CEL SCI CORP
Form 10-K
December 23, 2011

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended September 30, 2011.

o 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 1-11889

CEL-SCI CORPORATION
(Exact name of registrant as specified in its charter)

COLORADO (State or other jurisdiction of incorporation or organization)	84-0916344 (I.R.S. Employer Identification No.)
8229 Boone Blvd., Suite 802 Vienna, Virginia (Address of principal executive offices)	22182 (Zip Code)

Registrant's telephone number, including area code: (703) 506-9460
Securities registered pursuant to Section 12(b) of the Act: None
Securities registered pursuant to Section 12(g) of the Act:

Common Stock, $.01 par value
(Title of Class)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. o

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. o

Indicate by check mark whether the registrant (1) has filed all reports 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 þ No o

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 (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes þ No o

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. þ

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.

Large accelerated filer	o	Accelerated filer	o
Non-accelerated filer (Do not check if a smaller reporting company)	o	Smaller reporting company	þ

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

The aggregate market value of the voting stock held by non-affiliates of the Registrant, based upon the closing sale price of the common stock on March 31, 2011, as quoted on the NYSE Amex, was $127,184,966.

As of December 9, 2011, the Registrant had 229,889,691 issued and outstanding shares of common stock.

Documents Incorporated by Reference: None

PART I

ITEM 1. BUSINESS

CEL-SCI Corporation (CEL-SCI) was formed as a Colorado corporation in 1983. CEL-SCI's principal office is located at 8229 Boone Boulevard, Suite 802, Vienna, VA 22182. CEL-SCI's telephone number is 703-506-9460 and its web site is www.cel-sci.com. CEL-SCI makes its electronic filings with the Securities and Exchange Commission (SEC), including its annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to these reports available on its website free of charge as soon as practicable after they are filed or furnished to the SEC.

OVERVIEW

CEL-SCI's business consists of the following:

1) Multikine® (Leukocyte Interleukin, Injection) investigational cancer therapy;

2) LEAPS technology, with two products, pandemic flu treatment for hospitalized patients and CEL-2000, a rheumatoid arthritis treatment vaccine, in development.

MULTIKINE

CEL-SCI's lead investigational therapy, Multikine (Leukocyte Interleukin, Injection), is currently being developed as a potential therapeutic agent directed at using the immune system to produce an anti-tumor immune response. Data from Phase I and Phase II clinical trials suggest Multikine has the potential to directly affect the tumor cells. These data also indicate that it appears to activate the patient's own anti-tumor immune response. Multikine (Leukocyte Interleukin, Injection) is the full name of this investigational therapy, which, for simplicity, is referred to in the remainder of this document as Multikine. Multikine is the trademark that CEL-SCI has registered for this investigational therapy, and this proprietary name is subject to FDA review in connection with our future anticipated regulatory submission for approval. Multikine has not been licensed or approved by the FDA or any other regulatory agency. Neither has its safety or efficacy been established for any use.

CEL-SCI's lead investigational therapy, Multikine, is cleared for a Phase III clinical trial in advanced primary head and neck cancer. It has received a go-ahead by the US FDA as well as the Canadian, Polish, Hungarian, Russian, Israeli, Indian and Taiwanese regulators.

It is also thought to be the first Phase III study in the world in which immunotherapy is given to cancer patients first, i.e., prior to their receiving any conventional treatment for cancer, including surgery, radiation and/or chemotherapy. This could be shown to be important because conventional therapy may weaken the immune system, and may compromise the potential effect of immunotherapy. Because Multikine is given before conventional cancer therapy, when the immune system may be more intact, we believe the possibility exists for it to have a greater likelihood of activating an anti-tumor immune response under these conditions. This likelihood is one of the clinical aspects being evaluated in the ongoing global Phase III clinical trial.

Multikine is a different kind of investigational therapy in the fight against cancer; Multikine is a defined mixture of cytokines. It is a combination immunotherapy, possessing both active and passive properties.

During the early investigational phase, in Phase I and Phase II clinical trials in over 220 subjects who received the investigational therapy Multikine in daily doses of 200 to 3200 IU as IL-2, no serious adverse events were reported as being expressly due to administration of this investigational therapy Multikine. The most frequently reported adverse events included pain at the injection site, local minor bleeding and edema at the injection site, diarrhea, headache, nausea, and constipation. No "abnormal" laboratory results were reported following Multikine treatment - other than those commonly seen by treating physicians in this patient population - regardless of Multikine administration. Similarly, in these early-phase clinical studies in patients, there was no reported increased toxicity of follow-on treatments as a result of Multikine administration. No complications following surgery (such as increased time for wound healing) were reported. No definitive conclusions can be drawn from these data about the safety or efficacy profile of this investigational therapy, and further research is required and the global Phase III study is ongoing in an effort to confirm these results. Potential conclusions could only be drawn if the initial observations in the early-phase studies relating to the potential adverse events associated with Multikine administration and its potential efficacy in treating head and neck cancer are confirmed in the well-controlled Multikine Phase III clinical study, CEL-SCI's Phase III efficacy study is completed successfully, and the FDA licenses the product following their review of all of the data related to Multikine submitted in CEL-SCI's license application.

Currently, Multikine has not yet been licensed or approved for sale, barter or exchange by the FDA or by any other regulatory agency. Similarly, its safety or efficacy has not been established for any use.

The following is a summary of results from CEL-SCI’s last Phase II study conducted with Multikine. This study used the same treatment protocol as will be used in CEL-SCI’s Phase III study:

Phase II clinical trials: In the final Phase II clinical study, using the same dosages and Multikine treatment regimen as is being used in the Phase III study, head and neck cancer patients with locally advanced primary disease who received the investigational therapy Multikine as first-line therapy followed by surgery and radiotherapy were reported by the clinical investigators to have had a 63.2% overall survival (OS) rate at 3.5 years from surgery. This percentage OS was arrived at as follows: of the 22 subjects enrolled in this final Phase II study, the consent for the survival follow-up portion of the study was received from 19 subjects. One subject did not consent to the follow-up portion of the study. The other 2 subjects did not have squamous cell carcinoma of the oral cavity and were thus not evaluable per the protocol. The overall survival rate of subjects receiving the investigational therapy in this study was compared to the overall survival rate that was calculated based upon a review of 55 clinical trials conducted in the same cancer population with a total of 7294 subjects patients studied, which were reported in the peer reviewed scientific literature between 1987 and 2007. Review of this literature showed an approximate survival rate of 47.5% at 3.5 year from treatment. Therefore, the results of CEL-SCI’s final Phase II study were considered to be potentially favorable in terms of overall survival recognizing the limitations of this early-phase study. It should be noted that an earlier investigational therapy Multikine study appears to lend support to the overall survival findings described above – Feinmesser et al Arch Otolaryngol. Surg. 2003. However, no definitive conclusions can be drawn from these data about the potential efficacy or safety profile of this investigational therapy. Moreover, further research is required, and these results must be confirmed in the well-controlled Phase III clinical trial of this investigational therapy that is currently in progress. Subject to completion of that Phase III trial and FDA's review and acceptance of CEL-SCI's entire data set on this investigational therapy, CEL-SCI believes that these early-stage clinical trial results indicate the potential for this investigational therapy to become a treatment for advanced primary head and neck cancer.

The primary clinical endpoint in CEL-SCI's ongoing Phase III clinical trial specifies that a 10% improvement in overall survival in the Multikine treatment arm plus the current standard of care (SOC - consists of surgery + radiotherapy or surgery + radiochemotherapy) over that which can be achieved in the SOC arm alone must be achieved in order to meet the primary endpoint of the Phase III study. Based on what is presently known about the current survival statistics for this population, CEL-SCI believes that achievement of this endpoint should enable CEL-SCI, subject to further consultations with FDA, to move forward, prepare and submit a Multikine Biologic License Application for marketing approval to FDA.

Reported average of 50% reduction in tumor cells in Phase II trials: The clinical investigators who administered the 3 week Multikine treatment regimen used in Phase II studies reported that, as was determined in a controlled pathology study, Multikine administration appeared to have caused, on average, the disappearance of about half of the cancer cells present at surgery (as determined by histopathology assessing the area of Stroma/Tumor (Mean+/- Standard Error of the Mean of the number of cells counted per filed)) even before the start of standard therapy with radiation and chemotherapy (Timar et al JCO 2005).

Reported 12% complete response in the final Phase II trial: The clinical investigators who administered the 3 week Multikine investigational treatment regimen used in the Phase II study reported that, as was determined in a controlled pathology study, the tumor apparently was no longer present in approximately 12 % of patients (2 of 17 evaluable by pathology). This determination was made by three blinded pathologists from the surgical specimen after a 3 week treatment with Multikine (Timar et al JCO 2005).

Adverse events reported in clinical trials: In clinical trials conducted to date with the Multikine investigational therapy, adverse events which have been reported by the clinical investigators as possibly or probably related to Multikine administration included pain at the injection site, local minor bleeding and edema at the injection site, diarrhea, headache, nausea, and constipation.

The clinical significance of these and other data, to date, from the multiple Multikine clinical trials is not yet known. These preliminary clinical data do suggest the potential to demonstrate a possible improvement in the clinical outcome for patients treated with Multikine. However, no definitive conclusions can be drawn from these data about the safety or efficacy profile of this investigational therapy, and further research is required and the global Phase III study is ongoing in an effort to confirm these results.

Multikine has been cleared for a global Phase III trial in advanced primary head and neck cancer. It has received a go-ahead by the US FDA as well as the Canadian, Polish, Hungarian, Russian, Israeli, Indian and Taiwanese regulators.

The trial will test the hypothesis that Multikine treatment administered prior to the current standard therapy for head and neck cancer patients (surgical resection of the tumor and involved lymph nodes followed by radiotherapy or radiotherapy and concurrent chemotherapy) will extend the overall survival, enhance the local/regional control of the disease and reduce the rate of disease progression in patients with advanced oral squamous cell carcinoma.

In November 2000, CEL-SCI entered into an agreement with Orient Europharma of Taiwan which provides Orient Europharma with the exclusive marketing rights to Multikine for all cancer indications in Taiwan, Singapore, Hong Kong and Malaysia. In December 2008, the agreement was expanded to include South Korea, the Philippines, Australia and New Zealand. The agreement requires Orient Europharma to fund the clinical trials needed to obtain marketing approvals in these countries for head and neck cancer, naso-pharyngeal cancer and potentially cervical cancer.

Pursuant to an agreement dated May 2003, Eastern Biotech is due a royalty equal to 2% of CEL-SCI's net sales worldwide of Multikine and CEL-1000 prior to May 30, 2033.

In August 2008, CEL-SCI entered into an agreement with Teva Pharmaceutical Industries, Ltd., which provides Teva with the exclusive license to market and distribute CEL-SCI's cancer drug Multikine in Israel, Turkey, and in August 2011, added Serbia and Croatia. Pursuant to the agreement, Teva will participate in CEL-SCI's upcoming Phase III clinical trial and will fund a portion of the Phase III trial in Israel.

In March 2009, CEL-SCI entered into a licensing agreement with Byron Biopharma LLC ("Byron") under which CEL-SCI granted Byron an exclusive license to market and distribute Multikine in the Republic of South Africa.

Pursuant to the agreement, Byron will be responsible for registering the product in South Africa. Once Multikine has been approved for sale, CEL-SCI will be responsible for manufacturing the product, while Byron will be responsible for sales in South Africa. Revenues will be divided equally between CEL-SCI and Byron. To maintain the license Byron, among other requirements, was required to pay $125,000 to CEL-SCI before March 15, 2010. Byron made the $125,000 payment on March 8, 2010.

In August 2011, CEL-SCI entered into an exclusive Sales, Marketing and Distribution agreement with IDC-GP Pharm LLC ("IDC-GP Pharm") under which CEL-SCI has granted IDC-GP Pharm an exclusive license to market Multikine in the countries of Argentina and Venezuela (the "Territory"). IDC-GP Pharm is a Joint Venture between two groups of experienced pharmaceutical entrepreneurs with expertise in the registration and commercialization of pharmaceutical products in South America, among other regions. One of these two groups represents former employees of a large pharmaceutical company, while the other group is GP Pharm, headquartered in Barcelona, Spain, with operations in each major country in Latin America either directly or through local partners. Pursuant to the agreement, IDC-GP Pharm will be responsible for receiving regulatory approval to use Multikine in the territory. Once Multikine has been approved in either of the two countries, CEL-SCI will be responsible for manufacturing the product, while IDC-GP Pharm will be responsible for sales in the Territory. Revenues will be split 50/50 between CEL-SCI and IDC-GP Pharm after payment to CEL-SCI for the manufacturing costs of Multikine.

Before starting the Phase III trial, CEL-SCI needed to build a dedicated manufacturing facility to produce Multikine. This facility has been completed and validated, and has produced several clinical lots for the Phase III clinical trial. CEL-SCI estimates the cost of the Phase III trial, with the exception of the parts that will be paid by its licensees, Teva Pharmaceuticals and Orient Europharma, to be approximately $26,000,000. Out of the planned 48 sites 35 sites have completed their site initiation visits and patients are being screened/enrolled in several places.

Manufacturing Facility

CEL-SCI completed validation of its new manufacturing facility in January 2010. The state-of-the-art facility is being used to manufacture Multikine for CEL-SCI's Phase III clinical trial. In addition to using this facility to manufacture Multikine, CEL-SCI, only if the facility is not being used for Multikine, may offer the use of the facility as a service to pharmaceutical companies and others, particularly those that need to "fill and finish" their drugs in a cold environment (4 degrees Celsius, or approximately 39 degrees Fahrenheit), however, priority will always be given to Multikine. Fill and finish is the process of filling injectable drugs in a sterile manner and is a key part of the manufacturing process for many medicines.

