated company of Purdue Pharma, L.P. ("Purdue"). The Collaboration Agreement provides for Mundipharma to pay the Company royalties and fixed milestone payments based on sales and commercial launches in the licensed territories. For countries in which patents are held, the Collaboration Agreement expires on a country-by-country basis within the Mundipharma Territory on the earlier of (1) expiration of the last applicable Novelos patent within the country or (2) the determination that any patents within the country are invalid, obvious or otherwise unenforceable. For countries in which no patents are held, the Collaboration Agreement expires the earlier of 15 years from its effective date or upon generic product competition in the country resulting in a 20% drop in Mundipharma's market share. The Company 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.

The Company has suspended development of the products covered by the collaboration agreements described above. The Company does not anticipate that the collaboration agreements will have a material effect on its future results of operations, cash flows, and financial position.

## 7. CONVERTIBLE DEBT

On January 25, 2010, Collectar issued nine convertible promissory notes (“Convertible Notes”) in an aggregate principal amount of \$2,720,985. The Convertible Notes provided for interest of 12% compounded annually with a maturity date of the earlier of (i) the date on which Collectar’s cash reserves fall below \$250,000 or (ii) January 20, 2011. Upon an event of default, as defined, the interest rate increased by 10% to 22%. The outstanding principal balance, together with any unpaid interest, was convertible immediately, by the lenders, into common stock of the Company at \$0.82987 per share (giving effect to the Exchange Ratio). Furthermore, the Convertible Notes were subject to an automatic conversion feature equal to 70% of the per share price of a qualified financing, should the Company complete a qualified financing transaction which raises at least \$20,000,000 in proceeds to the Company. Since the Convertible Notes were convertible into common stock at date of issuance at a per share price which was less than the estimated fair value of the Company’s common stock at that date, the Convertible Notes contained a beneficial conversion feature (“BCF”). The estimated intrinsic value of the BCF of \$213,792 was determined as the difference between the conversion price and the estimated fair value of Collectar common stock on the date of issuance, multiplied by the 3,278,786 shares of common stock into which the Convertible Notes were convertible at issuance. This amount was recorded as a component of interest expense on the date of issuance. The estimated per-share fair value of Collectar common stock was determined by management based on a number of factors including an independent valuation, which was determined to be the best indication of the fair value as of the issuance date of the Convertible Notes. Since the conversion price was subject to adjustment in the event of a qualified transaction, as defined, the Convertible Notes also contain a contingent beneficial conversion feature (“CBCF”). This contingency did not materialize; therefore no intrinsic value was allocated to the CBCF. As of December 31, 2011 and 2010, principal of \$0 and \$2,720,985 was outstanding, respectively, on the Convertible Notes.

As of December 31, 2010, the Convertible Notes were classified as a long-term obligation on the accompanying December 31, 2010 balance sheet as a result of the conversion of the short-term obligation through the issuance of equity securities in connection with the Acquisition.

On January 20, 2011, the Convertible Notes matured but remained unpaid. Following the maturity and default of the Convertible Notes, the holders of the Convertible Notes agreed that all of the outstanding Convertible Notes would be automatically converted simultaneous with the completion of an acquisition and financing (the “Conversion Time”), if completed. The amount of shares issued upon such conversion would be dependent on the amount of investment made by the note holders at the Conversion Time and were negotiated based on outstanding principal and projected accrued interest based on an assumed closing date for the acquisition and financing. Since the number of shares to be issued upon conversion could not be determined until the Conversion Time, the Convertible Notes contained a CBCF. On April 1, 2011, Collectar’s Board of Directors voted to accept the note holders consent to convert the Convertible Notes into 4,181,535 shares of common stock immediately prior to the Acquisition. On April 8, 2011, immediately prior to the Acquisition, the principal and unpaid interest on the Convertible Notes was converted into the agreed total of 4,181,535 shares of common stock. Upon conversion of the Convertible Notes, the Company reclassified the aggregate outstanding principal and interest totaling \$3,184,707 to a component of additional paid-in capital. The revised conversion terms resulted in the issuance of an additional 343,963 shares of common stock over the 3,837,572 shares of common stock that would have been issued if the unpaid principal and accrued interest on the Convertible Notes had been converted on that date in accordance with their original terms at the stated conversion price. On the date of conversion, the Company determined that the value of these additional shares was \$257,973, based on the \$0.75 per share offering price of the common stock sold in the private placement completed concurrently with the Acquisition, which is the best indication of fair value on the date of conversion. Since the conversion was not completed until April 8, 2011, the value of the additional shares of \$257,973 was recorded as a component of interest expense during the second quarter of 2011.

## 8. LONG-TERM NOTES PAYABLE

On January 11, 2008, Collectar entered into a loan agreement with a bank to borrow up to \$1,200,000. The borrowing, evidenced by a note (the "Bank Note"), bore interest at a rate of 7.01% per annum, could be prepaid without penalty and was payable in 48 monthly principal and interest payments of \$20,520 with a balloon payment of any remaining unpaid principal and interest on March 28, 2012. In the event of default of payment, Collectar would be required to pay a late charge equal to 5% of the delinquent payment and the interest rate on the unpaid principal would be increased by 3%. The Bank Note was collateralized by substantially all assets of Collectar and a deposit account in the amount of \$500,000. As of December 31, 2010, the cash collateral is classified as restricted cash in the accompanying balance sheet. On April 8, 2011, immediately prior to the Acquisition, Collectar paid approximately \$627,000 in full settlement of the Bank Note. The payment was made in order to avoid an event of default that would have occurred as a result of the change of control that occurred at the time of the Acquisition. As of December 31, 2011 and 2010, \$0 and \$470,941 are classified as a long-term note payable in the accompanying balance sheets, respectively.

On September 15, 2010, Collectar entered into certain loan agreements with the Wisconsin Department of Commerce ("WDOC Notes") to borrow a total of \$450,000. The WDOC Notes bear interest at 2% per annum beginning on the date of disbursement and allow for the deferral of interest and principal payments until April 30, 2015. In the event of default of payment, interest on the delinquent payment is payable at a rate equal to 12% per annum. Monthly payments of \$20,665 for principal and interest shall commence on May 1, 2015 and continue for 23 equal installments with the final installment of any remaining unpaid principal and interest due on April 1, 2017. As of December 31, 2011 and 2010, \$450,000 is classified as a long-term note payable in the accompanying balance sheets.

Long-term notes payable consists of the following as of December 31:

	<u>2011</u>	<u>2010</u>
Bank Note, 7.01% interest	\$ —	\$ 675,743
Wisconsin Department of Commerce, 2% interest	450,000	450,000
	<u>450,000</u>	<u>1,125,743</u>
Less current portion	—	(204,802)
Long-term note payable, net of current portion	<u>\$ 450,000</u>	<u>\$ 920,941</u>

As of December 31, 2011, long-term notes payable matures as follows:

Years ended December 31,	
2012	\$ —
2013	—
2014	—
2015	119,957
2016	243,591
Thereafter	86,452
	<u>\$ 450,000</u>

For the years ended December 31, 2011 and 2010, the Company incurred approximately \$17,500 and \$62,000 of interest expense related to these long-term notes payable.

## 9. STOCKHOLDERS' EQUITY

On January 1, 2008, Collectar converted from a Wisconsin limited liability company to a Wisconsin corporation (the "Conversion"). Each issued and outstanding unit of equity in the limited liability company immediately prior to the Conversion was converted into one issued and outstanding share of Collectar common stock and each unexercised unit option outstanding immediately prior to the Conversion was converted into an option to acquire the same number of shares of the corporation's common stock. For the purpose of presentation in these financial statements, all amounts and disclosures related to equity issuances prior to the Acquisition have been retroactively restated by applying the Exchange Ratio in order to reflect the capital structure of Novelos and therefore the issuance of Novelos common stock, rather than member units in the limited liability company or common stock of Collectar, as applicable.

From inception until December 31, 2010, Collectar issued 12,559,218 shares of common stock for net proceeds of approximately \$21,710,000.

### *April 2011 Private Placement*

Concurrently with and conditioned upon the execution of the Merger Agreement, the Company entered into a Securities Purchase Agreement with certain accredited investors under which the Company sold an aggregate of 6,846,537 units, each unit consisting of one share of its common stock and a warrant to purchase one share of its common stock, at a price of \$0.75 per unit, for gross proceeds of approximately \$5,135,000 (the "April Private Placement"). The warrants have an exercise price of \$0.75 and expire on March 31, 2016. The warrant exercise price and/or the common stock issuable pursuant to such warrant will be 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. The relative fair value of the warrants issued to the investors was \$2,124,286 at issuance and has been included as a component of stockholders' equity. The Company uses the Black-Scholes option pricing model to value warrants and applies assumptions that consider, among other variables, the fair value of the underlying stock, risk-free interest rate, volatility, expected life and dividend rates in estimating fair value for the warrants. Assumptions used are generally consistent with those disclosed for stock-based compensation (see Note 10).

The Securities Purchase Agreement includes certain registration requirements which were subsequently extended by the consent of purchasers holding a majority of shares of the Company's common stock issued in the April Private Placement, which holders constituted the requisite holders, as defined. The Company is required to file with the SEC no later than May 29, 2012 (the "Filing Deadline"), a registration statement covering the resale of the shares of common stock, and the shares of common stock underlying the warrants, issued pursuant to the Securities Purchase Agreement that are not otherwise saleable under an available exemption from registration requirements. The Company is also required to use commercially reasonable efforts to have the registration statement declared effective by July 28, 2012 (the "Effectiveness Deadline"), and to keep the registration statement continuously effective under the Securities Act of 1933, as amended (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 Securities Purchase Agreement, or if it fails to obtain effectiveness of this registration on or prior to July 28, 2012 (if there is no review by the SEC) or by August 28, 2012 (if there is review by the SEC) with respect to the maximum number of shares permitted to be registered by the SEC, the Company will be required to pay to the purchasers 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 units purchased until the registration statement is filed or declared effective, as applicable, not to exceed 5% of the aggregate purchase price. The Company will be allowed to suspend the use of the registration statement for not more than 30 consecutive days, on not more than two occasions, in any 12-month period. The Company has also granted piggy-back registration rights with respect to any shares of common stock that it is required to exclude from the registration statement as a condition of its effectiveness, and has also agreed to file further registration statements with respect to any such shares six months after the effective date of the initial registration statement. As of December 31, 2011, and through the date of this filing, the Company has not concluded that it is probable that damages will become due; therefore, no accrual for damages has been recorded.

The Company paid to Rodman, the placement agent for the financing, a cash fee equal to \$200,000 and issued warrants to purchase 192,931 shares of its common stock (having an exercise price of \$0.75 and which expire March 31, 2016) in consideration for their advisory services with respect to the financing pursuant to the placement agency agreement between Rodman and the Company. Rodman is entitled to registration rights with respect to the shares of common stock issuable upon exercise of these warrants. The cash fee was recorded as a reduction of gross proceeds received. The estimated fair value of the warrants issued to the placement agent was \$112,096 and was recorded as a component of stockholders' equity.

#### ***December 2011 Underwritten Offering***

On December 6, 2011, the Company completed an underwritten public offering of 10,081,667 shares of its common stock and warrants to purchase up to an aggregate of 10,081,667 shares of its common stock at an exercise price of \$0.60 per share, expiring on December 6, 2016, for gross proceeds of \$6,049,000 and net proceeds of \$5,298,140 after deducting transaction costs (the "Underwritten Offering"). The warrant exercise price and the common stock issuable pursuant to such warrant are subject to adjustment only for stock dividends, stock splits and similar capital reorganizations so that the rights of the warrant holders after such event will be equivalent to the rights of the warrant holders prior to such event. The relative fair value of the warrants issued to the investors was \$2,350,320 at issuance and has been included as a component of stockholders' equity. The Company uses the Black-Scholes option pricing model to value warrants and applies assumptions that consider, among other variables, the fair value of the underlying stock, risk-free interest rate, volatility, expected life and dividend rates in estimating fair value for the warrants. Assumptions used are generally consistent with those disclosed for stock-based compensation (see Note 10). In connection with the Underwritten Offering, the Company paid to Rodman, the underwriting agent, a cash fee of \$302,000, which was recorded as a reduction of the gross proceeds received.

#### ***Legacy Warrants***

Outstanding warrants to purchase 315,164 shares of common stock, originally issued in connection with Novelos equity and debt financings from 2007 through 2010, remained outstanding subsequent to the Acquisition (Note 4).

#### ***Common Stock Warrants***

The following table summarizes information with regard to outstanding warrants to purchase common stock as of December 31, 2011. There were no outstanding common stock purchase warrants as of December 31, 2010.

<b>Offering</b>	<b>Number of Shares Issuable Upon Exercise of Outstanding Warrants</b>	<b>Exercise Price</b>	<b>Expiration Date</b>
December 6, 2011 Underwritten Offering	10,081,667	\$ 0.60	December 6, 2016
April 8, 2011 Private Placement	7,039,468	\$ 0.75	March 31, 2016
Legacy warrants (1)	77,729	\$ 0.60	July 27, 2015
Legacy warrants	105,040	\$ 16.065	July 27, 2015
Legacy warrants	91,524	\$ 99.45-100.98	December 31, 2015
Legacy warrants	8,561	\$ 191.25	May 2, 2012
Total	17,403,989		

(1) The exercise prices of these warrants are subject to adjustment for "down-rounds" and have been accounted for as derivative instruments as described in Note 3.

On May 4, 2011, 18,153 shares of common stock were issued in connection with the cashless exercise of warrants to purchase 27,310 shares of common stock at \$0.75 per share. The Company reclassified \$48,339 from the derivative liability to additional paid-in capital upon the exercise of the warrants. In connection with the December 2011 Underwritten Offering, 5,000 warrants previously issued to Rodman were cancelled.

**Reserved Shares**

The following shares were reserved for future issuance upon exercise of stock options and warrants or conversion of debt:

	<u>December 31,</u>	
	<u>2011</u>	<u>2010</u>
Warrants	17,403,989	—
Stock options	4,827,638	769,189
Convertible notes	—	3,646,370
<b>Total number of shares reserved for future issuance</b>	<b><u>22,231,627</u></b>	<b><u>4,415,559</u></b>

**10. STOCK-BASED COMPENSATION**

Prior to the Acquisition, Collectar’s Board of Directors determined exercise prices and vesting periods on the date of grant, subject to the provisions of the 2006 Unit Option Plan and the 2008 Stock Incentive Plan (collectively, the “Collectar Plans”). Options have been granted at or above the estimated fair-market value of the common stock at the grant date. Options granted pursuant to the 2006 Collectar Plan and 2008 Plan generally would have become fully vested in the event of a business combination whereby the options are not assumed or replaced by the surviving company, as defined. On March 17, 2011, in contemplation of the Acquisition, Collectar terminated the remaining options outstanding granted under the Collectar Plans and the Collectar Plans were terminated.

In connection with the Acquisition, the Company assumed options to purchase 49,159 shares of common stock at exercise prices ranging from \$1.53 to \$1,072.53.

*2006 Novelos Stock Option Plan.* Following the Acquisition, option grants to directors and employees will be made under the Novelos Therapeutics 2006 Stock Incentive Plan (the “Plan”). On May 18, 2011, the Board of Directors of the Company approved certain amendments to the Plan to, among other things, increase the aggregate number of shares of the Company’s common stock reserved for issuance under the Plan (including any shares that have already been issued thereunder), to 7,000,000 and remove the 750,000 share annual individual limitation on grants under the Plan. On June 30, 2011, the Company’s stockholders approved those amendments.

A total of 7,000,000 shares of common stock are reserved for issuance under the 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 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 between one and four years. Options granted pursuant to the 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. As of December 31, 2011, there are an aggregate of 2,281,112 shares available for future grants under the Plan.

## Accounting for Stock-Based Compensation

The Company uses the Black-Scholes option-pricing model to calculate the grant-date fair value of stock option awards. The resulting compensation expense, net of expected forfeitures, for non-performance based awards is recognized on a straight-line basis over the service period of the award, which is generally three years for stock options. For stock options with performance-based vesting provisions, recognition of compensation expense, net of expected forfeitures, commences if and when the achievement of the performance criteria is deemed probable. The compensation expense, net of expected forfeitures, for performance-based stock options is recognized over the relevant performance period. Evaluation of the probability of meeting performance targets is evaluated at the end of each reporting period. Non-employee stock-based compensation is accounted for in accordance with the guidance of FASB ASC Topic 505, *Equity*. As such, the Company recognizes 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 and deemed completed 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 granted to non-employee consultants:

	<b>Year Ended December 31,</b>		<b>Cumulative Development- Stage Period from November 7, 2002 through December 31,</b>
	<b>2011</b>	<b>2010</b>	<b>2011</b>
<b>Employee and director stock option grants:</b>			
Research and development	\$ 190,172	\$ 61,791	\$ 488,558
General and administrative	<u>570,884</u>	<u>291,549</u>	<u>2,148,187</u>
	761,056	353,340	2,636,745
<b>Non-employee consultant stock option grants:</b>			
Research and development	36,157	—	36,157
General and administrative	<u>110,247</u>	<u>—</u>	<u>181,971</u>
	<u>146,404</u>	<u>—</u>	<u>218,128</u>
<b>Total stock-based compensation</b>	<u>\$ 907,460</u>	<u>\$ 353,340</u>	<u>\$ 2,854,873</u>

On July 14, 2010, the expiration date of vested options held by a former employee was extended until July 8, 2015. The extension constituted a modification to the terms of the award and additional stock-based compensation was measured as the excess of the fair value of the modified award over the fair value of the original award immediately before the modification. Accordingly, incremental stock-based compensation expense of approximately \$20,000 was recorded in connection with the modification.

The Company granted 5,026,500 stock options to employees and non-employees during the twelve months ended December 31, 2011 under the Plan, of which 670,200 were performance-based awards. As of December 31, 2011, 335,100 of these performance-based awards were outstanding and 335,100 had been forfeited. No compensation expense has been recognized related to the performance-based awards as the Company does not believe that it is probable that the performance targets will be met. The Company issued options to purchase a total of 200,000 shares of common stock to non-employees outside of any formalized plan, but 100,000 were forfeited as a result of the cancellation and replacement as described below. Exercise prices for all grants made in the during the twelve months ended December 31, 2011 were equal to the market value of the Company's common stock on the date of grant.

On May 18, 2011, the Company cancelled 100,000 options originally granted on April 25, 2011 with an exercise price of \$3.00 per share and issued 100,000 replacement stock option awards with an exercise price of \$1.40. The cancellation and replacement constituted a modification to the terms of the award and additional stock-based compensation was measured as the excess of the fair value of the modified award over the fair value of the original award immediately before the modification. Accordingly, incremental stock-based compensation expense of \$4,494 was recorded in connection with the modification.

#### **Assumptions Used In 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. The estimated fair value of the non-employee options is amortized to expense over the period during which a non-employee is required to provide services for the award (usually the vesting period).

*Volatility.* Collectar estimated volatility based on a review of volatility estimates of publicly held drug development companies in a similar stage of development. Subsequent to the Acquisition, the Company estimates volatility based on an average of (1) the Company's historical volatility since its common stock has been publicly traded and (2) review of volatility estimates of publicly held drug development companies with similar market capitalizations.

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

*Expected term.* The expected term of stock options granted is based on an estimate of when options will be exercised in the future. The Company applied the simplified method of estimating the expected term of the options, as described in the SEC's Staff Accounting Bulletins 107 and 110, as the Company has had a significant change in its business operations as result of the Acquisition and the historical experience is not indicative of the expected behavior in the future. The expected term, calculated under the simplified method, is applied to groups of stock options that have similar contractual terms. Using this method, the expected term is determined using the average of the vesting period and the contractual life of the stock options granted. The Company applied the simplified method to non-employees who have a truncation of term based on termination of service and utilizes the contractual life of the stock options granted for those non-employee grants which do not have a truncation of service.