The fastest area of growth in the biopharmaceutical and pharmaceutical markets is biologics, and most recently stem cell products. These compounds and therapies are derived from or mimic human cells or proteins and other molecules (e.g., hormones, etc.). Nearly all of the major drugs developed for unmet medical needs (e.g., Avastin®, Erbitux®, Rituxan®, Herceptin®, Copaxon®, etc.) are biologics. Biologics are usually very sensitive to heat and quickly lose their biological activity if exposed to room or elevated temperature. Room or elevated temperatures may also affect the shelf-life of a biologic with the result that the product cannot be stored for as long as desired. However, these products do not generally lose activity when kept at 4 degrees Celsius.

The FDA and other regulatory agencies require a drug developer to demonstrate the safety, purity and potency of a drug being produced for use in humans. When filling a product at 4 degrees Celsius, minimal to no biological losses occur and therefore the potency of the drug is maintained throughout the final critical step of the drug's manufacturing process. If the same temperature sensitive drug is instead aseptically filled at room temperature, expensive and time-consuming validation studies must be conducted, first, to be able to obtain a complete understanding of the product's potency loss during the room temperature fill process, and second, to create solutions to the drug's potency losses, which require further testing and validation.

CEL-SCI's unique, cold aseptic filling suite can be operated at temperatures between 2 degrees Celsius and room temperatures, and at various humidity levels. CEL-SCI's aseptic filling suites are maintained at FDA and EU ISO classifications of 5/6. CEL-SCI also has the capability to formulate, inspect, label and package biologic products at cold temperatures.

CEL-SCI's lease on the manufacturing facility expires on October 31, 2028. Since October 2008 CEL-SCI has been required to make monthly base rent payments of $131,250. Beginning October 31, 2009, the annual base rent escalates each year at 3%. CEL-SCI is also required to pay all real and personal property taxes, insurance premiums, maintenance expenses, repair costs and utilities associated with the building, which were approximately $33,000 per month as of October 15, 2011.

In December 2008, CEL-SCI was not in compliance with certain lease requirements (i.e., failure to pay an installment of rent). However, the landlord did not declare CEL-SCI formally in default under the terms of the lease and renegotiated the lease. In January 2009, as part of an amended lease agreement, CEL-SCI repriced the 3,000,000 warrants issued to the landlord in July 2007 at $1.25 per share and which were to expire on July 12, 2013. These warrants were repriced at $0.75 per share and now expire on January 26, 2014. In addition, 787,500 additional warrants were issued to the landlord. The warrants are exercisable at a price of $0.75 per share and expire on January 26, 2014. In 2009 CEL-SCI issued the landlord an additional 2,296,875 warrants in accordance with the amendment to the lease. In August 2011, CEL-SCI was required to deposit the equivalent of one year's base rent in accordance with the contract. The $1,670,917 was required to be deposited when CEL-SCI's cash position fell below the amount stipulated in the lease.

LEAPS

CEL-SCI's patented T-cell Modulation Process, referred to as LEAPS (Ligand Epitope Antigen Presentation System), uses "heteroconjugates" to direct the body to choose a specific immune response. LEAPS is designed to potentially stimulate the human immune system to more effectively fight bacterial, viral and parasitic infections as well as autoimmune, allergies, transplantation rejection and cancer, when it cannot do so on its own. Administered like vaccines, LEAPS combines T-cell binding ligands with small, disease associated, peptide antigens and may provide a new method to treat and prevent certain diseases.

The ability to generate a specific immune response is important because many diseases are often not combated effectively due to the body's selection of the "inappropriate" immune response. The capability to specifically reprogram an immune response may offer a more effective approach than existing vaccines and drugs in attacking an underlying disease.

Using the LEAPS technology, CEL-SCI has created a potential peptide treatment for H1N1 (swine flu) hospitalized patients. This LEAPS flu treatment is designed to focus on the conserved, non-changing epitopes of the different strains of Type A Influenza viruses (H1N1, H5N1, H3N1, etc.), including "swine", "avian or bird", and "Spanish Influenza", in order to minimize the chance of viral "escape by mutations" from immune recognition. Therefore one should think of this treatment not really as an H1N1 treatment, but as a pandemic flu treatment. CEL-SCI's LEAPS flu treatment contains epitopes known to be associated with immune protection against influenza in animal models.

On September 16, 2009, the U.S. Food and Drug Administration advised CEL-SCI that it could proceed with its first clinical trial to evaluate the effect of LEAPS-H1N1 treatment on the white blood cells of hospitalized H1N1 patients. This followed an expedited initial review of CEL-SCI's regulatory submission for this study proposal.

On November 6, 2009, CEL-SCI announced that The Johns Hopkins University School of Medicine had given clearance for CEL-SCI's first clinical study to proceed using LEAPS-H1N1. Soon after the start of the study, the number of hospitalized H1N1 patients dramatically declined and the study has been unable to complete the enrollment of patients. If the disease reemerges, then CEL-SCI may be able to continue the study.

This pandemic flu work is being pursued in collaboration with the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health, USA. In May 2011 NIAID scientists presented data at the Keystone Conference on "Pathogenesis of Influenza: Virus-Host Interactions" in Hong Kong, China, showing the positive results of efficacy studies in mice of L.E.A.P.S. H1N1 activated dendritic cells (DCs) to treat the H1N1 virus. Scientists at the NIAID found that H1N1-infected mice treated with LEAPS-H1N1 DCs showed a survival advantage over mice treated with control DCs. The work was performed in collaboration with scientists led by Kanta Subbarao, M.B.B.S., M.P.H, of the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health, USA.

With its LEAPS technology, CEL-SCI also developed a second peptide named CEL-2000, a potential rheumatoid arthritis vaccine. The data from animal studies of rheumatoid arthritis using the CEL-2000 treatment vaccine demonstrated that CEL-2000 could potentially be an effective treatment against arthritis with fewer administrations than those required by other anti-rheumatoid arthritis treatments, including Enbrel®. CEL-2000 is also potentially a more disease type-specific therapy, is calculated to be significantly less expensive and may be useful in patients unable to tolerate or who may not be responsive to existing anti-arthritis therapies.

In February 2010 CEL-SCI announced that its CEL-2000 vaccine demonstrated that it was able to block the progression of rheumatoid arthritis in a mouse model. The results were published in the scientific peer-reviewed Journal of International Immunopharmacology (online edition) in an article titled "CEL-2000: A Therapeutic Vaccine for Rheumatoid Arthritis Arrests Disease Development and Alters Serum Cytokine/Chemokine Patterns in the Bovine Collagen Type II Induced Arthritis in the DBA Mouse Model" with lead author Dr. Daniel Zimmerman. The study was co-authored by scientists from CEL-SCI, Washington Biotech, Northeastern Ohio Universities Colleges of Medicine and Pharmacy and Boulder BioPath.

None of the LEAPS investigational products have been approved for sale, barter or exchange by the FDA or any other regulatory agency for any use to treat disease in animals or humans. The safety or efficacy of these products has not been established for any use. Lastly, no definitive conclusions can be drawn from these early-phase, preclinical-trials data involving these investigational products. Before obtaining marketing approval from the FDA in the United States, and by comparable agencies in most foreign countries, these product candidates must undergo rigorous preclinical and clinical testing which is costly and time consuming and subject to unanticipated delays. There can be no assurance that these approvals will be granted.

PATENTS

CEL-SCI currently has eight patents issued in the United States and twenty-nine patent applications pending in Europe, Japan, China, India, Hong Kong, Canada and the United States. Three patents cover certain aspects of Multikine and will expire between 2023 and 2024. The remaining five patents cover CEL-SCI's LEAPS technology and will expire between December 2014 and April 2022. CEL-SCI believes that the greatest level of protection for Multikine is not based on patents but comes from the confidential and proprietary process relating to the manufacture of Multikine.

RESEARCH AND DEVELOPMENT

Since 1983, and through September 30, 2011, approximately $88,988,600 has been spent on CEL-SCI-sponsored research and development, including $11,745,600, $11,911,600 and $6,011,800 respectively during the three years ended September 30, 2011.

The costs associated with the clinical trials relating to CEL-SCI's technologies, research expenditures and CEL-SCI's administrative expenses have been funded with the public and private sales of CEL-SCI's securities and borrowings from third parties, including affiliates of CEL-SCI. The extent of CEL-SCI's clinical trials and research programs is primarily based upon the amount of capital available to CEL-SCI and the extent to which CEL-SCI has received regulatory approvals for clinical trials.

GOVERNMENT REGULATION

New drug development and approval process

Regulation by governmental authorities in the United States and other countries is a significant factor in the manufacture and marketing of biological and other drug products and in ongoing research and product development activities. CEL-SCI's products will require regulatory approval by governmental agencies prior to commercialization. In particular, these products are subject to rigorous preclinical and clinical testing and other premarket approval requirements by the FDA and regulatory authorities in other countries. In the United States, various statutes and regulations also govern or influence the manufacturing, safety, labeling, storage, record keeping and marketing of pharmaceutical and biological drug products. The lengthy process of seeking these approvals, and the subsequent compliance with applicable statutes and regulations, require the expenditure of substantial resources. CEL-SCI believes that it is currently in compliance with applicable statutes and regulations that are relevant to its operations. CEL-SCI has no control, however, over the compliance of its partners.

The FDA's statutes, regulations, or policies may change and additional statutes or government regulations may be enacted which could prevent or delay regulatory approvals of biological or other drug products. CEL-SCI cannot predict the likelihood, nature or extent of adverse governmental regulation that might arise from future legislative or administrative action, either in the U.S. or abroad.

Regulatory approval, when and if obtained, may be limited in scope. In particular, regulatory approvals will restrict the marketing of a product to specific uses. Further, approved biological and other drugs, as well as their manufacturers, are subject to ongoing review. Discovery of previously unknown problems with these products may result in restrictions on their manufacture, sale or use or in their withdrawal from the market. Failure to comply with regulatory requirements may result in criminal prosecution, civil penalties, recall or seizure of products, total or partial suspension of production or injunction, as well as other actions affecting CEL-SCI. Any failure by CEL-SCI or its partners to obtain and maintain, or any delay in obtaining, regulatory approvals could materially adversely affect CEL-SCI's business.

The process for new drug approval has many steps, including:

Preclinical testing

Once a biological or other drug candidate is identified for development, the drug candidate enters the preclinical testing stage. During preclinical studies, laboratory and animal studies are conducted to show biological activity of the drug candidate in animals, both healthy and with the targeted disease. Also, preclinical tests evaluate the safety of drug candidates. These tests typically take approximately two years to complete. Preclinical tests must be conducted in compliance with good laboratory practice regulations. In some cases, long-term preclinical studies are conducted while clinical studies are ongoing.

Investigational new drug application

When the preclinical testing is considered adequate by the sponsor to demonstrate the safety and the scientific rationale for initial human studies, an investigational new drug application (IND) is filed with the FDA to seek authorization to begin human testing of the biological or other drug candidate. The IND becomes effective if not rejected by the FDA within 30 days after filing. The IND must provide data on previous experiments, how, where and by whom the new studies will be conducted, the chemical structure of the compound, the method by which it is believed to work in the human body, any toxic effects of the compound found in the animal studies and how the compound is manufactured. All clinical trials must be conducted under the supervision of a qualified investigator in accordance with good clinical practice regulations. These regulations include the requirement that all subjects provide informed consent. In addition, an institutional review board (IRB), comprised primarily of physicians and other qualified experts at the hospital or clinic where the proposed studies will be conducted, must review and approve each human study. The IRB also continues to monitor the study and must be kept aware of the study's progress, particularly as to adverse events and changes in the research. Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if adverse events occur. In addition, the FDA may, at any time during the 30-day period after filing an IND or at any future time, impose a clinical hold on proposed or ongoing clinical trials. If the FDA imposes a clinical hold, clinical trials cannot commence or recommence without FDA authorization, and then only under terms authorized by the FDA. In some instances, the IND process can result in substantial delay and expense.

Some limited human clinical testing may also be done under a physician's IND that allows a single individual to receive the drug, particularly where the individual has not responded to other available therapies. A physician's IND does not replace the more formal IND process, but can provide a preliminary indication as to whether further clinical trials are warranted, and can, on occasion, facilitate the more formal IND process.

Clinical trials are typically conducted in three sequential phases, but the phases may overlap.

Phase I clinical trials

Phase I human clinical trials usually involve between 20 and 80 healthy volunteers or patients and typically take one to two years to complete. The tests study a biological or other drug's safety profile, and may seek to establish the safe dosage range. The Phase I clinical trials also determine how a drug candidate is absorbed, distributed, metabolized and excreted by the body, and the duration of its action.

Phase II clinical trials

In Phase II clinical trials, controlled studies are conducted on an expanded population of patients with the targeted disease. The primary purpose of these tests is to evaluate the effectiveness of the drug candidate on the volunteer patients as well as to determine if there are any side effects or other risks associated with the drug. These studies generally take several years and may be conducted concurrently with Phase I clinical trials. In addition, Phase I/II clinical trials may be conducted to evaluate not only the efficacy of the drug candidate on the patient population, but also its safety.

Phase III clinical trials

This phase typically lasts several years and involves an even larger patient population, often with several hundred or even several thousand patients depending on the use for which the drug is being studied. Phase III trials are intended to establish the overall risk-benefit ratio of the drug and provide, if appropriate, an adequate basis for product labeling. During the Phase III clinical trials, physicians monitor the patients to determine efficacy and to observe and report any reactions or other safety risks that may result from use of the drug candidate.