*Forfeitures.* Stock-based compensation expense is recorded only for those awards that are expected to vest. FASB ASC Topic 718 requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. The term "forfeitures" is distinct from "cancellations" or "expirations" and represents only the unvested portion of the surrendered option. An annual forfeiture rate of 0% was applied to all unvested options as of December 31, 2010 as Collectar had experienced very few forfeitures through 2009 and there was insufficient history to develop an accurate estimate of future forfeitures. An annual forfeiture rate of 0% was applied to all unvested options as of December 31, 2011 as the historical experience of forfeitures is not representative of expected future forfeiture rates as a result of the significant changes in the business operations as a result of the Acquisition. Additionally, the majority of the 2011 forfeitures were related to unmet milestones on performance-based options that are not representative of the expected future forfeiture rates for the Company's service-based awards. 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>Twelve Months Ended December 31, 2011</b>	
Volatility	110 - 115%	
Risk-free interest rate	0.89% – 3.17%	
Expected life (years)	5.5 – 6.25	
Dividend	0%	
Weighted-average exercise price	\$	1.16
Weighted-average grant-date fair value	\$	0.98

### Stock Option Activity

A summary of stock option activity under stock option plans is as follows:

	<b>Number of Shares Issuable Upon Exercise of Outstanding Options</b>	<b>Weighted Average Exercise Price</b>	<b>Weighted Average Remaining Contracted Term in Years</b>	<b>Aggregate Intrinsic Value</b>
Outstanding at November 7, 2002	—			
Granted	922,654	\$ 2.52		
Forfeited	<u>(12,653)</u>	\$ 3.04		
Outstanding at January 1, 2009	910,001	\$ 2.86		
Granted	90,929	\$ 0.76		
Forfeited	<u>(9,194)</u>	\$ 2.72		
Outstanding at December 31, 2009	991,736	\$ 2.68		
Canceled	<u>(222,547)</u>	\$ 2.63		
Outstanding at December 31, 2010	769,189	\$ 2.69		
Canceled	(769,189)	\$ 2.69		
Options acquired in connection with a business combination	49,159	\$ 100.52		
Granted	5,226,500	\$ 1.16		
Canceled	(9,992)	\$ 115.16		
Forfeited	<u>(438,029)</u>	\$ 2.44		
Outstanding at December 31, 2011	<u>4,827,638</u>	\$ 1.82		
Vested, December 31, 2010	<u>743,450</u>	\$ 2.69	4.07	\$ —
Unvested, December 31, 2010	<u>25,739</u>	\$ 2.62	5.08	\$ —
Exercisable at December 31, 2010	<u>743,450</u>	\$ 2.69	4.07	\$ —
Vested, December 31, 2011	<u>636,634</u>	\$ 6.48	9.17	\$ —
Unvested, December 31, 2011	<u>4,191,004</u>	\$ 1.12	9.59	\$ —
Exercisable at December 31, 2011	<u>636,634</u>	\$ 6.48	9.17	\$ —

There were no stock options granted during the twelve months ended December 31, 2010.

The aggregate intrinsic value of options outstanding is calculated based on the positive difference between the estimated per-share fair value of common stock at the end of the respective period and the exercise price of the underlying options. At the end of the periods shown, the estimated fair-market value of common stock was less than the exercise price of the underlying options, as such, the aggregate intrinsic value is \$0. There have been no option exercises to date. Shares of common stock issued upon the exercise of options are from authorized but unissued shares.

The weighted-average grant-date fair value of options granted during the year ended December 31, 2011 and for the period from November 7, 2002 to December 31, 2011 was \$0.98 and \$1.28, respectively. There were no options granted during the year ended December 31, 2010. The total fair value of shares vested during December 31, 2011 and 2010 and for the period November 7, 2002 (date of inception) to December 31, 2011 was \$756,400, \$199,600 and \$2,806,400, respectively. The weighted-average grant-date fair value of vested and unvested options outstanding at December 31, 2011 and 2010 was \$1.31 and \$0.89 and \$2.01 and \$1.91, respectively.

As of December 31, 2010, there was approximately \$58,000 of total unrecognized compensation cost, all of which was attributable to unvested stock-based compensation arrangements related to employees, which was recognized in the twelve months ended December 31, 2011.

On March 4, 2011, in contemplation of the Acquisition and in accordance with terms of the applicable option agreements, Cellestar accelerated the vesting on all outstanding and unvested options at that date and notified all option holders that any unexercised options as of March 17, 2011 would then be terminated. On March 17, 2011, Cellestar terminated all outstanding options. The remaining unamortized compensation expense of \$58,000 was recorded related to the acceleration of outstanding options in the quarter ended March 31, 2011. No additional compensation expense was recorded related to the acceleration of unvested shares as the acceleration did not represent a modification to the original terms of the options.

As of December 31, 2011, there was \$2,956,117 of total unrecognized compensation cost related to unvested stock-based compensation arrangements. Of this total amount, the Company expects to recognize \$1,321,168, \$1,051,631, \$507,630 and \$75,688 during 2012, 2013, 2014 and 2015, respectively. The Company expects 4,191,004 in unvested options to vest in the future.

## 11. INCOME TAXES

	<u>2011</u>	<u>2010</u>
Tax provision (benefit)		
Current		
Federal	\$ —	\$ —
State	—	—
Total current	—	—
Deferred		
Federal	(944,333)	(1,592,000)
State	(161,963)	(290,000)
Total deferred	(1,106,296)	(1,882,000)
Change in valuation	1,106,296	1,882,000
Total	<u>\$ —</u>	<u>\$ —</u>

Deferred tax assets consisted of the following at December 31:

	<u>2011</u>	<u>2010</u>
<b>Deferred tax assets</b>		
Federal net operating loss	\$ 19,447,371	\$ 6,116,804
Federal research and development tax credit carryforwards	1,956,146	390,600
State net operating loss	2,444,816	814,492
State research and development tax credit carryforwards	597,608	220,738
Capitalized research and development expenses	13,007,013	—
Capital loss carryforward (expires beginning in 2012)	340,000	—
Stock-based compensation expense	333,206	552,859
Intangible assets	555,198	—
Charitable contribution carryforwards	44,370	49,725
Accrued liabilities	<u>35,314</u>	<u>25,327</u>
Total deferred tax assets	38,761,042	8,170,545
<b>Deferred tax liabilities</b>		
Depreciable assets	(346,870)	(434,056)
Total deferred tax liabilities	(346,870)	(434,056)
<b>Net deferred tax assets</b>	<u>38,414,172</u>	<u>7,736,489</u>
Less valuation allowance	<u>(38,414,172)</u>	<u>(7,736,489)</u>
<b>Total deferred tax assets</b>	<u>\$ —</u>	<u>\$ —</u>

As of December 31, 2011, the Company had federal and state net operating loss carryforwards (“NOLs”) of approximately \$57,198,000 and \$46,533,000 respectively, which expire beginning in 2031 and 2025, respectively. In addition, the Company has federal and state research and development and investment tax credits of approximately \$1,956,000 and \$905,000, respectively. The amount of NOLs which may be utilized annually in future periods will 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 Company has not quantified the amount of such limitations.

Because of the Company’s limited operating history, continuing losses and uncertainty associated with the utilization of the NOLs in the future, management has provided a full allowance against the gross deferred tax asset.

The Company did not have unrecognized tax benefits or accrued interest and penalties at any time during the years ended December 31, 2011 or 2010, and does not anticipate having unrecognized tax benefits over the next twelve months. The Company is subject to audit by the IRS and state taxing authorities for tax periods commencing January 1, 2008. Additionally, the Company may be subject to examination by the IRS for years beginning prior to January 1, 2008 as a result of its NOLs. However, any adjustment related to these periods would be limited to the amount of the NOL generated in the year(s) under examination.

## 12. NET LOSS PER SHARE

Basic net loss per share is computed by dividing net loss 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, as adjusted, by the sum of the weighted average number of shares of common stock and the dilutive potential common stock equivalents then outstanding. Potential common stock equivalents consist of stock options and convertible debt. Since there is a net loss attributable to common stockholders for the years ended December 31, 2011 and 2010, the inclusion of common stock equivalents in the computation for those periods would be antidilutive. Accordingly, basic and diluted net loss per share is the same for all periods presented.

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

	Twelve Months Ended		Cumulative
	December 31,		Development-
	2011	2010	Stage Period
			from November
			7, 2002
			(inception)
			through
			December 31,
			2011
Convertible debt	—	3,646,370	—
Warrants	17,403,989	—	17,403,989
Stock options	4,827,638	769,189	4,827,638

### 13. COMMITMENTS

#### *Real Property Leases*

On September 5, 2007, Collectar entered into a 36-month lease for office and manufacturing space, commencing September 15, 2007. The lease provides for the option to extend the lease under its current terms for seven additional two-year terms. Rent is \$8,050 per month for the first year and then escalates by 3% per year for the duration of the term including any lease extension terms. The lease also requires the payment of monthly rent of \$1,140 for approximately 3,400 square feet of expansion space. The monthly rent for the expansion space is fixed until such time as the expansion space is occupied at which time the rent would increase to the current per square foot rate in effect under the original lease terms. The Company is responsible for certain building-related costs such as property taxes, insurance, and repairs and maintenance. Rent expense is recognized on a straight-line basis and accordingly the difference between the recorded rent expense and the actual cash payments has been recorded as deferred rent as of each balance sheet dates. Due to the significant value of leasehold improvements purchased during the initial 3-year lease term and the economic penalty for not extending the building lease, straight-line rent expense and the associated deferred rent has been calculated over 17 years, which represents the full term of the lease, including all extensions.

The Company is required to remove certain alterations, additions and improvements upon termination of the lease that altered a portion of the rentable space. In no event shall the cost of such removal, at commercially reasonable rates, paid by the Company exceed \$55,000 ("Capped Amount"). Any amount in excess of the Capped Amount shall be the obligation of the landlord. The Company is required to maintain a certificate of deposit equal to the Capped Amount during the term of the lease, which amount is shown as restricted cash on the accompanying balance sheets.

The lease has been extended, in accordance with its terms, through September 14, 2014. Future minimum lease payments under this non-cancelable lease are approximately as follows:

Years ended December 31,	
2012	\$ 126,000
2013	123,000
2014	94,000
2015	—
Thereafter	—
	<u>\$ 343,000</u>

The Company also leases office space in Newton, MA, which has a term that is month-to-month and requires monthly rental payments of \$5,300.

Rent expense was approximately \$197,000 and \$159,000 for the years ended December 31, 2011 and 2010, respectively and approximately \$1,141,000 from inception to December 31, 2011.

#### ***Equipment Lease***

Certain equipment is leased under a capital lease. The lease agreement requires monthly principal and interest payments of \$217 and expires on September 3, 2014. The outstanding obligation is being amortized using a 7% interest rate based on comparable borrowing rates.