Chemical and formulation development

Concurrent with clinical trials and preclinical studies, companies also must develop information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the product in accordance with current good manufacturing practice requirements (cGMPs). The manufacturing process must be capable of consistently producing quality batches of the product and the manufacturer must develop methods for testing the quality, purity, and potency of the final drugs. Additionally, appropriate packaging must be selected and tested and chemistry stability studies must be conducted to demonstrate that the product does not undergo unacceptable deterioration over its shelf-life.

New drug application or biological license application

After the completion of the clinical trial phases of development, if the sponsor concludes that there is substantial evidence that the biological or other drug candidate is effective and that the drug is safe for its intended use, a new drug application (NDA) or biologics license application (BLA) may be submitted to the FDA. The application must contain all of the information on the biological or other drug candidate gathered to that date, including data from the clinical trials.

The FDA reviews all NDAs and BLAs submitted before it accepts them for filing. It may request additional information rather than accepting an application for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth review of the application. The FDA may refer the application to an appropriate advisory committee, typically a panel of clinicians, for review, evaluation and a recommendation. The FDA is not bound by the recommendation of an advisory committee. If FDA evaluations of the NDA or BLA and the manufacturing facilities are favorable, the FDA may issue an approval letter authorizing commercial marketing of the drug or biological candidate for specified indications. The FDA could also issue an approvable letter, which usually contains a number of conditions that must be met in order to secure final approval of the NDA or BLA. When and if those conditions have been met to the FDA's satisfaction, the FDA will issue an approval letter. On the other hand, if the FDA's evaluation of the NDA or BLA or manufacturing facilities is not favorable, the FDA may refuse to approve the application or issue a non-approvable letter.

Among the conditions for NDA or BLA approval is the requirement that each prospective manufacturer's quality control and manufacturing procedures conform to current good manufacturing practice standards and requirements (cGMPs). Manufacturing establishments are subject to periodic inspections by the FDA and by other federal, state or local agencies.

COMPETITION AND MARKETING

Many companies, nonprofit organizations and governmental institutions are conducting research on cytokines. Competition in the development of therapeutic agents incorporating cytokines is intense. Large, well-established pharmaceutical companies are engaged in cytokine research and development and have considerably greater resources than CEL-SCI has to develop products. Licensing and other collaborative arrangements between governmental and other nonprofit institutions and commercial enterprises, as well as the seeking of patent protection of inventions by nonprofit institutions and researchers, could result in strong competition for CEL-SCI. Any new developments made by such organizations may render CEL-SCI's licensed technology and know-how obsolete.

Several biotechnology companies are producing compounds that utilize cytokines. However, CEL-SCI believes that its main advantage lies in two areas and that those two areas will allow it to be successful: 1) Multikine is given prior to surgery, radiation and/or chemotherapy, a time when the immune system can be activated more easily. Other companies give their immunotherapy drugs after these cancer treatments. At that time the immune system is already so weakened that it is unlikely to be able to mount a complete immune response. 2) Multikine simulates the activities of a healthy person's immune system, which battles cancer every day. Multikine is a cancer immunotherapy that both affects/kills cancer cells directly and activates the general immune system to destroy the cancer. In addition, since Multikine is a complex biologic, CEL-SCI believes that it will be extremely difficult for someone to copy Multikine and its manufacturing.

EMPLOYEES

As of November 30, 2011, CEL-SCI had 44 employees. Nine employees are involved in administration, 32 employees are involved in manufacturing, and 3 employees are involved in general research and development with respect to CEL-SCI's products.

ITEM 1A. RISK FACTORS

Investors should be aware that the risks described below could adversely affect the price of CEL-SCI's common stock and the future prospects of CEL-SCI.

Risks Related to CEL-SCI

Since CEL-SCI has earned only limited revenues and has a history of losses, CEL-SCI will require additional capital to remain in operation, complete its clinical trials and fund pre-marketing expenses.

CEL-SCI has had only limited revenues since it was formed in 1983. Since the date of its formation and through September 30, 2011, CEL-SCI incurred net losses of approximately $(187,500,000). CEL-SCI has relied principally upon the proceeds of public and private sales of its securities to finance its activities to date.

If CEL-SCI cannot obtain additional capital, CEL-SCI may have to postpone development and research expenditures, which will delay CEL-SCI's ability to produce a competitive product. Delays of this nature may depress the price of CEL-SCI's common stock. In addition, although CEL-SCI is not aware of a direct competitor for Multikine, it is possible that one exists. There are many potential competitors of LEAPS. If competitors develop, any delay in the development of CEL-SCI's products may provide opportunities to those competitors.

The condition of the overall economy may continue to affect both the availability of capital and CEL-SCI's stock price. In addition, future capital raises, which will be necessary for CEL-SCI's survival, will be further dilutive to current shareholders. There can be no assurance that CEL-SCI will be able to raise the capital it will need.

All of CEL-SCI's potential products, with the exception of Multikine, are in the early stages of development, and any commercial sale of these products will be many years away.

Even potential product sales from Multikine are years away, since cancer trials can be lengthy. Accordingly, CEL-SCI expects to incur substantial losses for the foreseeable future.

Since CEL-SCI does not intend to pay dividends on its common stock, any potential return to investors will result only from any increases in the price of CEL-SCI's common stock.

At the present time, CEL-SCI intends to use available funds to finance its operations. Accordingly, while payment of dividends rests within the discretion of CEL-SCI's Directors, no common stock dividends have been declared or paid by CEL-SCI and CEL-SCI has no intention of paying any common stock dividends in the foreseeable future. Any gains for CEL-SCI's investors will most likely result from increases in the price of CEL-SCI's common stock, which has been volatile in the recent past. If CEL-SCI's stock price does not increase, which likely will depend primarily upon the results of the Multikine clinical trials, an investor is unlikely to receive any return on an investment in CEL-SCI's common stock.

The costs of CEL-SCI's product development and clinical trials are difficult to estimate and will be very high for many years, preventing CEL-SCI from making a profit for the foreseeable future, if ever.

Clinical and other studies necessary to obtain approval of a new drug can be time consuming and costly, especially in the United States, but also in foreign countries. CEL-SCI's estimates of the costs associated with future clinical trials and research may be substantially lower than what CEL-SCI actually experiences. It is impossible to predict what CEL-SCI will face in the development of a product, such as LEAPS. The purpose of clinical trials is to provide both CEL-SCI and regulatory authorities with safety and efficacy data in humans. It is relatively common to revise a trial or add subjects to a trial in progress. These examples of common vagaries in product development and clinical investigations demonstrate how predicted costs may exceed reasonable expectations. The different and often complex steps necessary to obtain regulatory approval, especially that of the United States Food and Drug Administration ("FDA") and the European Union's European Medicine's Agency ("EMA"), involve significant costs and may require several years to complete. CEL-SCI expects that it will need substantial additional financing over an extended period of time in order to fund the costs of future clinical trials, related research, and general and administrative expenses.

The extent of CEL-SCI's clinical trials and research programs are primarily based upon the amount of capital available to CEL-SCI and the extent to which it receives regulatory approvals for clinical trials. CEL-SCI has established estimates of the future costs of the Phase III clinical trial for Multikine, but, as explained above, that estimate may not prove correct.

Compliance with changing regulations concerning corporate governance and public disclosure may result in additional expenses.

Changing laws, regulations and standards relating to corporate governance and public disclosure may create uncertainty regarding compliance matters. New or changed laws, regulations and standards are subject to varying interpretations in many cases. As a result, their application in practice may evolve over time. CEL-SCI is committed to maintaining high standards of corporate governance and public disclosure. Complying with evolving interpretations of new or changing legal requirements may cause CEL-SCI to incur higher costs as it revises current practices, policies and procedures, and may divert management time and attention from potential revenue-generating activities to compliance matters. If CEL-SCI's efforts to comply with new or changed laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to practice, CEL-SCI's reputation may also be harmed. Further, CEL-SCI's board members, chief executive officer, president and the other executive officers of CEL-SCI could face an increased risk of personal liability in connection with the performance of their duties. As a result, CEL-SCI may have difficulty attracting and retaining qualified board members and executive officers, which could harm its business.

CEL-SCI has not established a definite plan for the marketing of Multikine.

CEL-SCI has not established a definitive plan for marketing nor has it established a price structure for any of its products. However, CEL-SCI intends, if it is in a position to do so, to sell Multikine itself in certain markets and to enter into written marketing agreements with various major pharmaceutical firms with established sales forces. The sales forces in turn would, CEL-SCI believes, target CEL-SCI's products to cancer centers, physicians and clinics involved in head and neck cancer. CEL-SCI has already licensed Multikine to four companies, Teva Pharmaceuticals in Israel, Turkey, Serbia and Croatia, Orient Europharma in Taiwan, Singapore, Hong Kong, Malaysia, South Korea, the Philippines, Australia and New Zealand, Byron BioPharma, LLC in South Africa, and IDC-GP Pharm in Argentina and Venezuela. CEL-SCI believes that these companies have the resources to market Multikine appropriately in their respective territories, but there is no guarantee that they will. There is no assurance that CEL-SCI will find qualified parties willing to market CEL-SCI’s product in other areas.

CEL-SCI may encounter problems, delays and additional expenses in developing marketing plans with outside firms. In addition, even if Multikine is cost effective and proven to increase overall survival, CEL-SCI may experience other limitations involving the proposed sale of Multikine, such as uncertainty of third-party reimbursement. There is no assurance that CEL-SCI can successfully market any products which CEL-SCI may develop.

CEL-SCI hopes to expand its clinical development capabilities in the future, and any difficulties hiring or retaining key personnel or managing this growth could disrupt CEL-SCI’s operations.

CEL-SCI is highly dependent on the principal members of CEL-SCI’s management and development staff. If the Multikine clinical trial is successful, CEL-SCI expects to expand its clinical development and manufacturing capabilities, which will involve hiring additional employees. Future growth will require CEL-SCI to continue to implement and improve CEL-SCI’s managerial, operational and financial systems and to continue to retain, recruit and train additional qualified personnel, which may impose a strain on CEL-SCI’s administrative and operational infrastructure. The competition for qualified personnel in the biopharmaceutical field is intense. CEL-SCI is highly dependent on its ability to attract, retain and motivate highly qualified management and specialized personnel required for clinical development. Due to CEL-SCI’s limited resources, CEL-SCI may not be able to manage effectively the expansion of its operations or recruit and train additional qualified personnel. If CEL-SCI is unable to retain key personnel or manage its growth effectively, CEL-SCI may not be able to implement its business plan.

Future sales of CEL-SCI’s securities may dilute the value of current investors’ holdings.

In order to raise additional capital, CEL-SCI may need to sell shares of its common stock, or securities convertible into common stock, at prices that may be below the prevailing market price of CEL-SCI's common stock at the time of sale. Since CEL-SCI’s stock price has been volatile, even a sale at market price one week may represent a substantial “discount” over the prior week’s price. Future sales of CEL-SCI’s securities will dilute CEL-SCI’s current stockholders and investors and may have a negative effect on the market price of its common stock.

Multikine is made from components of human blood, which involves inherent risks that may lead to product destruction or patient injury.

Multikine is made, in part, from components of human blood. There are inherent risks associated with products that involve human blood such as possible contamination with viruses, including Hepatitis or HIV. Any possible contamination could require CEL-SCI to destroy batches of Multikine or cause injuries to patients who receive the product, thereby subjecting CEL-SCI to possible financial losses, lawsuits, and harm to its business.

Although CEL-SCI has product liability insurance for Multikine, the successful prosecution of a product liability case against CEL-SCI could have a materially adverse effect upon its business if the amount of any judgment exceeds CEL-SCI's insurance coverage. Such a suit also could damage the reputation of Multikine and make successful marketing of the product less likely. CEL-SCI commenced the Phase III clinical trial for Multikine in December 2010. Although no claims have been brought to date, participants in CEL-SCI's clinical trials could bring civil actions against CEL-SCI for any unanticipated harmful effects arising from the use of Multikine or any drug or product that CEL-SCI may attempt to develop.

CEL-SCI's directors are allowed to issue shares of preferred stock and warrants with provisions that could be detrimental to the holders of CEL-SCI's common stock.

The provisions in CEL-SCI's Articles of Incorporation relating to CEL-SCI's preferred stock allow CEL-SCI's directors to issue preferred stock with rights to multiple votes per share and dividend rights which would have priority over any dividends paid with respect to CEL-SCI's common stock. The issuance of preferred stock with such rights may make more difficult the removal of management even if such removal would be considered beneficial to shareholders generally, and will have the effect of limiting shareholder participation in certain transactions such as mergers or tender offers if such transactions are not favored by incumbent management. In addition, CEL-SCI has issued warrants in the past and may do so in the future. These warrants, providing a future right to purchase shares of CEL-SCI’s common stock at the established price, may further dilute the ownership of current shareholders.

Our Independent Registered Public Accountants have included in its report on our financial statements a paragraph stating that we may be unable to continue as a going concern.

As a result of our recurring losses from operations, our independent registered public accounting firm, BDO USA, LLP, has issued a report in connection with their audit of our consolidated financial statements for the year ended September 30, 2011, that included an explanatory paragraph referring to our recurring losses from operations and expressing substantial doubt in our ability to continue as a going concern without additional capital becoming available. The doubt about our ability to continue as a going concern could have an adverse impact on our ability to execute our business plan, result in the reluctance on the part of certain suppliers to do business with us, or adversely affect our ability to raise additional debt or equity capital.

Risks Related to Government Approvals

CEL-SCI's product candidates must undergo rigorous preclinical and clinical testing and regulatory approvals, which could be costly and time-consuming and subject CEL-SCI to unanticipated delays or prevent CEL-SCI from marketing any products.

Therapeutic agents, drugs and diagnostic products are subject to approval, prior to general marketing, from the FDA in the United States, the EMA in the European Union, and by comparable agencies in most foreign countries. Before obtaining marketing approval, these product candidates must undergo costly and time consuming preclinical and clinical testing which could subject CEL-SCI to unanticipated delays and may prevent CEL-SCI from marketing its product candidates. There can be no assurance that such approvals will be granted.

CEL-SCI cannot be certain when or under what conditions it will undertake clinical trials. A variety of issues may delay or prevent CEL-SCI's Phase III clinical trial for Multikine or preclinical and early clinical trials for other products. For example, early trials, or the plans for later trials, may not satisfy the requirements of regulatory authorities, such as the FDA. CEL-SCI may fail to find subjects willing to enroll in CEL-SCI's trials. CEL-SCI manufactures Multikine, but CEL-SCI relies on third party vendors for managing the trial process and other activities, and these vendors may fail to meet appropriate standards. Accordingly, the clinical trials relating to CEL-SCI's product candidates may not be completed on schedule, the FDA or foreign regulatory agencies may order CEL-SCI to stop or modify its research, or these agencies may not ultimately approve any of CEL-SCI's product candidates for commercial sale. Varying interpretations of the data obtained from pre-clinical and clinical testing could delay, limit or prevent regulatory approval of CEL-SCI's product candidates. The data collected from CEL-SCI's clinical trials may not be sufficient to support regulatory approval of its various product candidates, including Multikine. CEL-SCI's failure to adequately demonstrate the safety and efficacy of any of its product candidates would delay or prevent regulatory approval of its product candidates in the United States, which could prevent CEL-SCI from achieving profitability. Although CEL-SCI had positive results in its Phase II trials for Multikine, those results were for a very small sample set, and CEL-SCI will not know definitively how Multikine will perform until CEL-SCI is well into, or completes, its Phase III clinical trial.

The requirements governing the conduct of clinical trials, manufacturing, and marketing of CEL-SCI's product candidates, including Multikine, outside the United States vary from country to country. Foreign approvals may take longer to obtain than FDA approvals and can require, among other things, additional testing and different trial designs. Foreign regulatory approval processes include all of the risks associated with the FDA approval process. Some of those agencies also must approve prices for products approved for marketing. Approval of a product by the FDA or the EMA does not ensure approval of the same product by the health authorities of other countries. In addition, changes in regulatory requirements for product approval in any country during the clinical trial process and regulatory agency review of each submitted new application may cause delays or rejections.

CEL-SCI has only limited experience in filing and pursuing applications necessary to gain regulatory approvals. CEL-SCI's lack of experience may impede its ability to obtain timely approvals from regulatory agencies, if at all. CEL-SCI will not be able to commercialize Multikine and other product candidates until it has obtained regulatory approval. In addition, regulatory authorities may also limit the types of patients to which CEL-SCI or others may market Multikine or CEL-SCI's other products. Any failure to obtain or any delay in obtaining required regulatory approvals may adversely affect the ability of CEL-SCI or potential licensees to successfully market CEL-SCI's products.

Even if CEL-SCI obtains regulatory approval for its product candidates, CEL-SCI will be subject to stringent, ongoing government regulation.

If CEL-SCI's products receive regulatory approval, either in the United States or internationally, CEL-SCI will continue to be subject to extensive regulatory requirements. These regulations are wide-ranging and govern, among other things:

product design, development and manufacture;

product application and use

adverse drug experience;

product advertising and promotion;

product manufacturing, including good manufacturing practices

record keeping requirements;

registration and listing of CEL-SCI's establishments and products with the FDA, EMA and other state and national agencies;

product storage and shipping;

drug sampling and distribution requirements;

electronic record and signature requirements; and

labeling changes or modifications.

CEL-SCI and any third-party manufacturers or suppliers must continually adhere to federal regulations setting forth requirements, known as current Good Manufacturing Practices, or cGMPs, and their foreign equivalents, which are enforced by the FDA, the EMA and other national regulatory bodies through their facilities inspection programs. If CEL-SCI's facilities, or the facilities of CEL-SCI’s contract manufacturers or suppliers, cannot pass a pre-approval plant inspection, the FDA, EMA, or other national regulators will not approve the marketing applications of CEL-SCI's product candidates. In complying with cGMP and foreign regulatory requirements, CEL-SCI and any of its potential third-party manufacturers or suppliers will be obligated to expend time, money and effort in production, record-keeping and quality control to ensure that CEL-SCI’s products meet applicable specifications and other requirements. State regulatory authorities and the regulatory authorities of other countries have similar requirements.

If CEL-SCI does not comply with regulatory requirements at any stage, whether before or after marketing approval is obtained, CEL-SCI may be subject to license suspension or revocation, criminal prosecution, seizure, injunction, fines, be forced to remove a product from the market or experience other adverse consequences, including restrictions or delays in obtaining regulatory marketing approval for such products or for other products for which it seeks approval. This could materially harm CEL-SCI's financial results, reputation and stock price. Additionally, CEL-SCI may not be able to obtain the labeling claims necessary or desirable for product promotion. CEL-SCI may also be required to undertake post-marketing trials, which will be evaluated by applicable authorities to determine if CEL-SCI's products may remain on the market. If CEL-SCI or other parties identify adverse effects after any of CEL-SCI's products are on the market, or if manufacturing problems occur, regulatory approval may be suspended or withdrawn. CEL-SCI may be required to reformulate its products, conduct additional clinical trials, make changes in product labeling or indications of use, or submit additional marketing applications to support any changes. If CEL-SCI encounters any of the foregoing problems, its business and results of operations will be harmed and the market price of its common stock may decline.

Also, CEL-SCI cannot predict the extent of adverse government regulations which might arise from future legislative or administrative action. Without government approval, CEL-SCI will be unable to sell any of its products.

Foreign governments often impose strict price controls, which may adversely affect CEL-SCI's future profitability.

CEL-SCI intends to seek approval to market Multikine in both the United States and foreign jurisdictions. If CEL-SCI obtains approval in one or more foreign jurisdictions, CEL-SCI will be subject to rules and regulations in those jurisdictions relating to Multikine. In some foreign countries, particularly in the European Union, prescription drug pricing is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a drug candidate. To obtain reimbursement or pricing approval in some countries, CEL-SCI may be required to conduct a clinical trial that compares the cost-effectiveness of Multikine to other available therapies. If reimbursement of Multikine is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, CEL-SCI may be unable to achieve or sustain profitability.

Risks Related to Intellectual Property

CEL-SCI may not be able to achieve or maintain a competitive position, and other technological developments may result in CEL-SCI's proprietary technologies becoming uneconomical or obsolete.

CEL-SCI is involved in a biomedical field that is undergoing rapid and significant technological change. The pace of change continues to accelerate. The successful development of products from CEL-SCI's compounds, compositions and processes through CEL-SCI-financed research, or as a result of possible licensing arrangements with pharmaceutical or other companies, is not assured.

Many companies are working on drugs designed to cure or treat cancer or cure and treat viruses, such as H1N1. Many of these companies have substantial financial, research and development, and marketing resources, much greater than CEL-SCI's, and are capable of providing significant long-term competition either by establishing in-house research groups or by forming collaborative ventures with other entities. In addition, smaller companies and non-profit institutions are active in research relating to cancer and infectious diseases. CEL-SCI's market share will be reduced or eliminated if CEL-SCI's competitors develop and obtain approval for products that are safer or more effective than CEL-SCI's products.

CEL-SCI's patents might not protect CEL-SCI's technology from competitors, in which case CEL-SCI may not have any advantage over competitors in selling any products which it may develop.

Certain aspects of CEL-SCI's technologies are covered by U.S. and foreign patents. In addition, CEL-SCI has a number of new patent applications pending. There is no assurance that the applications still pending or which may be filed in the future will result in the issuance of any patents. Furthermore, there is no assurance as to the breadth and degree of protection any issued patents might afford CEL-SCI. Disputes may arise between CEL-SCI and others as to the scope and validity of these or other patents. Any defense of the patents could prove costly and time consuming and there can be no assurance that CEL-SCI will be in a position, or will deem it advisable, to carry on such a defense. A suit for patent infringement could result in increasing costs, delaying or halting development, or even forcing CEL-SCI to abandon a product. Other private and public concerns, including universities, may have filed applications for, may have been issued, or may obtain additional patents and other proprietary rights to technology potentially useful or necessary to CEL-SCI. CEL-SCI currently is not aware of any such patents, but the scope and validity of such patents, if any, and the cost and availability of such rights are impossible to predict. Also, as far as CEL-SCI relies upon unpatented proprietary technology, there is no assurance that others may not acquire or independently develop the same or similar technology.

Much of CEL-SCI’s intellectual property is protected as a trade secret, not as a patent.

Much of CEL-SCI’s intellectual property pertains to its manufacturing system, certain aspects of which may not be suitable for patent filing and must be protected as a trade secret. Those trade secrets must be protected diligently by CEL-SCI to protect their disclosure to competitors, since legal protections after disclosure may be minimal or non-existent. Accordingly, much of CEL-SCI’s value is dependent upon its ability to keep its trade secrets confidential. Although CEL-SCI takes measures to ensure confidentiality, CEL-SCI may fail in that attempt. In addition, in some cases a regulator considering CEL-SCI’s application for product approval may require the disclosure of some or all of CEL-SCI’s proprietary information. In such a case, CEL-SCI must decide whether to disclose the information or forego approval in a particular country. If CEL-SCI is unable to market its products in key countries, CEL-SCI’s opportunities and value may suffer.

Risks Related to CEL-SCI’s Common Stock

The market price for CEL-SCI's common stock is volatile, so investors may not be able to sell any of CEL-SCI's shares at a profit.

The market price of CEL-SCI's common stock, as well as the securities of other biopharmaceutical and biotechnology companies, have historically been highly volatile, and the market has from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. During the twelve months ended September 30, 2011, CEL-SCI's stock price has ranged from a low of $0.35 per share to a high of $1.05 per share. Factors such as fluctuations in CEL-SCI's operating results, announcements of technological innovations or new therapeutic products by CEL-SCI or its competitors, governmental regulation, developments in patent or other proprietary rights, public concern as to the safety of products developed by CEL-SCI or other biotechnology and pharmaceutical companies, publications by market analysts, law suits, and general market conditions may have a significant effect on the future market price of CEL-SCI's common stock.

Shares issuable upon the conversion of notes or upon the exercise of outstanding warrants and options may substantially increase the number of shares available for sale in the public market and may depress the price of CEL-SCI's common stock.

CEL-SCI has outstanding convertible notes and debt, as well as options and warrants, which as of November 30, 2011, could potentially allow the holders to acquire a substantial number of shares of CEL-SCI's common stock. Until the convertible notes and debt are repaid, and the options and warrants expire, the holders will have an opportunity to profit from any increase in the market price of CEL-SCI's common stock without assuming the risks of ownership. Holders of convertible notes and debt, options and warrants may convert or exercise these securities at a time when CEL-SCI could obtain additional capital on terms more favorable than those provided by the options or warrants. The conversion of the notes or debt or the exercise of the options and warrants will dilute the voting interest of the current owners of outstanding shares by adding a substantial number of additional shares of common stock.

Substantially all of the shares of common stock that are issuable upon the conversions of the notes or debt, of the exercise of outstanding options and warrants, may be sold in the public market. The sale of common stock described above, or the perception that such sales could occur, may adversely affect the market price of CEL-SCI's common stock.

In December 2010, CEL-SCI entered into a sales agreement with McNicoll Lewis & Vlak, LLC (MLV) relating to shares of common stock which have been registered by means of a shelf registration statement. CEL-SCI may offer and sell shares of its common stock, having an aggregate offering price of up to $30 million from time to time through MLV acting as agent, on a best efforts basis, and/or principal. CEL-SCI is not required to sell any shares to MLV and MLV is not required to sell any shares on CEL-SCI's behalf or purchase any of shares for its own account. MLV is entitled to a commission in an amount equal to the greater of 3% of the gross proceeds from each sale of the shares, or $0.025 for each share sold, provided, that, in no event will MLV receive a commission greater than 8.0% of the gross proceeds from the sale of the shares. The agreement was terminated in December 2011.

CEL-SCI's outstanding shares will be diluted by the number of shares sold to MLV and CEL-SCI's stock price may decrease as a result of the sale of such shares. Any decline in the price of CEL-SCI's common stock may encourage short sales, which could place further downward pressure on the price of CEL-SCI's common stock. Short selling is a practice of selling shares which are not owned by a seller at that time, with the expectation that the market price of the shares will decline in value after the sale, providing the short seller a profit.

ITEM 1B. UNRESOLVED SEC COMMENTS

None

ITEM 2. PROPERTIES

CEL-SCI leases office space at 8229 Boone Blvd., Suite 802, Vienna, Virginia at a monthly rental of approximately $8,900. The lease on the office space expires in June 2012. CEL-SCI believes this arrangement is adequate for the conduct of its present business.

CEL-SCI has a 17,900 square foot laboratory located in Baltimore, Maryland. The laboratory is leased by CEL-SCI at a cost of approximately $11,000 per month. The laboratory lease expires in February 2014.

In August 2007, CEL-SCI leased a building near Baltimore, Maryland. The building, which consists of approximately 73,000 square feet, has been remodeled in accordance with CEL-SCI's specifications so that it can be used by CEL-SCI to manufacture Multikine for CEL-SCI's Phase III clinical trial and sales of the drug if approved by the FDA. The lease expires on October 31, 2028 and requires annual base rent payments of approximately $1,667,000 during the twelve months ending September 30, 2011, in accordance with the lease agreement. The annual base rent escalates each year thereafter at 3% beginning on November 1st. CEL-SCI is also required to pay all real and personal property taxes, insurance premiums, maintenance expenses, repair costs and utilities. The lease allows CEL-SCI, at its election, to extend the lease for two ten-year periods or to purchase the building at the end of the 20-year lease. The lease required CEL-SCI to pay $3,150,000 towards the remodeling costs, which will be recouped by reductions in the annual base rent of $303,228 beginning in 2014. In August 2011, the Company was required to deposit the equivalent of one year of base rent in accordance with the contract. The $1,670,917 is included in non-current assets on September 30, 2011 was required to be deposited when the amount of cash the Company had dropped below the amount stipulated in the lease.