The following table provides the estimated future minimum rental payments under all capital leases together with the present value of the net minimum lease payments as of December 31, 2011:

	<b>Minimum lease payments</b>	<b>Less interest</b>	<b>Present value of net minimum lease payments</b>
2012	\$ 2,608	\$ 373	\$ 2,235
2013	2,608	211	2,397
2014	1,739	45	1,694
	<u>\$ 6,955</u>	<u>\$ 629</u>	<u>\$ 6,326</u>

The equipment recorded under capitalized leases is included in fixed assets as of December 31:

	<u>2011</u>	<u>2010</u>
Office equipment	\$ 10,973	\$ 10,973
Less accumulated amortization	(5,123)	(2,928)
	<u>\$ 5,850</u>	<u>\$ 8,045</u>

#### **14. CONTINGENCIES**

##### **Litigation**

Following the Acquisition, the Company is party to certain legal matters that existed with Novelos prior to the Acquisition. The following summarizes the status of those matters.

### *Class Action*

A putative federal securities class action complaint was filed on March 5, 2010 in the United States District Court for the District of Massachusetts by an alleged shareholder of Novelos, on behalf of himself and all others who purchased or otherwise acquired Novelos common stock in the period between December 14, 2009 and February 24, 2010, against Novelos and its President and Chief Executive Officer, Harry S. Palmin. On October 1, 2010, the court appointed lead plaintiffs (Boris Urman and Ramona McDonald) and appointed lead plaintiffs' counsel. On October 22, 2010, an amended complaint was filed. The amended complaint claims, among other things, that Novelos violated Section 10(b) of the Securities Exchange Act of 1934, as amended, and Rule 10b-5 promulgated thereunder in connection with alleged misleading disclosures related to the progress of the Phase 3 clinical trial of NOV-002 for non-small cell lung cancer. On December 6, 2010, the defendants filed a motion to dismiss the complaint with prejudice. On January 20, 2011, the plaintiffs filed their opposition to our motion and on March 3, 2011, the defendants filed their response to the opposition. On June 23, 2011, the motion to dismiss was granted and the case was dismissed without prejudice. Because the dismissal was without prejudice, the plaintiffs could reinstitute the proceeding by filing an amended complaint. On August 5, 2011, the plaintiffs filed a second amended complaint realleging that the defendants violated Section 10(b) of the Exchange Act and Rule 10b-5 in connection with alleged misleading disclosures related to the Phase 3 clinical trial for NOV-002 in non-small cell lung cancer. On September 9, 2011, the defendants filed a motion to dismiss the second amended complaint. The plaintiffs' opposition to the motion was filed on October 14, 2011 and the defendants filed a reply brief on November 4, 2011. The Company and Mr. Palmin believe the allegations are without merit and intend to continue to vigorously defend against them.

### *BAM Dispute*

On June 28, 2010, Novelos received a letter from counsel to ZAO BAM and ZAO BAM Research Laboratories (Russian companies, collectively referred to as "BAM") alleging that it modified the chemical composition of NOV-002 without prior notice to or approval from BAM, constituting a material breach of a technology and assignment agreement Novelos had entered into with BAM on June 20, 2000 (the "June 2000 Agreement"). The letter references the amendment, submitted to the FDA on August 30, 2005, to Novelos' investigational new drug application dated August 1999 as the basis for BAM's claims and demands the transfer of all intellectual property rights concerning NOV-002 to BAM. Mark Balazovsky, a director of Novelos from June 1996 until November 2006 and a shareholder of Novelos through at least June 25, 2010, is, to our knowledge, still the general director and principal shareholder of ZAO BAM. On September 24, 2010, Novelos filed a complaint in Suffolk Superior Court seeking a declaratory judgment by the court that the June 2000 Agreement has been replaced by a subsequent agreement between the parties dated April 1, 2005 (the "April 2005 Agreement"), that Novelos' obligations to BAM are governed solely by the April 2005 Agreement and that the obligations of the June 2000 agreement have been performed and fully satisfied. On November 29, 2010, BAM answered the complaint, denying the material allegations, and stating its affirmative defenses and certain counterclaims. On January 14, 2011, Novelos responded to the counterclaims, denying BAM's material allegations and stating its affirmative defenses. On June 9, 2011, BAM filed an amended counterclaim alleging additional claims related to Novelos' acquisition of Collectar. In that amended counterclaim, BAM alleges that the acquisition evidences Novelos' abandonment of the technology assigned to it by BAM constituting a breach of the June 2000 Agreement or, if that agreement is determined to no longer be in effect, a breach of the April 2005 Agreement and/or a breach of the implied duty of good faith and fair dealing with respect to the April 2005 Agreement. On June 15, 2011 the Company filed its response to their amended counterclaim. On August 5, 2011, the Company filed a motion for judgment on the pleadings as to its declaratory judgment count and all counts of BAM's amended counterclaim. The motion was opposed by BAM and a hearing on the motion was held on September 27, 2011. On October 17, 2011, the court ruled on the Company's behalf for each of its declaratory judgment claims and dismissed all counts of BAM's counterclaim. Judgment in favor of the Company was entered on October 20, 2011. On November 14, 2011, BAM filed a notice of appeal.

We do not anticipate that these litigation contingencies will have a material impact on the Company's future financial position, results of operations or cash flows.

## 15. EMPLOYEE RETIREMENT PLAN

On January 1, 2009, Collectar adopted a Safe Harbor defined contribution plan under Section 401(k) of the Internal Revenue Code which covered eligible employees who meet minimum age requirements and allowed participants to contribute a portion of their annual compensation on a pre-tax basis. Collectar contributed 3% of each participant's compensation. Contributions made for the year ended December 31, 2010 was \$23,000. The plan was canceled effective August 30, 2010.

Following the Acquisition, the Company has a defined contribution plan under Section 401(k) of the Internal Revenue Code which allows eligible employees who meet minimum age requirements to contribute a portion of their annual compensation on a pre-tax basis. The Company has not made any matching contributions under this plan.

## 16. RELATED PARTY TRANSACTIONS

Jamey Weichert, the Company's Chief Scientific Officer and principal founder of Collectar, and a director and shareholder of the Company, is a faculty member at the University of Wisconsin-Madison ("UW").

During the year ended December 31, 2011, the Company made contributions totaling \$206,500 to UW, for use towards unrestricted research activities. No payments were made to UW during the year ended December 31, 2010.

## 17. SUPPLEMENTAL PRO FORMA INFORMATION

The table below summarizes net loss for the periods shown as though the Acquisition occurred as of January 1, 2010:

	<u>For the Twelve Months Ended December 31,</u>	
	<u>2011</u>	<u>2010</u>
Net loss	\$ (7,256,438)	\$ (1,704,966)

The pro forma net loss has been adjusted for the following:

- 1) Elimination of \$165,000, and \$361,000 of interest expense for the twelve months ended December 31, 2011 and 2010, respectively; such amounts relate to interest accrued on the Convertible Notes which were converted immediately prior to the Acquisition (see Note 7) and the Bank Note which was paid in full settlement of the note immediately prior to the Acquisition (see Note 8).
- 2) Recognition of an additional beneficial conversion feature ("BCF") of \$463,000 in the year ended December 31, 2010 and the elimination of BCF of \$258,000 in the year ended December 31, 2011 in connection with the conversion of the Convertible Notes, which is assumed to have occurred on January 1, 2010 for the purpose of pro forma presentation (see Note 7).
- 3) Elimination of Acquisition costs incurred during the year ended December 31, 2011 and 2010, which are assumed to have been incurred prior to January 1, 2010 for the purpose of presentation in the pro forma statements of operations.
- 4) Elimination of \$450,000 of investment banking fees incurred upon the consummation of the Acquisition on April 8, 2011 from the twelve months ended December 31, 2011.
- 5) Elimination of dividends and deemed dividends on Novelos' preferred convertible stock, which is assumed to have been exchanged for common stock at January 1, 2010 in order to reflect the post-acquisition capital structure for the purpose of pro forma presentation.
- 6) Elimination of Novelos historical revenue related to the amortization of deferred revenue that was determined to have no fair value in purchase accounting.
- 7) Elimination of liquidated damages accrued in 2010 related to Novelos' convertible preferred stock. The liquidated damages are assumed not to have accrued as the preferred stock is assumed to have been exchanged for common stock at January 1, 2010 in order to reflect the post-acquisition capital structure for the purpose of pro forma presentation.

## 18. PROPOSED REVERSE STOCK SPLIT

On June 30, 2011, the Company held a special meeting of stockholders. At the meeting, the stockholders approved, among other things, separate amendments to the certificate of incorporation that would effect a reverse split of the Company's common stock within a range of 1:2 to 1:10, and authorized the Company's board of directors to determine the ratio at which the reverse split will be effected by filing the appropriate amendment to the certificate of incorporation, or to determine not to proceed with the reverse split at all. The purpose of the proposed reverse split was to increase the price per share of the Company's common stock in order to exceed the minimum price per share required to secure a listing on a national securities exchange and was contemplated in connection with the Company's underwritten public offering that closed on December 6, 2011 (see Note 9). The Company did not obtain the NASDAQ listing and did not effect the reverse split in connection with the offering. While the Company may effect a reverse split at a later date, the Company has no immediate plans to proceed with the reverse split or a listing on a national securities exchange.

### Item 9. Changes in 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 Securities Exchange Act of 1934, as amended (the "Exchange Act"). Internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on criteria established in the *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Management's evaluation included such elements as the design and operating effectiveness of key financial reporting controls, process documentation, accounting policies, and our overall control environment. Based on this evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, 2011. 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, as allowed by the SEC.

*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 December 31, 2011, our principal executive officer and principal financial officer have concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) are effective to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms.

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



*Changes in internal control over financial reporting.* Our management, in connection with its evaluation of internal controls (with the participation of our principal executive officer and principal financial officer), did not identify any change in internal control over the financial reporting process that occurred during our fourth fiscal quarter of 2011 that would have materially affected, or would have been reasonably likely to materially affect, our internal control over financial reporting.

*Important Considerations.* The effectiveness of our disclosure controls and procedures is subject to various inherent limitations, including cost limitations, judgments used in decision making, assumptions about the likelihood of future events, the soundness of our systems, the possibility of human error, and the risk of fraud. Because of these limitations, there can be no assurance that any system of disclosure controls and procedures will be successful in preventing all errors or fraud or in making all material information known in a timely manner to the appropriate levels of management.