ITEM 3. LEGAL PROCEEDINGS

Not Applicable.

ITEM 4. (REMOVED AND RESERVED)

ITEM 5. MARKET FOR CEL-SCI'S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS.

As of September 30, 2011, there were approximately 1,100 record holders of CEL-SCI's common stock. CEL-SCI's common stock is traded on the NYSE Amex under the symbol "CVM". Set forth below are the range of high and low quotations for CEL-SCI's common stock for the periods indicated as reported on the NYSE Amex. The market quotations reflect inter-dealer prices, without retail mark-up, mark-down or commissions and may not necessarily represent actual transactions.

Quarter Ending	High	Low
12/31/08	$0.50	$0.18
3/31/09	$0.40	$0.14
6/30/09	$0.80	$0.20
9/30/09	$2.10	$0.38

Quarter Ending	High	Low
12/31/09	$1.79	$0.85
3/31/10	$1.12	$0.50
6/30/10	$0.76	$0.45
9/30/10	$0.84	$0.43
12/31/10	$1.05	$0.60
3/31/11	$0.86	$0.51
6/30/11	$0.74	$0.46
9/30/11	$0.57	$0.35

Holders of common stock are entitled to receive dividends as may be declared by the Board of Directors out of legally available funds and, in the event of liquidation, to share pro rata in any distribution of CEL-SCI's assets after payment of liabilities. The Board of Directors is not obligated to declare a dividend. CEL-SCI has not paid any dividends on its common stock and CEL-SCI does not have any current plans to pay any common stock dividends.

The provisions in CEL-SCI's Articles of Incorporation relating to CEL-SCI's preferred stock would allow CEL-SCI's directors to issue preferred stock with rights to multiple votes per share and dividend rights which would have priority over any dividends paid with respect to CEL-SCI's Common Stock. The issuance of preferred stock with such rights may make more difficult the removal of management even if such removal would be considered beneficial to shareholders generally, and will have the effect of limiting shareholder participation in certain transactions such as mergers or tender offers if such transactions are not favored by incumbent management.

The market price of CEL-SCI's common stock, as well as the securities of other biopharmaceutical and biotechnology companies, have historically been highly volatile, and the market has from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. Factors such as fluctuations in CEL-SCI's operating results, announcements of technological innovations or new therapeutic products by CEL-SCI or its competitors, governmental regulation, developments in patent or other proprietary rights, public concern as to the safety of products developed by CEL-SCI or other biotechnology and pharmaceutical companies, and general market conditions may have a significant effect on the market price of CEL-SCI's common stock.

The graph below matches the cumulative 5-year total return of holders of CEL-SCI's common stock with the cumulative total returns of the NYSE Amex Composite index and the RDG MicroCap Biotechnology index. The graph assumes that the value of an investment in CEL-SCI's common stock and in each of the indexes (including reinvestment of dividends) was $100 on 9/30/2006 and tracks it through 9/30/2011.

	9/06	9/07	9/08	9/09	9/10	9/11
CEL-SCI Corporation	100.00	100.84	64.52	277.42	103.87	58.87
NYSE Amex Composite	100.00	127.85	99.27	103.93	122.61	125.42
RDG MicroCap Biotechnology	100.00	96.23	54.05	54.24	38.88	25.57

The stock price performance included in this graph is not necessarily indicative of future stock price performance.

ITEM 6. SELECTED FINANCIAL DATA

The following selected historical consolidated financial data are qualified by reference to, and should be read in conjunction with the consolidated financial statements and the related notes thereto, appearing elsewhere in this report, as well as Item 7 of this report.

Statements of Operations	2011	2010	2009	2008	2007
Rent and grant revenue and other	$956,154	$153,300	$80,093	$5,065	$57,043
Operating expenses:					
Research and development	11,745,629	11,911,626	6,011,750	4,101,563	2,528,528
Depreciation and amortization	531,316	516,117	417,205	215,060	176,186
General and administrative	6,664,883	6,285,810	5,671,595	5,200,735	6,704,538
Gain (loss) on derivative instruments	4,432,148	28,843,772	(28,491,650)	1,799,393	868,182
Other expenses (3)	(12,000,000)	-	-	-	-
Interest income	164,163	362,236	-	483,252	562,973
Interest expense	(322,980)	(162,326)	(397,923)	(473,767)	(1,708,603)
Net income (loss)	(25,712,343)	10,483,429	(40,910,030)	(7,703,415)	(9,629,657)
Modification of warrants	(1,068,369)	(1,532,456)	(490,728)	(424,815)	-
Net income (loss) available to common shareholders	$(26,780,712)	$8,950,973	$(41,400,758)	$(8,128,230)	$(9,629,657)
Statements of Operations					
Net income (loss) per common share					
Basic	$(0.13)	$0.04	$(0.31)	$(0.07)	$(0.10)
Diluted	$(0.15)	$(0.06)	$(0.31)	$(0.07)	$(0.10)
Weighted average common shares outstanding					
Basic	208,488,987	202,102,859	133,535,050	117,060,866	97,310,488
Diluted (1)	208,488,987	202,102,859	133,535,050	117,060,866	97,310,488

Balance Sheets	2011	2010	2009	2008	2007
Working capital	$1,796,349	$25,799,304	$34,339,772	$(2,492,555)	$10,257,568
Total assets	18,625,440	37,804,985	46,027,598	14,683,672	20,730,802
Convertible note and derivative instruments - current (2)	5,068,552	424,286	-	3,018,697	782,732
Derivative instruments – noncurrent (2)	2,192,521	6,521,765	35,113,970	-	4,831,252
Total liabilities	9,546,616	9,950,220	37,186,954	3,847,637	6,060,703
Stockholders' equity	9,078,824	27,854,765	8,840,644	10,836,035	14,670,099

(1) The calculation of diluted earnings per share for the years ended September 30, 2011, 2010, 2009, 2008 and 2007 excluded the potentially dilutive shares because their effect would have been anti-dilutive.

(2) Included in total liabilities.

(3) The $12 million other expense was the cost of the lawsuit settlement. See Financial Statement Footnotes for discussion of the lawsuit settlement.

25

CEL-SCI's net income (losses) available to common shareholders for each fiscal quarter during the two years ended September 30, 2011 were:

Quarter	Net income (loss)	Net income (loss) per share Basic	Diluted
12/31/2009	$19,159,517	$0.10	$0.02
3/31/2010	$(2,176,975)	$(0.01)	$(0.03)
6/30/2010	$(601,124)	$(0.00)	$(0.02)
9/30/2010	$(7,430,445)	$(0.04)	$(0.04)
12/31/2010	$(6,250,952)	$(0.03)	$(0.03)
3/31/2011	$(15,097,973)	$(0.07)	$(0.09)
6/30/2011	$(3,114,255)	$(0.01)	$(0.02)
9/30/2011	$(2,317,532)	$(0.01)	$(0.02)

CEL-SCI has experienced large swings in its quarterly gains and losses in 2011 and 2010. These swings are caused by the changes in the fair value of the convertible debt and outstanding warrants accounted for as derivatives each quarter. These changes in the fair value of the convertible debt and warrants are recorded on the consolidated statements of operations. In addition, the cost of options granted to consultants, as discussed in the results of operations in this report, has affected the quarterly losses recorded by CEL-SCI. The settlement of the lawsuit, discussed in Note 11 to the financial statements accompanying this report, resulted in a $12,000,000 charge to earnings in the second quarter of the fiscal year ended September 30, 2011.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion should be read in conjunction with the consolidated financial statements and the related notes thereto appearing elsewhere in this report.

CEL-SCI’s lead investigational therapy, Multikine, is cleared for a Phase III clinical trial in advanced primary head and neck cancer. It has received a go-ahead by the US FDA as well as the Canadian, Polish, Hungarian, Russian, Israeli, Indian and Taiwanese regulators.

CEL-SCI also owns and is developing a pre-clinical technology called LEAPS (Ligand Epitope Antigen Presentation System).

All of CEL-SCI’s projects are under development. As a result, CEL-SCI cannot predict when it will be able to generate any revenue from the sale of any of its products.

Since inception, CEL-SCI has financed its operations through the issuance of equity securities, convertible notes, loans and certain research grants. CEL-SCI’s expenses will likely exceed its revenues as it continues the development of Multikine and brings other drug candidates into clinical trials. Until such time as CEL-SCI becomes profitable, any or all of these financing vehicles or others may be utilized to assist CEL-SCI’s capital requirements.

Results of Operations

Fiscal 2011

During the year ended September 30, 2011, revenue increased by $802,854. In November 2010, CEL-SCI received a $733,437 grant under The Patient Protection and Affordable Care Act of 2010 (PPACA). The grant was related to three of CEL-SCI's projects, including the Phase III trial of Multikine. The PPACA provides small and mid-sized biotech, pharmaceutical and medical device companies with up to a 50% tax credit for investments in qualified therapeutic discoveries for tax years 2009 and 2010, or a grant for the same amount tax-free. The tax credit/grant program covers research and development costs from 2009 and 2010 for all qualified "therapeutic discovery projects." CEL-SCI recognizes revenue as the expenses are incurred. Additionally, CEL-SCI has received $221,530 from a Phase III clinical trial partner for participation in the Phase III clinical trial.

During the year ended September 30, 2011, research and development expenses decreased by $165,997 compared to fiscal 2010. CEL-SCI's research and development expenses will fluctuate based on the activity level of its Phase III clinical trial.

During the year ended September 30, 2011, general and administrative expenses increased by $379,073, compared to fiscal 2010. This increase was primarily due to an increase in legal fees for the lawsuit.

During the year ended September 30, 2011, other expenses increased by $12 million, compared to fiscal 2010. This increase was due to the $12 million settlement of the lawsuit.

The Settlement Agreement, signed in May 2011, between CEL-SCI and thirteen hedge funds (the "plaintiffs") resolved all claims arising from a lawsuit initiated by the plaintiffs in October 2009. As previously disclosed by CEL-SCI in its public filings, in August 2006 the plaintiffs (or their predecessors) purchased from CEL-SCI Series K notes convertible into CEL-SCI's common stock and Series K warrants to purchase CEL-SCI's common stock under agreements which provided the Series K notes and warrants with anti-dilution protection if CEL-SCI sold additional shares of common stock, or securities convertible into common stock, at a price below the then applicable conversion price of the notes or the exercise price of the warrants. In their lawsuit, the plaintiffs alleged that a March 2009 drug marketing and distribution agreement in which CEL-SCI sold units of common stock and warrants to an unrelated third party triggered these anti-dilution provisions, and that CEL-SCI failed to give effect to these provisions. The plaintiffs sought $30 million in actual damages, $90 million in punitive damages, the issuance of additional shares of common stock and warrants, and a reduction in the conversion price of the Series K notes and the exercise price of the Series K warrants. CEL-SCI denied the plaintiffs' allegations in the lawsuit and asserted that the 2009 agreement was a strategic transaction which did not trigger the anti-dilution provisions of the 2006 financing agreements.

Although CEL-SCI believed the plaintiffs' claims were without merit, CEL-SCI was of the opinion that a settlement of the lawsuit was in the best interests of its shareholders. The settlement was entered into to avoid the substantial costs of further litigation and the risk and uncertainty that the litigation entails. By ending this dispute, and ending the significant demands on the time and attention of CEL-SCI's management necessary to respond to the litigation, CEL-SCI is better able to focus on executing its ongoing Phase III clinical trial with its investigational cancer drug Multikine.

Under the terms of the Settlement Agreement and related agreements, the plaintiffs and CEL-SCI terminated the pending litigation and released each other from all claims each may have had against the other, with certain customary exceptions. CEL-SCI agreed to make a $3 million cash payment and issue convertible promissory notes in the principal amount of $4.95 million and 4,050 shares of Series A Preferred Stock. As of September 1, 2011 CEL-SCI had redeemed all of the Series A Preferred shares for approximately $4,080,371. As a result, all Series A Preferred

shares have been cancelled and are no longer outstanding.

The notes will be redeemed through five monthly installment payments of approximately $1 million each, plus interest at the rate of 8% per annum, with payments beginning on November 1, 2011 and ending on March 1, 2012. The notes are convertible, at the option of the holders, into CEL-SCI's common stock at a fixed price of $0.67 per share. The first and second payments were made on November 1 and December 1, 2011 per the settlement agreement.

CEL-SCI has pledged all of its assets as collateral for the repayment of the notes. While the notes are outstanding, CEL-SCI is generally prohibited from paying dividends, incurring new debt or making any payments (other than interest) on existing debt, and is subject to certain restrictions on the transfer of its assets.

As of November 30, 2011, the remaining Series K warrants allow the holders to purchase up to 3,091,195 shares of CEL-SCI's common stock at a price of $0.30 per share at any time prior to February 4, 2012. If CEL-SCI sells any additional shares of common stock or any securities convertible into common stock at a price below $0.30, the warrant exercise price will be lowered to the price at which the shares were sold or the lowest price at which the securities are convertible, as the case may be.

The parties' respective obligations under the Settlement Agreement, including CEL-SCI's obligation to pay cash and issue notes and preferred shares to the plaintiffs, were subject to obtaining court approval of an order exempting the issuance to the plaintiffs of the notes and preferred shares from registration under Section 3(a)(10) of the Securities Act of 1933. This was to permit the notes, and the shares of common stock issuable upon any conversion of the notes, to be freely tradeable.

As a condition of the settlement agreement, all claims against CEL-SCI were dismissed. As a result, the $81,395 overpayment by one of the claimants was dismissed and the liability was written off during the three months ended June 30, 2011.

The foregoing summary of the settlement is qualified in its entirety by the detailed terms of the Settlement Agreement and the related agreements and documents which were filed as exhibits to CEL-SCI's report on Form 10-Q for the three months ended March 31, 2011.

Interest income during the year ended September 30, 2011 decreased by $198,073, compared to fiscal 2010. The decrease was due to the decrease in the funds available for investment and lower interest rates.

The gain on derivative instruments of $4,432,148 for the year ended September 30, 2011 was the result of the change in fair value of the derivative liabilities during the period.

The interest expense of $322,980 for the year ended September 30, 2011 was interest on the loan from CEL-SCI's President ($177,109), the dividends paid on the mandatorily redeemable preferred stock ($30,371) that are considered to be interest in accordance with generally accepted accounting principles and accrued interest on the convertible notes ($115,500). The interest expense of $162,326 for the year ended September 30, 2010 was interest on the loan from CEL-SCI's President, offset by the final $3,282 in amortization of the loan premium in October, 2009.

Fiscal 2010

During the year ended September 30, 2010, research and development expenses increased by $5,899,876 compared to the year ended September 30, 2009. This increase was due to continuing expenses relating to the preparation for the Phase III clinical trial on Multikine.

During the year ended September 30, 2010, general and administrative expenses increased by $614,215 compared to the year ended September 30, 2009, primarily due to legal fees caused by the Iroquois lawsuit.

Interest income during the year ended September 30, 2010 increased by $362,236 compared to the year ended September 30, 2009. The increase was due to the greater amount of capital CEL-SCI had for investment in money market funds.

The gain on derivative instruments of $28,843,772 for the year ended September 30, 2010, was the result of the change in the fair value of the derivative liabilities on the balance sheet. The Series A-E warrants issued in conjunction with several financings during the fiscal year ended September 30, 2009, as well as others are considered derivative liabilities and must be valued at the end of each period. The fluctuation of the price of CEL-SCI's common stock is a major cause of derivative gains or losses.

The interest expense of $162,326 for the year ended September 30, 2010 was interest on the related party loan. Previous years included amortization of the Series K discount and the premium on the related party loan.

Research and Development Expenses

During the five years ended September 30, 2011 CEL-SCI's research and development efforts involved Multikine and LEAPS. The table below shows the research and development expenses associated with each project during this five-year period.

	2011	2010	2009	2008	2007
MULTIKINE	$11,257,157	$10,868,046	$5,281,999	$3,765,258	$2,217,108
LEAPS	488,472	1,043,580	729,751	336,305	311,420
TOTAL	$11,745,629	$11,911,626	$6,011,750	$4,101,563	$2,528,528

In January 2007, CEL-SCI received a "no objection" letter from the FDA indicating that it could proceed with Phase III trials with Multikine in head & neck cancer patients. CEL-SCI had previously received a "no objection" letter from the Canadian Biologics and Genetic Therapies Directorate which enabled CEL-SCI to begin its Phase III clinical trial in Canada. Subsequently, CEL-SCI received go-ahead from the Polish, Hungarian, Russian, Israeli, Indian and Taiwanese regulators.

CEL-SCI's Phase III clinical trial began in December 2010 after the completion and validation of CEL-SCI's dedicated manufacturing facility.

As explained in Item 1 of this report, as of November 30, 2011, CEL-SCI was involved in a number of pre-clinical studies with respect to its LEAPS technology. As with Multikine, CEL-SCI does not know what obstacles it will encounter in future pre-clinical and clinical studies involving its LEAPS technology. Consequently, CEL-SCI cannot predict with any certainty the funds required for future research and clinical trials and the timing of future research and development projects.

Clinical and other studies necessary to obtain regulatory approval of a new drug involve significant costs and require several years to complete. The extent of CEL-SCI's clinical trials and research programs are primarily based upon the amount of capital available to CEL-SCI and the extent to which CEL-SCI has received regulatory approvals for clinical trials. The inability of CEL-SCI to conduct clinical trials or research, whether due to a lack of capital or regulatory approval, will prevent CEL-SCI from completing the studies and research required to obtain regulatory approval for any products which CEL-SCI is developing. Without regulatory approval, CEL-SCI will be unable to sell any of its products.

Liquidity and Capital Resources

CEL-SCI has had only limited revenues from operations since its inception in March 1983. CEL-SCI has relied upon capital generated from the public and private offerings of its common stock and convertible notes. In addition, CEL-SCI has utilized short-term loans to meet its capital requirements. Capital raised by CEL-SCI has been expended primarily to acquire an exclusive worldwide license to use, and later purchase, certain patented and unpatented proprietary technology and know-how relating to the human immunological defense system. Capital has also been used for patent applications, debt repayment, research and development, administrative costs, and the construction of CEL-SCI's laboratory facilities. CEL-SCI does not anticipate realizing significant revenues until it enters into licensing arrangements regarding its technology and know-how or until it receives regulatory approval to sell its products (which could take a number of years). As a result CEL-SCI has been dependent upon the proceeds from the sale of its securities to meet all of its liquidity and capital requirements and anticipates having to do so in the future.

CEL-SCI will be required to raise additional capital or find additional long-term financing in order to continue with its research efforts. The ability of CEL-SCI to complete the necessary clinical trials and obtain Federal Drug Administration (FDA) approval for the sale of products to be developed on a commercial basis is uncertain. Ultimately, CEL-SCI must complete the development of its products, obtain the appropriate regulatory approvals and obtain sufficient revenues to support its cost structure. CEL-SCI believes that, counting its cash on hand and access to the capital markets established over the years, it will have enough capital to support its operations for more than the next twelve months. The cash required to pay CEL-SCI's outstanding convertible notes (in the principal amount of $2.97 million as of December 1, 2011), will be dependent on the price of CEL-SCI's common stock prior to March 1, 2012, the maturity date of the notes. If CEL-SCI's stock price is above $0.67, which is the conversion price of the notes, the notes may be converted into CEL-SCI common stock, in which case the notes, or part of the notes, will be retired without the payment of cash.

CEL-SCI has two partners who have agreed to participate in and pay for part of the Phase III clinical trial for Multikine. On December 29, 2010, CEL-SCI announced that it had commenced the Phase III clinical trial for Multikine. The net cost to CEL-SCI of the Phase III clinical trial is estimated to be $26 million.

In August 2007, CEL-SCI leased a building near Baltimore, Maryland. The building, which consists of approximately 73,000 square feet, has been remodeled in accordance with CEL-SCI's specifications so that it can be used by CEL-SCI to manufacture Multikine for CEL-SCI's Phase III clinical trials and sales of the drug if approved by the FDA. The lease expires on October 31, 2028, and requires annual base rent payments of approximately $1,667,000 during the twelve months ending September 30, 2011. See Item 1 of this report for more information concerning the terms of this lease.

On August 18, 2008, CEL-SCI sold 1,383,389 shares of common stock and 2,075,084 warrants in a private financing for $1,037,500. The shares were sold at $0.75, a significant premium over the closing price of CEL-SCI's common stock. In June 2009, an additional 1,166,667 shares and 1,815,698 warrants were issued to the investors as a result of a subsequent financing. In October 2011, an additional 833,333 shares and 1,296,927 warrants were issued to the investors as a result of a subsequent financing. Each warrant entitles the holder to purchase one share of CEL-SCI's common stock at a price of $0.30 per share at any time prior to August 18, 2014.

On March 6, 2009, CEL-SCI sold 3,750,000 Units as further consideration under a licensing agreement with an unrelated third party at a price of $0.20 per Unit, or $750,000 in total. Each Unit consisted of one share of CEL-SCI's common stock and two warrants. Each warrant entitles the holder to purchase one share of CEL-SCI's common stock at a price of $0.25 per share. The warrants are exercisable at any time prior to March 6, 2016.

Between June 23 and July 8, 2009, CEL-SCI sold 15,349,346 shares of its common stock at a price of $0.40 per share totaling $6,139,739. The investors in this offering also received 10,284,060 Series A warrants. Each Series A warrant entitles the holder to purchase one share of CEL-SCI's common stock. The Series A warrants may be exercised at any time on or after December 24, 2009 and on or prior to December 24, 2014 at a price of $0.50 per share. As of September 30, 2011, 8,813,088 Series A warrants had been exercised. The remaining Series A warrants allow the holders to purchase up to 1,470,972 shares of CEL-SCI's common stock.

On July 31, 2009, CEL-SCI borrowed $2,000,000 from two institutional investors. The loans were repaid on September 29, 2009. The Series B note holders also received Series B warrants which allow the holders to purchase up to 500,000 shares of CEL-SCI's common stock at a price of $0.68 per share. The Series B warrants may be exercised at any time on or after March 3, 2010 and on or prior to September 4, 2014.

On August 20, 2009, CEL-SCI sold 10,784,435 shares of its common stock to a group of private investors for $4,852,995 or $0.45 per share. The investors also received Series C warrants which entitle the investors to purchase 5,392,217 shares of CEL-SCI's common stock. The Series C warrants may be exercised at any time on or after February 20, 2010 and on or prior to February 20, 2015 at a price of $0.55 per share. As of September 30, 2011, 757,331 Series C warrants had been exercised. The remaining Series C warrants allow the holders to purchase up to 4,634,886 shares of CEL-SCI's common stock.

On September 21, 2009, CEL-SCI sold 14,285,715 shares of its common stock to a group of private investors for $20,000,000 or $1.40 per share. The investors also received Series D warrants which entitle the investors to purchase up to 4,714,284 shares of CEL-SCI's common stock. The Series D warrants may be exercised at any time prior to September 21, 2011, at a price of $1.50 per share. On September 21, 2011, 4,714,284 Series D warrants expired. In addition, the broker for the placement agent received 714,286 Series E warrants. The Series E warrants may be exercised at any time prior to August 12, 2014, at a price of $1.75.

Between December 2008 and June 2009, Maximilian de Clara, CEL-SCI's President and a director, loaned CEL-SCI $1,104,057. The loan was initially payable at the end of March 2009, but was extended to the end of June 2009. At the time the loan was due, and in accordance with the loan agreement, CEL-SCI issued Mr. de Clara a warrant which entitles Mr. de Clara to purchase 1,648,244 shares of CEL-SCI's common stock at a price of $0.40 per share. The warrant is exercisable at any time prior to December 24, 2014. Although the loan was to be repaid from the proceeds of CEL-SCI's recent financing, CEL-SCI's Directors deemed it beneficial not to repay the loan and negotiated a second extension of the loan with Mr. de Clara on terms similar to the June 2009 financing. Pursuant to the terms of the second extension the note was due on July 6, 2014, but, at Mr. de Clara's option, the loan can be converted into shares of CEL-SCI's common stock. Subsequently, on May 13, 2011, to recognize Mr. de Clara's willingness to agree to subordinate his note to the convertible preferred shares and convertible debt as part of the settlement agreement, the Company extended the maturity date of the note to July 6, 2015. The number of shares which will be issued upon any conversion will be determined by dividing the amount to be converted by $0.40. As further consideration for the second extension, Mr. de Clara received warrants which allow Mr. de Clara to purchase 1,849,295 shares of CEL-SCI's common stock at a price of $0.50 per share at any time prior to January 6, 2015. The loan from Mr. de Clara bears interest at 15% per year and is secured by a lien on substantially all of CEL-SCI's assets. CEL-SCI does not have the right to prepay the loan without Mr. de Clara's consent.

Between July 29, 2009 and September 30, 2011, CEL-SCI received approximately $15,624,400 from the exercise of stock options and other warrants (including a number of CEL-SCI's Series A, J, K and L warrants) previously issued to private investors.

On December 10, 2010 CEL-SCI entered into a sales agreement with McNicoll Lewis & Vlak LLC relating to the sale of shares of its common stock which have been registered by means of a registration statement CEL-SCI filed with the Securities and Exchange Commission in July 2009. In accordance with the terms of the sales agreement, CEL-SCI may offer and sell shares of its common stock through McNicoll Lewis & Vlak acting as CEL-SCI's agent. CEL-SCI may also sell its common stock to McNicoll Lewis & Vlak, as principal for its own account, at a price negotiated at the time of sale. On December 5, 2011 CEL-SCI, per the terms of the agreement, exercised its right to terminate the agreement.

Sales of CEL-SCI's common stock, if any, may be made in sales deemed to be "at-the-market" equity offerings, including sales made directly on or through the NYSE Amex, sales made to or through a market maker other than on an exchange, in negotiated transactions at market prices prevailing at the time of sale or at prices related to prevailing market prices, and/or any other method permitted by law. CEL-SCI is not required to sell any shares to McNicoll Lewis & Vlak and McNicoll Lewis & Vlak is not required to sell any shares on CEL-SCI's behalf or purchase any of CEL-SCI's shares for its own account.

McNicoll Lewis & Vlak is entitled to a commission in an amount equal to the greater of 3% of the gross proceeds from each sale of the shares, or $0.025 for each share sold, provided, that, in no event will McNicoll Lewis & Vlak receive a commission greater than 8.0% of the gross proceeds from the sale of the shares.

During the year ended September 30, 2011 CEL-SCI sold 7,424,982 shares of its common stock to McNicoll Lewis & Vlak for $4,144,712, net of commissions and fees of $194,694 and attorney fees of $13,735.

Inventory increased by approximately $95,000 in the fiscal year ended September 30, 2011 as CEL-SCI continued to purchase supplies for the manufacturing of Multikine for the Phase III trial. In addition, prepaids increased by approximately $1,730,000 due to prepayment of certain Phase III clinical trial expenses.