**Item 9B. Other Information.**

None.

**PART III**

**Item 10. Directors, Executive Officers and Corporate Governance.**

Our current directors and executive officers are:

<b>Name</b>	<b>Age</b>	<b>Position</b>
Stephen A. Hill, B.M. B.Ch., M.A., F.R.C.S. (1)	53	Chairman of the Board (term expiring at 2012 annual meeting or upon his successor being duly elected and qualified)
Harry S. Palmin	42	President, Chief Executive Officer and Director (term as Director expiring at 2013 annual meeting or upon his successor being duly elected and qualified)
J. Patrick Genn	55	Vice President of Investor Relations
Kimberly A. Hawkins	40	Vice President of Clinical Development
Christopher J. Pazoles, Ph.D.	62	Senior Vice President of Research and Development
Joanne M. Protano	43	Vice President, Chief Financial Officer and Treasurer
Jamey P. Weichert, Ph.D.	55	Chief Scientific Officer and Director (term as Director expiring at 2013 annual meeting or upon his successor being duly elected and qualified)
Thomas Rockwell Mackie, Ph.D. (2)	57	Director (term expiring at 2011 annual meeting or upon his successor being duly elected and qualified) (3)
James S. Manuso, Ph.D. (2)(1)	63	Director (term expiring at 2011 annual meeting or upon his successor being duly elected and qualified) (3)
John Neis (4)(2)	56	Director (term expiring at 2012 annual meeting or upon his successor being duly elected and qualified)
John E. Niederhuber, M.D. (4)(1)	73	Director (term expiring at 2011 annual meeting or upon his successor being duly elected and qualified) (3)
Howard M. Schneider (4)	68	Director (term expiring at 2013 annual meeting or upon his successor being duly elected and qualified)
Michael F. Tweedle, Ph.D. (2)	60	Director (term expiring at 2012 annual meeting or upon his successor being duly elected and qualified)

(1) Member of the nominating and corporate governance committee

(2) Member of the compensation committee

- (3) Our certificate of incorporation provides for the division of the Board into three classes, Class I, Class II and Class III, as nearly equal in size as possible with staggered three-year terms. At each annual meeting of our stockholders, the terms of one such class expires. The terms of the Class I directors were to expire at the 2011 annual meeting of stockholders. However, we did not hold an annual meeting of stockholders in 2011. Accordingly, each such director is currently serving in accordance with our by-laws until his successor is duly elected and qualified.
- (4) Member of the audit committee.

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

**Stephen A. Hill.** Dr. Hill was elected the chairman of the board of directors of Novelos in September 2007. Dr. Hill was the President and CEO of 21CB, a nonprofit initiative of UPMC designed to provide the United States government with a domestic solution for its biodefense and infectious disease biologics portfolio, from March 2011 until December 2011. Dr. Hill served as the President and Chief Executive Officer of Solvay Pharmaceuticals, Inc. since April 2008 until its acquisition by Abbott Laboratories in 2010. Prior to joining Solvay, Dr. Hill had served as ArQule's President and Chief Executive Officer since April 1999. Prior to his tenure at ArQule, Dr. Hill was the Head of Global Drug Development at F. Hoffmann-La Roche Ltd. from 1997 to 1999. Dr. Hill joined Roche in 1989 as Medical Adviser to Roche Products in the United Kingdom. He held several senior positions at Roche, including Medical Director where he was responsible for clinical trials of compounds across a broad range of therapeutic areas, including CNS, HIV, cardiovascular, metabolic and oncology products. Subsequently, he served as Head of International Drug Regulatory Affairs at Roche headquarters in Basel, Switzerland, where he led the regulatory submissions for seven major new chemical entities. Dr. Hill also was a member of Roche's Portfolio Management, Research, Development and Pharmaceutical Division Executive Boards. Prior to Roche, Dr. Hill served seven years with the National Health Service in the United Kingdom in General and Orthopedic Surgery. Dr. Hill is a Fellow of the Royal College of Surgeons of England and holds his scientific and medical degrees from St. Catherine's College at Oxford University. Dr. Hill's extensive experience in a broad range of senior management positions with companies in the life sciences sector make him a highly qualified member of our board of directors.

**Harry S. Palmin.** Mr. Palmin has served as our president and a director since 1998 and our chief executive officer since January 2005. From 1998 to September 2005, he served as our acting chief financial officer. From 1996 to 1998, he was a vice president at Lehman Brothers and from 1993 to 1996, he was an associate at Morgan Stanley & Co. Mr. Palmin earned a B.A. in economics and business and a M.A. in international economics and finance from the International Business School at Brandeis University. He has also studied at the London School of Economics and the Copenhagen Business School. Mr. Palmin's experience managing the funding and development of our product candidates for 13 years and his knowledge of capital markets are strong qualifications to serve on our board of directors.

**J. Patrick Genn.** Mr. Genn was appointed vice president of investor relations in December 2011. He has 28 years of senior management experience in finance, banking and investment management. Mr. Genn was previously President of Continuum Investment Holdings, Inc. from 2006 through mid-2010 while serving on the board of directors of several biotech and technology companies including Collectar, Inc. From 2001 through 2005, he was an advisor and consultant to several companies including Carmel Valley Ventures and Continuum Investment Partners. Mr. Genn held several senior management positions at Wells Fargo between 1987 and 2001. He was a member of the senior management team that launched the mortgage lending division in 1987 and the premier banking division in 1993. He was also a member of the core mergers and acquisitions integration team and managed private client services in San Diego, CA. Mr. Genn received a B.B.A. in Marketing and a M.S. in Product Management from the University of Wisconsin-Madison.

**Kimberly A. Hawkins.** Ms. Hawkins has served as our vice president of clinical development since November 2010 and served as our director of clinical development since May 2006. She has worked for 17 years in the biopharmaceutical industry managing and overseeing clinical operations for multiple global Phase 1, 2 and 3 clinical studies. From 2001 to 2006, Ms. Hawkins was a senior manager in clinical development at Antigenics, Inc., a cancer biotechnology company where she managed multiple Phase 1 and 2 studies. From 1994 to 2001 she was employed by Genzyme Corporation, Center for Clinical Research Practice where she held the positions of clinical research associate, trainer of good clinical practice and study coordinator. From 1993 to 1994 she held the position of clinical research coordinator at Boston Medical Center. Ms. Hawkins has a B.S. degree in Human Physiology from Boston University and a Masters Degree in Public Health from Boston University School of Public Health.

**Christopher J. Pazoles.** Dr. Pazoles has served as our vice president of research and development since July 2005. He has 30 years of biopharmaceutical research and development and senior management experience. 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 has 20 years of finance and senior management experience. 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.

**Jamey P. Weichert.** Dr. Weichert was the primary founder of Celectar serving as Celectar's Chairman and Chief Scientific Officer since 2002. He was appointed as the Chief Scientific Officer and a director of Novelos at the time of the Acquisition. Dr. Weichert is an Associate Professor of the Departments of Radiology, Medical Physics, Pharmaceutics and member of the Comprehensive Cancer Center at the University of Wisconsin, Madison. He has a bachelor's degree in chemistry from the University of Minnesota and a doctorate in medicinal chemistry from U. Mich. His research interests include the design, synthesis and evaluation of biomimetic CT and MRI imaging agents and diapaetic radiopharmaceuticals. He has been involved in molecularly targeted imaging agent development his entire professional career and has developed or co-developed several imaging agents nearing clinical trial status. Dr. Weichert serves or has served on the editorial boards of numerous scientific journals and has authored more than 40 peer reviewed publications and 150 abstracts. He also has 20 issued or pending patents related to drug delivery, imaging and contrast agent development. Dr. Weichert's experience founding and managing the development of Celectar's product candidates and his knowledge of radiation technology are strong qualifications to serve on our board of directors.

**Thomas Rockwell Mackie.** Dr. Mackie became a director of the Company at the time of the Acquisition. He served as a director of Celectar since December 2006. In 1997, he co-founded TomoTherapy Incorporated, a maker of advanced radiation therapy solutions for the treatment of cancer and other diseases and served as Chairman of its board of directors from 1999 until its Acquisition by Accuray Incorporated in June 2011. Dr. Mackie also served as President of TomoTherapy Inc. from 1997 until 1999 and as Treasurer from 1997 until 2000. Since 1987, Dr. Mackie has been a professor in the departments of Medical Physics and Human Oncology at the University of Wisconsin, where he established the TomoTherapy research program. Dr. Mackie also co-founded Geometrics Corporation (now merged with ADAC Corp.), which developed a radiotherapy treatment planning system. Dr. Mackie currently serves as a director of Shine Medical Technologies and Bioionix Inc. and served on the management committee of Wisconsin Investment Partners from 2006 to 2009. Dr. Mackie has a B.Sc. in Physics from the University of Saskatchewan and a Ph.D. in Physics from the University of Alberta in Edmonton. Dr. Mackie's qualifications to serve on our board of directors include his extensive senior management experience with radiation technology companies.

**James S. Manuso.** Dr. Manuso has served as one of our directors since August 2007. Since January 2005, Dr. Manuso has served as Chairman and Chief Executive Officer of SuperGen, Inc. (now renamed Astex Pharmaceuticals, Inc.), served as President of SuperGen from January 2005 through July 2011 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 directors of the Biotechnology Industry Organization (BIO) and its Health Section Governing Board and serves on the board of privately-held KineMed, Inc. He previously served on the boards of Merrion Pharmaceuticals Ltd. (Dublin, Ireland), Inflazyme Pharmaceuticals, Inc. (Vancouver, Canada), Symbionics, Inc., (ZyStor, Inc., sold to BioMarin), Quark Biotech, Inc., Galenica Pharmaceuticals, Inc., Supratek Pharma, Inc., and EuroGen, Ltd. (London, UK). Dr. Manuso earned a B.A. in economics and chemistry from New York University, a Ph.D. in experimental psychophysiology from the Graduate Faculty of The New School University, a certificate in health systems management from Harvard Business School, and an executive M.B.A. from Columbia Business School. Dr. Manuso's experience founding, leading and serving as a director for pharmaceutical companies makes him a highly qualified member of our board of directors.

**John Neis.** Mr. Neis became a director of our Company at the time of the Acquisition. He served as director of Collectar since February 2008. Mr. Neis has been Managing Director of Venture Investors LLC since 1986 and heads the firm's Healthcare practice. He has over 23 years' experience in the venture capital industry and serves on the Board of Directors of companies from formation through initial public offering or sale. Mr. Neis also currently serves on the boards of directors of Virent Energy Systems, Deltanoid Pharmaceuticals, Inviragen, Inc. and Mithridion, Inc. He is a former member of the Boards of Directors of several firms including TomoTherapy, Third Wave Technologies (acquired by Hologic) and NimbleGen Systems (acquired by Roche). Mr. Neis was appointed to the Board of the Wisconsin Technology Council and he also serves on the advisory boards for the Weinert Applied Ventures Program and Tandem Press at the University of Wisconsin - Madison. Mr. Neis has a B.S. in Finance from the University of Utah, and a M.S. in Marketing and Finance from the University of Wisconsin, Madison. He is a Chartered Financial Analyst. Mr. Neis' extensive experience leading emerging companies makes him a highly qualified member of our board of directors.

**John E. Niederhuber.** Dr. Niederhuber became a director of our Company at the time of the Acquisition. From August 2010 to the present, Dr. Niederhuber has served as executive vice president of Inova Health System and chief executive officer of the Inova Translational Medicine Institute. Since July 2011, he has been an adjunct Professor of Oncology at the Johns Hopkins University School of Medicine and Deputy Director of The Johns Hopkins Clinical Research Network. Since August 2010, Dr. Niederhuber has served as a Director on the Emergent Biosolutions Board. Dr. Niederhuber served as Director of the National Cancer Institute (NCI) from 2005 to 2010. He has also served as NCI's Chief Operating Officer and Deputy Director for Translational and Clinical Sciences. Dr. Niederhuber served as Chair of the National Cancer Advisory Board (NCAB) from 2002 to 2004. In addition to his management and advisory roles, Dr. Niederhuber has remained involved in research, through his laboratory on the National Institutes of Health (NIH) campus. Under his leadership, the Tumor and Stem Cell Biology Section, which is a part of the Cell and Cancer Biology Branch of NCI's Center for Cancer Research, is studying tissue stem cells as the cell-of-origin for cancer. Dr. Niederhuber also holds a clinical appointment on the NIH Clinical Center Medical Staff. As a surgeon, Dr. Niederhuber's clinical emphasis is on gastrointestinal cancer, hepatobiliary (liver, bile duct, and gall bladder) cancer, and breast cancer. He is recognized for his pioneering work in hepatic artery infusion chemotherapy and was the first to demonstrate the feasibility of totally implantable vascular access devices. Dr. Niederhuber is a graduate of Bethany College in West Virginia and the Ohio State University School of Medicine. He was an NIH Academic Trainee in Surgery at the University of Michigan from 1969 to 1970 and was a Visiting Fellow in the Division of Immunology at The Karolinska Institute in Stockholm, Sweden from 1970 to 1971. He completed his training in surgery at the University of Michigan in 1973 and was a member of the faculty of the University of Michigan from 1973 to 1987, being promoted to Professor of Microbiology/Immunology and Professor of Surgery in 1980. During 1986 and 1987, he was Visiting Professor in the Department of Molecular Biology and Genetics at The Johns Hopkins University School of Medicine in Baltimore, MD. Dr. Niederhuber's qualifications to serve on our board of directors include his extensive experience with cancer research.

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

**Michael F. Tweedle.** Dr. Tweedle became a director of Novelos at the time of the Acquisition. Since May 2009 he has served as Professor and Stefanie Spielman Chair in Cancer Imaging in Radiology and the James Comprehensive Cancer Center of Ohio State University, Director of the Wright Center Molecular Imaging (MI) Agents Laboratory of Ohio State University, and since May 2010, has had an adjunct appointment in the Chemistry Department of Ohio State University. Prior to joining Ohio State University, his academic appointments included Adjunct Associate Professor at University of Pennsylvania and the Science Advisory Board of New York University. Dr. Tweedle was the President of Bracco Research USA Inc. from 1995 to 2009 where he was the lead scientist and chief executive for creation of new molecular imaging pharmaceuticals. His industrial experience in drug discovery research also includes appointments at the Diagnostics Drug Discovery Division at Bristol-Myers Squibb, New England Nuclear, NEN/DuPont Pharmaceuticals, and The Squibb Institute for Medical Research. He has invented and led translational development of diagnostic imaging pharmaceuticals for nuclear medicine, one of the first gadolinium-based MRI agents (ProHance TM), X ray, Optical and US agents, and a radiotheranostic. In 2005 he won the Harry Fisher Medal. Dr. Tweedle holds a B.A from Knox College, B.A. (1973), a Ph.D. from Rice University (1978) and was a Stanford University NRS Fellow. Dr. Tweedle's qualifications to serve on our board of directors include his extensive experience with radiation and cancer research and drug discovery.

### **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, 2011 and whose annual compensation exceeded \$100,000 for that year.

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

<b>Name and Principal Position</b>	<b>Year</b>	<b>Salary (\$)</b>	<b>Bonus (\$) (1)</b>	<b>Option Awards (\$) (2)</b>	<b>All other compensation (\$)</b>	<b>Total (\$)</b>
Harry S. Palmin (3)(4)	2011	\$ 270,000	\$ 0	\$ 917,570	\$ 0	\$ 1,187,570
President, Chief Executive Officer	2010	\$ 270,000	\$ 0	\$ 0	\$ 0	\$ 270,000
Christopher J. Pazoles (3)	2011	\$ 246,250	\$ 0	\$ 271,470	\$ 0	\$ 517,720
Senior Vice President of Research and Development	2010	\$ 235,000	\$ 39,167	\$ 0	\$ 0	\$ 274,167
Joanne M. Protano (3)	2011	\$ 190,000	\$ 0	\$ 203,603	\$ 0	\$ 393,603
Vice President, Chief Financial Officer and Treasurer	2010	\$ 175,000	\$ 29,167	\$ 0	\$ 0	\$ 204,167

- (1) Bonus amounts for Dr. Pazoles and Ms. Protano in 2010 represent retention bonuses paid as of October 1, 2010 pursuant to their respective retention agreements dated May 14, 2010.
- (2) The amounts shown in this column represent the aggregate grant-date fair value of each stock award, without regard to the portion of the award that vested during the respective year and was estimated on the grant date using the Black-Scholes option-pricing model. There were no option grants during 2010. The compensation expense associated with the vested portion of the option grants as recorded in our statement of operations for the year ended December 31, 2011 was \$123,718 for Mr. Palmin, \$48,547 for Dr. Pazoles and \$36,411 for Ms. Protano. The unrecorded compensation expense associated with the unvested portion of the option grants is \$793,852 for Mr. Palmin, \$222,923 for Dr. Pazoles and \$167,192 for Ms. Protano. See Note 10 to the financial statements for a description of the assumptions used in estimating the fair value of stock options and recognition of compensation expense.
- (3) Effective January 1, 2012, all salaries were increased by 2%, including the salaries of the named executive officers.
- (4) The aggregate grant-date fair value for option awards granted to Mr. Palmin during 2011 excludes \$772,305 related to performance-based awards because such awards with an aggregate value of \$381,277 were forfeited during 2011 and it is not yet probable that performance awards with a grant-date fair value totaling \$391,028 will vest.

## 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, 2011 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 (as defined below) 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 provides for the vesting of unvested options upon a Change of Control, defined as the sale of all or substantially all of the assets or issued and outstanding capital stock of the Company, (ii) merger or consolidation involving the Company in which stockholders of the Company immediately before such merger or consolidation do not own immediately after such merger or consolidation capital stock or other equity interests of the surviving corporation or entity representing more than fifty percent (50%) in voting power of capital stock or other equity interests of such surviving corporation or entity outstanding immediately after such merger or consolidation, or (iii) a change, without the approval of the board of directors, in the composition of the board of directors such that directors who were serving as of the date of the agreement cease to constitute a majority of the board of directors. 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 June 1, 2011, the employment agreement between the Company and Harry Palmin dated January 31, 2006 was amended to remove the obligation of the Company to continue to pay Mr. Palmin's salary and benefits for a period of 11 months following termination by the Company without Cause or termination by Mr. Palmin with Good Reason. The Company may elect that the obligation of Mr. Palmin not to compete with the Company survive for a period of one year from his termination, provided however that Mr. Palmin would continue to receive his base salary during that one-year noncompetition period.

We had entered into retention agreements with each of our four vice presidents. The agreements provided for the lump-sum payment of six months' base salary and benefits to each such officer following a termination without cause or a resignation with good reason occurring on or before November 14, 2011. Certain of the agreements provided that if the executives were employed by us as of October 1, 2010, they would receive a payment of two months' base salary as a retention bonus on that date. The retention bonus was paid in October 2010 and would have been deducted from the severance amounts that became payable upon a subsequent involuntary termination. The retention agreements expired in November 2011.

## Outstanding Equity Awards at Fiscal Year-End

The following table sets forth certain information regarding stock options held as of December 31, 2011 by the executive officers named in the summary compensation table. There were no option grants during 2010.

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	2011(1)	—	335,100	\$ 0.45	12/16/2021
	2011(2)	—	335,100	1.40	5/18/2021
	2011(1)	83,775	586,425	1.40	5/18/2021
	2009(3)	1,090	543	114.75	12/8/2019
	2008(4)	2,614	—	65.79	12/15/2018
	2007(4)	1,307	—	69.00	12/17/2017
	2006(4)	980	—	139.23	12/11/2016
	2005(5)	1,633	—	1.53	1/31/2015
	2005(5)	980	—	1.53	3/31/2015
	2004(6)	2,156	—	1.53	4/1/2014
2003(7)	46	—	107.10	8/1/2013	
Christopher J. Pazoles	2011(3)	—	100,000	\$ 0.45	12/16/2021
	2011(3)	33,333	166,667	1.40	5/18/2021
	2009(3)	871	436	114.75	12/8/2019
	2008(4)	1,307	—	65.79	12/15/2018
	2007(4)	816	—	69.00	12/17/2017
	2006(4)	653	—	139.23	12/11/2016
	2005(8)	654	—	1.53	4/8/2015
Joanne M. Protano	2011(3)	—	75,000	\$ 0.45	12/16/2021
	2011(3)	24,999	125,001	1.40	5/18/2021
	2009(3)	871	436	114.75	12/8/2019
	2008(4)	1,307	—	65.79	12/15/2018
	2007(4)	653	—	69.00	12/17/2017
	2006(4)	261	—	139.23	12/11/2016
	2006(4)	392	—	139.23	6/16/2016

- (1) These shares vest quarterly in increments of one-sixteenth over four years from the date of grant. The exercise price equals the closing price on the date of grant.
- (2) These shares vest based on the achievement of specified milestones.
- (3) These shares vest quarterly in increments of one-twelfth over three years from the date of grant. The exercise price equals the closing price on the date of grant.
- (4) 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.
- (5) 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.
- (6) 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.
- (7) 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.