In May 2011, CEL-SCI settled a lawsuit which had been filed in October 2009. Pursuant to the terms of the Settlement Agreement, CEL-SCI paid the plaintiffs $3,000,000 in cash and issued securities with a face value of $9,000,000 to the plaintiffs. See the discussion above pertaining to of the results of operation for fiscal 2011 for more information concerning the settlement and CEL-SCI's obligation to repay notes in the principal amount of $4,950,000 as part of the settlement.

During the year ended September 30, 2011, CEL-SCI's cash decreased by $22,307,649. Significant components of this decrease include 1) approximately $7.05 million paid towards the settlement of the lawsuit, 2) approximately $1.6 million for the defense of the lawsuit, 3) $1.8 million in prepayments for the Phase III clinical trial which CEL-SCI expects to be used during fiscal year 2012 and 4) research and development expenses of $11.7 million and 5) administrative expenses, excluding the lawsuit settlement, of $5.06 million. During the year ended September 30, 2011 CEL-SCI also received $4.6 million from the sale of stock and exercise of stock options and warrants.

In October 2011, CEL-SCI sold 13,333,334 shares of its common stock to private investors for $4,000,000, or $0.30 per share. The investors also received 12,000,000 Series F warrants. Each Series F warrant entitles the holder to purchase one share of CEL-SCI's common stock at a price of $0.40 per share at any time prior to October 6, 2014. CEL-SCI paid the placement agent for this offering a commission consisting of $140,000 in cash and 666,667 Series G warrants. Each Series G warrant entitles the holder to purchase one share of CEL-SCI's common stock at a price of $0.40 per share at any time prior to August 12, 2014.

Future Capital Requirements

CEL-SCI is currently running a large multi-national Phase III clinical trial for head and neck cancer. Head and neck cancer accounts for about 6% of the world's annual cancer cases. This study, if successful, should address a major unmet medical need of a very large scale. Therefore the positive outcome of this trial carries the potential for a great amount of financial upside for shareholders. It is for this reason that CEL-SCI should have many avenues of funding available to it throughout the Phase III clinical trial. During 2011, CEL-SCI used an At The Market (ATM) transaction to raise money and, separately, raised money in a direct placement of shares and warrants to investors. While CEL-SCI cancelled the ATM in December 2011, management believes, based on current offers, that it could start the ATM again, if needed. CEL-SCI is also offered, on a regular basis, other financings. Management believes that, particularly under the current market conditions, it is imperative to be flexible to achieve the best outcome for the shareholders. Therefore, CEL-SCI expects that it will raise additional capital in fiscal year 2012 in the form of corporate partnerships, debt and/or equity financings to support its operations at its current rate. CEL-SCI believes that it will be able to obtain additional financing since Multikine is a Phase III product designed to treat cancer, an area that pharmaceutical companies are increasingly targeting. However, as stated in the CEL-SCI risk factors, there is no assurance that funds will be available to CEL-SCI. It is important to note that CEL-SCI's expenditures for fiscal year 2011 included several very large non-recurring expenses that amounted to approximately $10 million dollars, mostly related to the lawsuit and the settlement of the lawsuit. These expenses, with the exception of the settlement payments through March 1, 2012, will not recur in fiscal year 2012, thereby reducing CEL-SCI's expenditures significantly.

In general, CEL-SCI believes that it will be able to raise sufficient capital in 2012 to 1) expand the Phase III trial and 2) continue operations through December 2012. However, it is possible that CEL-SCI will not be able to generate enough cash to continue operations at its current level. CEL-SCI's registered independent public accounting firm has issued an audit opinion that includes an explanatory paragraph that expresses substantial doubt about CEL-SCI's ability to continue as a going concern mainly due to continued losses from operations and future liquidity needs of CEL-SCI. CEL-SCI's management has engaged in fundraising for over 20 years and believes that the manner in which it is proceeding will produce the best possible outcome for the shareholders. There can be no assurances that CEL-SCI will be successful in raising additional funds.

Other than funding operating losses, funding its research and development program, and paying its liabilities, CEL-SCI does not have any material capital commitments. Material future liabilities as of September 30, 2011 are as follows:

		Years Ending September 30,					
	Total	2012	2013	2014	2015	2016	2017 & thereafter
Operating Leases	$33,346,809	$1,896,205	$1,855,890	$1,579,931	$1,572,839	$1,629,121	$24,812,823
Employment Contracts	$3,850,862	$1,282,878	$1,214,639	$464,004	$464,004	$425,337	-
Convertible Notes	$4,950,000	$4,950,000	-	-	-	-	-
Interest on Notes	$215,705	$215,705	-	-	-	-	-

For additional information on employment contracts, see Item 11 of this report.

Further, CEL-SCI has contingent obligations with vendors for work that will be completed in relation to the Phase III trial. The timing of these obligations cannot be determined at this time. The amount of these obligations for the Phase III trial is approximately $26 million.

CEL-SCI will need to raise additional funds, either through its existing warrants/options, through a debt or equity financing or a partnering arrangement, to complete the Phase III trial and bring Multikine to market.

Clinical and other studies necessary to obtain regulatory approval of a new drug involve significant costs and require several years to complete. The extent of CEL-SCI's clinical trials and research programs are primarily based upon the amount of capital available to CEL-SCI and the extent to which CEL-SCI has received regulatory approvals for clinical trials. The inability of CEL-SCI to conduct clinical trials or research, whether due to a lack of capital or regulatory approval, will prevent CEL-SCI from completing the studies and research required to obtain regulatory approval for any products which CEL-SCI is developing. Without regulatory approval, CEL-SCI will be unable to sell any of its products.

In the absence of revenues, CEL-SCI will be required to raise additional funds through the sale of securities, debt financing or other arrangements in order to continue with its research efforts. However, there can be no assurance that such financing will be available or be available on favorable terms. Ultimately, CEL-SCI must complete the development of its products, obtain appropriate regulatory approvals and obtain sufficient revenues to support its cost structure.

Since all of CEL-SCI's projects are under development CEL-SCI cannot predict with any certainty the funds required for future research and clinical trials, the timing of future research and development projects, or when it will be able to generate any revenue from the sale of any of its products.

CEL-SCI's cash flow and earnings are subject to fluctuations due to changes in interest rates on its bank accounts, and, to an immaterial extent, foreign currency exchange rates.

Critical Accounting Policies

CEL-SCI's significant accounting policies are more fully described in Note 1 to the consolidated financial statements included as part of this report. However, certain accounting policies are particularly important to the portrayal of financial position and results of operations and require the application of significant judgments by management. As a result, the consolidated financial statements are subject to an inherent degree of uncertainty. In applying those policies, management uses its judgment to determine the appropriate assumptions to be used in the determination of certain estimates. These estimates are based on CEL-SCI's historical experience, terms of existing contracts, observance of trends in the industry and information available from outside sources, as appropriate. CEL-SCI's significant accounting policies include:

Patents — Patent expenditures are capitalized and amortized using the straight-line method over 17 years. In the event changes in technology or other circumstances impair the value or life of the patent, appropriate adjustment in the asset value and period of amortization is made. An impairment loss is recognized when estimated future undiscounted cash flows expected to result from the use of the asset, and from disposition, is less than the carrying value of the asset. The amount of the impairment loss is the difference between the estimated fair value of the asset and its carrying value.

Stock Options and Warrants — Effective October 1, 2005, the Company adopted the fair value recognition provisions of ASC 718 using the prospective transition method which requires the Company to apply the provisions of ASC 718 only to awards granted, modified, repurchased or cancelled after October 1, 2005. Compensation cost for all stock-based awards after October 1, 2005 is measured at fair value as of the grant date in accordance with the provisions of ASC 718. The fair value of the stock options is calculated using the Black-Scholes option pricing model. The Black-Scholes model requires various judgmental assumptions including volatility, forfeiture rates and expected option life. The stock-based compensation cost is recognized on the accelerated method as expense over the requisite service or vesting period.

Options to non-employees are accounted for in accordance with Codification 505-50-S99-1 Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services. Accordingly, compensation is recognized when goods or services are received and is measured using the Black-Scholes valuation model. The Black-Scholes model requires CEL-SCI's management to make assumptions regarding the fair value of the options at the date of grant and the expected life of the options.

Asset Valuations and Review for Potential Impairments — CEL-SCI reviews its fixed assets, intangibles and deferred rent every fiscal quarter. This review requires that CEL-SCI make assumptions regarding the value of these assets and the changes in circumstances that would affect the carrying value of these assets. If such analysis indicates that a possible impairment may exist, CEL-SCI is then required to estimate the fair value of the asset and, as deemed appropriate, expense all or a portion of the asset. The determination of fair value includes numerous uncertainties, such as the impact of competition on future value. CEL-SCI believes that it has made reasonable estimates and judgments in determining whether its long-lived assets have been impaired; however, if there is a material change in the assumptions used in its determination of fair values or if there is a material change in economic conditions or circumstances influencing fair value, CEL-SCI could be required to recognize certain impairment charges in the future. As a result of the reviews, no changes in asset values were required.

Prepaid Expenses and Inventory — Inventory consists of bulk purchases of laboratory supplies used on a daily basis in the lab and items that will be used for future production. The items in inventory are expensed when used in production or daily activity as Research and Development expenses. These items are disposables and consumables and can be used for both the manufacturing of Multikine for clinical studies and in the laboratory for quality control and bioassay use. They can be used in training, testing and daily laboratory activities. Prepaid expenses are payments for services over a long period and are expensed over the time period for which the service is rendered.

Derivative Instruments — CEL-SCI enters into financing arrangements that consist of freestanding derivative instruments or hybrid instruments that contain embedded derivative features. CEL-SCI accounts for these arrangement in accordance with Codification 815-10-50, "Accounting for Derivative Instruments and Hedging Activities", "Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock", as well as related interpretations of these standards. In accordance with accounting principles generally accepted in the United States ("GAAP"), derivative instruments and hybrid instruments are recognized as either assets or liabilities in the statement of financial position and are measured at fair value with gains or losses recognized in earnings or other comprehensive income depending on the nature of the derivative or hybrid instruments. Embedded derivatives that are not clearly and closely related to the host contract are bifurcated and recognized at fair value with changes in fair value recognized as either a gain or loss in earnings if they can be reliably measured. When the fair value of embedded derivative features cannot be reliably measured, CEL-SCI measures and reports the entire hybrid instrument at fair value with changes in fair value recognized as either a gain or loss in earnings. CEL-SCI determines the fair value of derivative instruments and hybrid instruments based on available market data using appropriate valuation models, giving consideration to all of the rights and obligations of each instrument and precluding the use of "blockage" discounts or premiums in determining the fair value of a large block of financial instruments. Fair value under these conditions does not necessarily represent fair value determined using valuation standards that give consideration to blockage discounts and other factors that may be considered by market participants in establishing fair value.

Accounting Pronouncements

In January 2010, the FASB issued ASU 2010-06, "Fair Value Measurements and Disclosures", which requires new disclosures for transfers in and out of Level 1 and Level 2 and activity in Level 3 of the fair value hierarchy. ASU 2010-06 requires separate disclosure of the amounts of significant transfers in and out of Level 1 and Level 2 fair value measurements and a description of the reasons for the transfers. In the reconciliation for fair value measurements using Level 3 inputs, a reporting entity should present separately information about purchases, sales, issuances and settlements. ASU 2010-06 is effective for new disclosures and clarification of existing disclosures for interim and annual periods beginning after December 15, 2009 except for disclosures about purchases, sales, issuances and settlements in the Level 3 activity rollforward, which are effective for fiscal years beginning after December 15, 2010, and for interim periods within those fiscal years. The adoption of ASU 2010-06 did not have a material impact on its financial statements.

In May 2011, the FASB issued Accounting Standards Update (ASU) No. 2011-04, "Fair Value Measurement (Topic 820) – Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs", which is effective for interim and annual periods beginning after December 15, 2011. The ASU is mainly the result of the joint efforts by the FASB and the International Accounting Standards Board to develop a single, converged fair value framework on how to measure fair value and common disclosure requirements for fair value measurements. The ASU amends various fair value guidance such as requiring the highest-and-best-use and valuation-premise concepts only to measuring the fair value of nonfinancial assets and prohibits the use of blockage factors and control premiums when measuring fair value. In addition, the ASU expands disclosure requirements particularly for Level 3 inputs and requires disclosure of the level in the fair value hierarchy of items that are not measured at fair value in the statement of financial position but whose fair value must be disclosed. The Company

does not believe that this amendment will have a material impact on its financial statements.

ITEMQUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISKS
7A.

Market risk is the potential change in an instrument's value caused by, for example, fluctuations in interest and currency exchange rates. CEL-SCI enters into financing arrangements that are or include freestanding derivative instruments or that are, or include, hybrid instruments that contain embedded derivative features. CEL-SCI does not enter into derivative instruments for trading purposes. Additional information is presented in the notes to consolidated financial statements. The fair value of these instruments is affected primarily by volatility of the trading prices of the CEL-SCI's common stock. For three years ended September 30, 2011, CEL-SCI recognized a gain or (loss) of $4,432,148, $28,843,772 and $(28,491,650), respectively, resulting from changes in fair value of derivative instruments. CEL-SCI has exposure to risks associated with foreign exchange rate changes because some of the expenses related to the Phase III trial are transacted in a foreign currency. The interest risk on investments on September 30, 2011 was considered immaterial due to the fact that the interest rates at that time were nominal at best and CEL-SCI keeps its cash and cash equivalents in short term maturities.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

See the consolidated financial statements included with this Report.