- (8) 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.

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, 2011.

<b>Name and Principal Position</b>	<b>Year</b>	<b>Director Fees (\$ (2))</b>	<b>Option Awards (\$ (3))</b>	<b>All other compensation (\$)</b>	<b>Total (\$)</b>
Stephen A. Hill, Chairman (1)	2011	\$ 46,250	\$ 201,368	\$ —	\$ 247,618
T. Rockwell Mackie (1)	2011	25,500	134,245	—	159,745
James S. Manuso, Director (1)	2011	27,500	134,245	—	161,745
John Neis, Director (1)	2011	24,750	134,245	—	158,995
John E. Niederhuber, Director (1)	2011	24,000	134,245	—	158,245
Howard M. Schneider, Director (1)	2011	40,500	134,245	—	174,745
Michael F. Tweedle, Director (1)	2011	21,750	134,245	—	155,995

- (1) As of December 31, 2011, outstanding options to purchase common stock held by directors were as follows: Dr. Hill 227,285; Dr. Mackie 150,000; Dr. Manuso 151,958; Mr. Neis 150,000; Dr. Niederhuber 150,000; Mr. Schneider 151,629; Dr. Tweedle 150,000.
- (2) Director fees include all fees earned for director services including quarterly fees, meeting fees and committee chairman fees.
- (3) The amounts shown in this column represent the aggregate grant-date fair value of the stock awards during the year, without regard to the portion of the awards that vested during the respective year and was estimated on the grant date using the Black-Scholes option-pricing model. The compensation expense associated with the vested portion of the option awards as recorded in our statement of operations for the year ended December 31, 2011 was \$54,005 for Dr. Hill and \$36,001 each for Dr. Mackie, Dr. Manuso, Mr. Neis, Dr. Niederhuber, Mr. Schneider and Dr. Tweedle. The unrecorded compensation expense associated with the unvested portion of the option awards was \$147,363 for Dr. Hill and \$98,244 each for Dr. Mackie, Dr. Manuso, Mr. Neis, Dr. Niederhuber, Mr. Schneider and Dr. Tweedle. The fair value of each stock award was estimated on the grant date using the Black-Scholes option-pricing model. See Note 10 to the financial statements for a description of the assumptions used in estimating the fair value of stock options and recognition of compensation expense.

During 2011, we paid our non-employee directors a cash fee of \$5,000 per quarter. The non-employee directors also received a fee of \$1,500 for any board or committee meeting attended and \$750 for each telephonic board or committee meeting in which the director participated. We also paid our chairman an additional annual fee in the amount of \$15,000, our non-employee director who serves as the chair of the audit committee an additional annual fee of \$10,000 and our non-employee directors who served as the chairman of the compensation and the 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 2012.

**Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.**

At the close of business on March 2, 2012, there were 36,907,824 shares of our common stock outstanding. The following table provides information regarding beneficial ownership of our common stock as of March 2, 2012:

- 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. In these cases, the information with respect to voting and investment power has been provided to us by the security holder. The identification of natural persons having voting or investment power over securities held by a beneficial owner listed on the table below does not constitute an admission of beneficial ownership of any such natural person. Shares included in the “Right to Acquire” column consist of shares that may be purchased through the exercise of options or warrants that are exercisable within 60 days of March 2, 2012.

<u>Name and Address of Beneficial Owner</u>	<u>Outstanding</u>	<u>Right to Acquire</u>	<u>Total</u>	<u>Percentage</u>
Venture Investors LLC (1) (2) University Technology Park 505 S. Rosa Road; Suite 201 Madison, Wisconsin 53719	5,634,308	3,143,750	8,778,058	21.9
CLS Capital Holdings Limited (3)(4) Bordeaux Court, Les Echelons St. Peter Port, Guernsey, GY13DR Channel Islands	3,333,334	3,333,334	6,666,668	16.6
Jamey P. Weichert (5) c/o Novelos Therapeutics, Inc. 3301 Agriculture Drive Madison, Wisconsin 53716	4,706,730	39,665	4,746,395	12.8
Fidelity Management and Research Co. (3)(6) 82 Devonshire Street Boston, Massachusetts 02109	2,500,000	2,500,000	5,000,000	12.7
Greenway Properties Inc. (7) 725 Heartland Trail, Suite 102 Madison, Wisconsin 53707	2,267,400	1,600,000	3,867,400	10.0
Harry S. Palmin (8)	4,190	157,545	161,735	*
Christopher J. Pazoles	0	62,742	62,742	*
Joanne M. Protano	0	47,341	47,341	*
Stephen A. Hill	0	67,910	67,910	*
Thomas Rockwell Mackie	116,121	43,750	159,871	*
James S. Manuso	0	45,708	45,708	*
John Neis (1) (2)	5,634,308	3,143,750	8,778,058	21.9
John E. Niederhuber	0	43,750	43,750	*
Howard M. Schneider	653	45,379	46,032	*
Michael F. Tweedle	0	43,750	43,750	*
All directors and officers as a group (13 persons)	10,532,655	3,872,239	14,404,894	35.3

- (1) Ownership consists of shares of common stock held by Venture Investors Early Stage Fund IV Limited Partnership and Advantage Capital Wisconsin Partners I, Limited Partnership. VIESF IV GP LLC is the general partner of Venture Investors Early Stage Fund IV Limited Partnership and Venture Investors LLC is the submanager and special limited partner of Advantage Capital Wisconsin Partners I, Limited Partnership. The investment decisions of VIESF IV GP LLC and Venture Investors LLC are made collectively by six managers, including Mr. Neis. Each such manager and Mr. Neis disclaim such beneficial ownership except to the extent of his pecuniary interest therein. The address of Mr. Neis is c/o Venture Investors LLC, 505 South Rosa Road, #201, Madison, Wisconsin 53719.
- (2) Shares in the “Right to Acquire” column consist of warrants to purchase 2,000,000 shares common stock at \$0.75 per share, expiring on March 31, 2016, warrants to purchase 1,100,000 shares of common stock at \$0.60 per share expiring on December 6, 2016, both held by Venture Investors Early Stage Fund IV Limited and options to purchase 43,750 shares of common stock at \$1.40 per share, issued to Mr. Neis.
- (3) Shares in the “Right to Acquire” column consist of warrants to purchase shares of common stock at \$0.60 per share expiring on December 6, 2016.
- (4) Interlock Director Ltd. has sole dispositive and voting power over shares held by CLS Capital Holdings Limited. Interlock Director Ltd. exercises such power through Michael Kupenga and a combination of two directors of Virtus Directors Limited. The Virtus directors consist of the following individuals: David Allison, Roderick Arthur, Nicholas Moss, Trevor Pinchemain, Stephen Kirk, Grada Hek, Martin LePage, Lesley Pinchemain, Cerisse Fisher, Pierre Renier and Jonathan Seymour.
- (5) Dr. Weichert serves as a director and our Chief Scientific Officer following the Acquisition. The shares beneficially owned by him have been included in the total of directors and officers as a group.
- (6) Consists of shares held by Fidelity Select Portfolios: Biotechnology Portfolio and Fidelity Advisor Series VII: Fidelity Advisor. Dispositive and voting power for the shares is held by the Fidelity Funds Board of Trustees.
- (7) Shares in the “Outstanding” column include shares held by Jeffrey Straubel. Jeffrey Straubel is the President and principal owner of Greenway Properties, Inc. and has sole dispositive and voting power over shares held by Greenway Properties, Inc. Shares in the “Right to Acquire” column consist of warrants to purchase 1,000,000 shares common stock at \$0.75 per share, expiring on March 31, 2016, warrants to purchase 600,000 shares of common stock at \$0.60 per share expiring on December 6, 2016.
- (8) Ownership of Harry Palmin includes shares owned by his wife, Deanna Palmin.

#### **Equity compensation plans**

The following table provides information as of December 31, 2011 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. During 2004 and 2005, we also issued options to our directors and consultants that were not approved by our stockholders and during 2011 we issued options to certain 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**

<b>Plan category</b>	<b>Number of shares to be issued upon exercise of outstanding options, warrants and rights (#)</b> (a)	<b>Weighted-average exercise price of outstanding options, warrants and rights (\$)</b> (b)	<b>Number of shares remaining available for future issuance under equity compensation plans (excluding shares reflected in column (a)) (#)</b> (c)
Equity compensation plans approved by stockholders	4,717,500	\$ 1.63	2,281,112
Equity compensation plans not approved by stockholders	110,138	\$ 10.16	0
<b>Total</b>	<u>4,827,638</u>	\$ 1.82	<u>2,281,112</u>

**Item 13. Certain Relationships and Related Transactions, and Director Independence.**

We do not have a written policy for the review, approval or ratification of transactions with related parties or conflicted transactions. When such transactions arise, they are referred to the Audit Committee for consideration or for referral to the Board of Directors for its consideration.

One of our directors, John Neis, is a managing director of Venture Investors LLC, which beneficially owns approximately 23% of our common stock.

Jamey Weichert, our Chief Scientific Officer, director, shareholder and principal founder of Collectar, is a faculty member at the University of Wisconsin-Madison (U. Wisc.). During the year ended December 31, 2011, we made contributions totaling \$206,500 to U. Wisc. for use towards unrestricted research activities.

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

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

On June 28, 2010, we received a letter from counsel to ZAO BAM and ZAO BAM Research Laboratories (collectively, “BAM”) alleging that we modified the chemical composition of NOV-002 without prior notice to or approval from BAM, constituting a material breach of a technology and assignment agreement we had entered into with BAM on June 20, 2000 (the “June 2000 Agreement”). The letter references our amendment, submitted to the FDA on August 30, 2005, to our investigational new drug application dated August 1999 as the basis for BAM’s claims and demands the transfer of all intellectual property rights concerning NOV-002 to BAM. Mark Balazovsky, a director of Novelos from June 1996 until November 2006 and a shareholder of Novelos through at least June 25, 2010, is, to our knowledge, still the general director and principal shareholder of ZAO BAM. On September 24, 2010, we filed a complaint in Suffolk Superior Court seeking a declaratory judgment by the court that the June 2000 Agreement has been replaced by a subsequent agreement between the parties dated April 1, 2005 (the “April 2005 Agreement”), that the Company’s obligations to BAM are governed solely by the April 2005 Agreement and that the obligations of the June 2000 agreement have been performed and fully satisfied. On November 29, 2010, BAM answered our complaint, denying the material allegations and stating its affirmative defenses and certain counterclaims. On January 14, 2011, we responded to the counterclaims, denying BAM’s material allegations and stating our affirmative defenses. On June 9, 2011, BAM filed an amended counterclaim alleging additional claims related to Novelos’ acquisition of Cellectar. In that amended counterclaim, BAM alleges that the acquisition evidences Novelos’ abandonment of the technology assigned to it by BAM constituting a breach of the June 2000 Agreement or, if that agreement is determined to no longer be in effect, a breach of the April 2005 Agreement and/or a breach of the implied duty of good faith and fair dealing with respect to the April 2005 Agreement. On June 15, 2011 we filed our response to their amended counterclaim. On August 5, 2011, we filed a motion for judgment on the pleadings as to our declaratory judgment count and all counts of BAM’s amended counterclaim. The motion was opposed by BAM and a hearing on the motion was held on September 27, 2011. On October 17, 2011, the court ruled on our behalf for each of our declaratory judgment claims and dismissed all counts of BAM’s counterclaim. Judgment in favor of the Company was entered on October 20, 2011. On November 14, 2011 BAM filed a notice of appeal.

As a result of the assignment to Novelos of the exclusive worldwide intellectual property and marketing rights of oxidized glutathione (excluding the Russian Territory), Novelos is obligated to the Oxford Group, Ltd., or its assignees, for future royalties. Simyon Palmin, a founder of Novelos, a director until August 15, 2008 and the father of our president and chief executive officer, is president of Oxford Group, Ltd. Mr. Palmin was also an employee of Novelos until September 2008 and performed consulting services to the Company through December 2009. Pursuant to the agreement, as revised May 26, 2005, Novelos is required to pay Oxford Group, Ltd., or its assignees, a royalty in the amount of 0.8% of our 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 and seven of our nine directors meet 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 and Jamey P. Weichert are not independent directors.

#### Item 14. Principal Accounting Fees and Services.

On May 25, 2011, we engaged Grant Thornton LLP (“GT”) as our principal accountant to audit our financial statements for the fiscal year ending December 31, 2011, as well as to review the Company’s interim financial statements during the remainder of 2011. The Company engaged GT to replace Stowe & Degon LLC (“SD”), whom the Company declined to re-engage, as the Company’s principal accountant as of May 25, 2011.

Aggregate fees for professional services rendered by our principal accountant (GT in 2011 and SD in 2010) for the following years were:

	<u>2011</u>	<u>2010</u>
Audit	\$ 260,277	\$ 89,800
Audit Related	—	—
Tax	12,584	—
All Other	—	—
<b>Total</b>	<b><u>\$ 272,861</u></b>	<b><u>\$ 89,800</u></b>

*Audit Fees:* Audit fees were for professional services rendered for the audit of our annual financial statements, the review of quarterly financial statements and the preparation of statutory and regulatory filings. The 2011 and 2010 amounts include approximately \$58,000 and \$8,300, respectively, in fees associated with work performed in connection with registration statements. Additionally, the 2011 audit fees also include the fees associated with audit of the Collectar financial statements for the year ended December 31, 2010, the review of the 2010 Collectar quarterly financial statements and the review of the quarterly financial statements of Collectar for the three months ended March 31, 2011.

*Audit-Related Fees:* Audit-related fees include fees for assurance and related services by the principal accountant that are reasonably related to the performance of audit and reviews but that are not included under “Audit Fees” above. No such services were provided by GT or SD.

*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 and mergers and acquisitions. No such services were provided by SD.

*All Other Fees:* All other fees include assistance with miscellaneous reporting requirements and interpretation of technical issues. No such services were provided by GT or SD.

***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 GT to provide those services.

Our audit committee has not established any pre-approval policies or procedures that would allow our management to engage GT 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 GT for 2011 or SD for 2010 were obtained in reliance on the waiver of the pre-approval requirement afforded in SEC regulations.

**PART IV**

**Item 15. Exhibits.**

Exhibit No.	Description	Filed with this Form 10-K	Incorporated by Reference		Exhibit No.
			Form	Filing Date	
2.1	Agreement and Plan of Merger by and among Novelos Therapeutics, Inc., Cell Acquisition Corp. and Collectar, Inc. dated April 8, 2011		8-K	April 11, 2011	2.1
3.1	Second Amended and Restated Certificate of Incorporation		8-K	April 11, 2011	3.1

3.2	Amended and Restated By-laws	8-K	June 1, 2011	3.1
4.1	Form of common stock certificate	S-1/A	November 9, 2011	4.1
10.1	Employment Agreement with Harry S. Palmin dated January 31, 2006 *	8-K	February 6, 2006	99.1
10.2	Second Amendment to Employment Agreement between the Company and Harry Palmin *	8-K	June 1, 2011	10.1
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	Consideration and new technology agreement dated April 1, 2005 with ZAO BAM	10-QSB	August 15, 2005	10.2
10.8	2006 Stock Incentive Plan, as amended *	8-K	May 23, 2011	10.1
10.9	Form of Incentive Stock Option under Novelos Therapeutics, Inc.'s 2006 Stock Incentive Plan*	8-K	December 15, 2006	10.1
10.10	Form of Non-Statutory Stock Option under Novelos Therapeutics, Inc.'s 2006 Stock Incentive Plan*	8-K	December 15, 2006	10.2
10.11	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
10.12	Collaboration Agreement dated February 11, 2009**	10-K	March 30, 2009	10.39
10.13	Common Stock Purchase Warrant dated February 11, 2009	8-K	February 18, 2009	4.2
10.16	Form of Placement Agent Agreement Between the Company and Rodman and Renshaw, LLC	S-1A	June 25, 2010	10.50
10.17	Written Consent and Waiver of Holders of Series C Convertible Preferred Stock and Series E Convertible Preferred Stock dated July 6, 2010	S-1A	July 7, 2010	10.52
10.18	Form of Common Stock Purchase Warrant issued pursuant to the Consent and Waiver of Holders of Series C Convertible Preferred Stock and Series E Convertible Preferred Stock dated July 6, 2010	S-1A	July 7, 2010	10.53

10.19	Form of Securities Purchase Agreement dated July 21, 2010	8-K	July 22, 2010	10.1
10.20	Amendment to Consent and Waiver of Holders of Series C Convertible Preferred Stock and Series E Convertible Preferred Stock dated July 21, 2010	8-K	July 22, 2010	10.2
10.21	Exchange Agreement dated November 30, 2010 between the Company and the holders of Series C Convertible Preferred Stock and Series E Convertible Preferred Stock	8-K	November 30, 2010	10.1
10.22	Form of Common Stock Purchase Warrant dated April 8, 2011	8-K	April 11, 2011	4.3
10.23	Securities Purchase Agreement dated April 8, 2011	8-K	April 11, 2011	10.1
10.24	Placement Agency Agreement dated April 1, 2011	8-K	April 11, 2011	99.1
10.25	License Agreement between Collectar, LLC and the Regents of the University of Michigan dated September 14, 2003, as amended through June 2010	S-1	July 1, 2011	10.31
10.26	Lease Agreement between Collectar, LLC and McAllen Properties LLC, as amended and extended to date	S-1	July 1, 2011	10.32
10.27	Loan Agreement between the Wisconsin Department of Commerce and Collectar, Inc. dated September 15, 2010	S-1	July 1, 2011	10.33
10.28	General Business Security Agreement dated September 15, 2010	S-1	July 1, 2011	10.34
10.29	Underwriting Agreement dated December 1, 2011 between the Company and Rodman and Renshaw, LLC	8-K	December 7, 2011	1.1
10.30	Form of Warrant dated December 6, 2011	S-1/A	November 9, 2011	4.2
21.1	List of Subsidiaries			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
101	Interactive Data Files	X

\* Management contract or compensatory plan or arrangement.

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

**SIGNATURES**

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

**NOVELOS THERAPEUTICS, INC.**

By: /s/ Harry S. Palmin  
Harry S. Palmin  
Title: President, Chief Executive Officer  
Date: March 9, 2012

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 9, 2012

By: /s/ Joanne M. Protano  
Joanne M. Protano  
Title: Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)  
Date: March 9, 2012

By: /s/ Stephen A. Hill  
Stephen A. Hill  
Title: Chairman of the Board of Directors  
Date: March 9, 2012

By: /s/ Thomas Rockwell Mackie  
Thomas Rockwell Mackie  
Title: Director  
Date: March 9, 2012

By: /s/ James S. Manuso  
James S. Manuso  
Title: Director  
Date: March 9, 2012

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By: /s/ John Neis

John Neis

Title: Director

Date: March 9, 2012

By: /s/ John E. Niederhuber

John E. Niederhuber

Title: Director

Date: March 9, 2012

By: /s/ Howard M. Schneider

Howard M. Schneider

Title: Director

Date: March 9, 2012

By: /s/ Michael F. Tweedle

Michael F. Tweedle

Title: Director

Date: March 9, 2012

By: /s/ Jamey P. Weichert

Jamey P. Weichert

Title: Chief Scientific Officer and Director

Date: March 9, 2012

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**NOVELOS THERAPEUTICS, INC.  
LIST OF SUBSIDIARIES**

Set forth below is a list of the subsidiaries of Novelos Therapeutics, Inc. as of December 31, 2011:

<b><u>Subsidiary Name</u></b>	<b><u>Jurisdiction of Organization</u></b>
Collectar, Inc.	Wisconsin

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**EXHIBIT 31.1**

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

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

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

Date: March 9, 2012

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

Date: March 9, 2012

/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, 2011, 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 9, 2012

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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