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

Not applicable

ITEM 9A. CONTROLS AND PROCEDURES

Under the direction and with the participation of CEL-SCI's management, including CEL-SCI's Chief Executive Officer and Chief Financial Officer, CEL-SCI carried out an evaluation of the effectiveness of the design and operation of its disclosure controls and procedures as of September 30, 2011. CEL-SCI maintains disclosure controls and procedures that are designed to ensure that information required to be disclosed in its periodic reports with the Securities and Exchange Commission is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and regulations, and that such information is accumulated and communicated to CEL-SCI's management, including its principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure. CEL-SCI's disclosure controls and procedures are designed to provide a reasonable level of assurance of reaching its desired disclosure control objectives. Based on the evaluation, the Chief Executive and Principal Financial Officer has concluded that CEL-SCI's disclosure controls were effective as of September 30, 2011.

Management's Report on Internal Control Over Financial Reporting

CEL-SCI's management is responsible for establishing and maintaining adequate internal control over financial reporting and for the assessment of the effectiveness of internal control over financial reporting. As defined by the Securities and Exchange Commission, internal control over financial reporting is a process designed by, or under the supervision of CEL-SCI's principal executive officer and principal financial officer and implemented by CEL-SCI's Board of Directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of CEL-SCI's financial statements in accordance with U.S. generally accepted accounting principles.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Geert Kersten, CEL-SCI's Chief Executive and Principal Financial Officer, evaluated the effectiveness of CEL-SCI's internal control over financial reporting as of September 30, 2011 based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission, or the COSO Framework. Management's assessment included an evaluation of the design of CEL-SCI's internal control over financial reporting and testing of the operational effectiveness of those controls.

Based on this evaluation, Mr. Kersten concluded that CEL-SCI's internal control over financial reporting was effective as of September 30, 2011.

There was no change in CEL-SCI's internal control over financial reporting that occurred during the fiscal year ended September 30, 2011 that has materially affected, or is reasonably likely to materially affect, CEL-SCI's internal control over financial reporting.

CEL-SCI's independent registered public accounting firm BDO USA, LLP has issued an attestation report on CEL-SCI's internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

Officers and Directors

Name	Age	Position
Maximilian de Clara	81	Director and President
Geert R. Kersten, Esq.	52	Director, Chief Executive Officer and Treasurer
Patricia B. Prichep	60	Senior Vice President of Operations and Secretary
Dr. Eyal Talor	55	Chief Scientific Officer
Dr. Daniel H. Zimmerman	70	Senior Vice President of Research, Cellular Immunology
John Cipriano	69	Senior Vice President of Regulatory Affairs
Alexander G. Esterhazy	69	Director
Dr. C. Richard Kinsolving	75	Director
Dr. Peter R. Young	66	Director

The directors of CEL-SCI serve in such capacity until the next annual meeting of CEL-SCI's shareholders and until their successors have been duly elected and qualified. The officers of CEL-SCI serve at the discretion of CEL-SCI's directors.

Mr. Maximilian de Clara, by virtue of his position as an officer and director of CEL-SCI, may be deemed to be the "parent" and "founder" of CEL-SCI as those terms are defined under applicable rules and regulations of the SEC.

All of CEL-SCI's directors have served as directors for a significant period of time. Consequently, their long-standing experience with CEL-SCI benefits both CEL-SCI and its shareholders.

The principal occupations of CEL-SCI's officers and directors, during the past several years, are as follows:

Maximilian de Clara has been a Director of CEL-SCI since its inception in March l983, and has been President of CEL-SCI since July l983. Prior to his affiliation with CEL-SCI, and since at least l978, Mr. de Clara was involved in the management of his personal investments and personally funding research in the fields of biotechnology and biomedicine. Mr. de Clara attended the medical school of the University of Munich from l949 to l955, but left before he received a medical degree. During the summers of l954 and l955, he worked as a research assistant at the University of Istanbul in the field of cancer research. For his efforts and dedication to research and development in the fight against cancer and AIDS, Mr. de Clara was awarded the "Pour le Merit" honorary medal of the Austrian Military Order "Merito Navale" as well as the honor cross of the Austrian Albert Schweitzer Society.

Geert Kersten has served in his current leadership role at CEL-SCI since 1995. Mr. Kersten has been with CEL-SCI from the early days of its inception since 1987. He has been involved in the pioneering field of cancer immunotherapy for over two decades and has successfully steered CEL-SCI through many challenging cycles in the biotechnology industry. Mr. Kersten also provides CEL-SCI with significant expertise in the fields of finance and law and has a unique vision of how CEL-SCI 's Multikine product could potentially change the way cancer is treated. Prior to CEL-SCI, Mr. Kersten worked at the law firm of Finley & Kumble and worked at Source Capital, an investment banking firm located in McLean, VA. He is a native of Germany, graduated from Millfield School in England, and completed his studies in the US. Mr. Kersten completed his Undergraduate Degree in Accounting, received an M.B.A. from George Washington University, and a law degree (J.D.) from American University in Washington, DC.

Patricia B. Prichep joined CEL-SCI in 1992 and has been CEL-SCI's Senior Vice President of Operations since March 1994. Between December 1992 and March 1994, Ms. Prichep was CEL-SCI's Director of Operations. Ms. Prichep became CEL-SCI's Corporate Secretary in May 2000. She is responsible for all day-to-day operations of CEL-SCI, including human resources and is the liaison with CEL-SCI’s independent registered public accounting firm for financial reporting. From June 1990 to December 1992, Ms. Prichep was the Manager of Quality and Productivity for the NASD’s Management, Systems and Support Department. She was responsible for the internal auditing and work flow analysis of operations. Between 1982 and 1990, Ms. Prichep was Vice President and Operations Manager for Source Capital, Ltd. She handled all operations and compliance for CEL-SCI and was licensed as a securities broker. Ms. Prichep received her B.A. from the University of Bridgeport in Connecticut.

Eyal Talor, Ph.D. joined CEL-SCI in October 1993. In October 2009, Dr. Talor was promoted to Chief Scientific Officer. Prior to this promotion he was the Senior Vice President of Research and Manufacturing since March of 1994. He is a clinical immunologist with over 19 years of hands-on management of clinical research and drug development for immunotherapy application; pre-clinical to Phase III, in the biopharmaceutical industry. His expertise includes; biopharmaceutical R&D and Biologics product development, GMP (Good Manufacturing Practices) manufacture, Quality Control testing, and the design and building of GMP manufacturing and testing facilities. He served as Director of Clinical Laboratories (certified by the State of Maryland) and has experience in the design of clinical trials (Phase I – III) and GCP (Good Clinical Practices) requirements. He also has broad experience in the different aspects of biological assay development, analytical methods validation, raw material specifications, and QC (Quality Control) tests development under FDA/GMP, USP, and ICH guidelines. He has extensive experience in the preparation of documentation for IND and other regulatory submissions. His scientific area of expertise encompasses immune response assessment. He is the author of over 25 publications and has published a number of reviews on immune regulations in relation to clinical immunology. Before coming to CEL-SCI, he was Director of R&D and Clinical Development at CBL, Inc., Principal Scientist - Project Director, and Clinical Laboratory Director at SRA Technologies, Inc. Prior to that he was a full time faculty member at The Johns Hopkins University, Medical Intuitions; School of Public Health. He holds two US patents; one on Multikine’s composition of matter and method of use in cancer, and one on a platform Peptide technology (‘Adapt’) for the treatment of autoimmune diseases, asthma, allergy, and transplantation rejection. He also has numerous product and process inventions as well as a number of pending US and PCT patent applications. He received his Ph.D. in Microbiology and Immunology from the University of Ottawa, Ottawa, Ontario, Canada, and had post-doctoral training in clinical

and cellular immunology at The John Hopkins University, Baltimore, Maryland, USA. He holds an Adjunct Associate teaching position at the Johns Hopkins University Medical Institutions.

Daniel H. Zimmerman, Ph.D., has been CEL-SCI's Senior Vice President of Cellular Immunology between 1996 and December 2008 and again since November 2009. He joined CEL-SCI in January 1996 as the Vice President of Research, Cellular Immunology. Dr. Zimmerman founded CELL-MED, Inc. and was its president from 1987-1995. From 1973-1987, Dr. Zimmerman served in various positions at Electronucleonics, Inc. His positions included: Scientist, Senior Scientist, Technical Director and Program Manager. Dr Zimmerman held various teaching positions at Montgomery College between 1987 and 1995. Dr. Zimmerman holds over a dozen US patents as well as many foreign equivalent patents. He is the author of over 40 scientific publications in the area of immunology and infectious diseases. He has been awarded numerous grants from NIH and DOD. From 1969-1973, Dr. Zimmerman was a Senior Staff Fellow at NIH. For the following 25 years, he continued on at NIH as a guest worker. Dr. Zimmerman received a Ph.D. in Biochemistry in 1969, a Masters in Zoology in 1966 from the University of Florida and a B.S. in Biology from Emory and Henry College in 1963.

John Cipriano, has been CEL-SCI's Senior Vice President of Regulatory Affairs between March 2004 and December 2008 and again since October 2009. Mr. Cipriano brings to CEL-SCI over 30 years of experience in both biotech and pharmaceutical companies. In addition, he held positions at the United States Food and Drug Administration (FDA) as Deputy Director, Division of Biologics Investigational New Drugs, Office of Biologics Research and Review and was the Deputy Director, IND Branch, Division of Biologics Evaluation, Office of Biologics. Mr. Cipriano completed his B.S. in Pharmacy from the Massachusetts College of Pharmacy in Boston, Massachusetts and his M.S. in Pharmaceutical Chemistry from Purdue University in West Lafayette, Indiana.

Alexander G. Esterhazy has been a Director of CEL-SCI since December 1999 and has been an independent financial advisor since November 1997. Between July 1991 and October 1997, Mr. Esterhazy was a senior partner of Corpofina S.A. Geneva, a firm engaged in mergers, acquisitions and portfolio management. Between January 1988 and July 1991, Mr. Esterhazy was a managing director of DG Bank in Switzerland. During this period Mr. Esterhazy was in charge of the Geneva, Switzerland branch of the DG Bank, founded and served as Vice President of DG Finance (Paris) and was the President and Chief Executive Officer of DG-Bourse, a securities brokerage firm.

C. Richard Kinsolving, Ph.D. has been a Director of CEL-SCI since April 2001. Since February 1999, Dr. Kinsolving has been the Chief Executive Officer of BioPharmacon, a pharmaceutical development company. Between December 1992 and February 1999, Dr. Kinsolving was the President of Immuno-Rx, Inc., a company engaged in immuno-pharmaceutical development. Between December 1991 and September 1995, Dr. Kinsolving was President of Bestechnology, Inc. a nonmedical research and development company producing bacterial preparations for industrial use. Dr. Kinsolving received his Ph.D. in Pharmacology from Emory University (1970), his Masters degree in Physiology/Chemistry from Vanderbilt University (1962), and his Bachelor's degree in Chemistry from Tennessee Tech. University (1957).

Peter R. Young, Ph.D. has been a Director of CEL-SCI since August 2002. Dr. Young has been a senior executive within the pharmaceutical industry in the United States and Canada for most of his career. Over the last 20 years he has primarily held positions of Chief Executive Officer or Chief Financial Officer and has extensive experience with acquisitions and equity financings. Since November 2001, Dr. Young has been the President of Agnus Dei, LLC, which acts as a partner in an organization managing immune system clinics which treat patients with diseases such as cancer, multiple sclerosis and hepatitis. Since January 2003, Dr. Young has been the President and Chief Executive Officer of SRL Technology, Inc., a company involved in the development of pharmaceutical (drug) delivery systems. Between 1998 and 2001, Dr. Young was the Chief Financial Officer of Adams Laboratories, Inc. Dr. Young received his Ph.D. in Organic Chemistry from the University of Bristol, England (1969), and his Bachelor's degree in Honors Chemistry, Mathematics and Economics also from the University of Bristol, England (1966).

All of CEL-SCI's officers devote substantially all of their time to CEL-SCI's business.

40

CEL-SCI's Board of Directors does not have a "leadership structure", as such, since each director is entitled to introduce resolutions to be considered by the Board and each director is entitled to one vote on any resolution considered by the Board. CEL-SCI's Chief Executive Officer is not the Chairman of CEL-SCI's Board of Directors.

CEL-SCI's Board of Directors has the ultimate responsibility to evaluate and respond to risks facing CEL-SCI. CEL-SCI's Board of Directors fulfills its obligations in this regard by meeting on a regular basis and communicating, when necessary, with CEL-SCI's officers.

Alexander G. Esterhazy, Dr. C. Richard Kinsolving and Dr. Peter R. Young are independent directors as that term is defined in section 803 of the listing standards of the NYSE Amex.

CEL-SCI has adopted a Code of Ethics which is applicable to CEL-SCI'S principal executive, financial, and accounting officers and persons performing similar functions. The Code of Ethics is available on CEL-SCI's website, located at www.cel-sci.com.

If a violation of this code of ethics act is discovered or suspected, the Senior Officer must (anonymously, if desired) send a detailed note, with relevant documents, to CEL-SCI's Audit Committee, c/o Dr. Peter Young, 2500 Marketplace Drive, Unit 431, Waco, TX 76711.

For purposes of electing directors at its annual meeting CEL-SCI does not have a nominating committee or a committee performing similar functions. CEL-SCI's Board of Directors does not believe a nominating committee is necessary since CEL-SCI's Board of Directors is small and the Board of Directors as a whole performs this function. The nominees to the Board of Directors are selected by a majority vote of CEL-SCI's independent directors.

CEL-SCI does not have any policy regarding the consideration of director candidates recommended by shareholders since a shareholder has never recommended a nominee to the Board of Directors and under Colorado law, any shareholder can nominate a person for election of a director at the annual shareholders' meeting. However, CEL-SCI's Board of Directors will consider candidates recommended by shareholders. To submit a candidate for the Board of Directors the shareholder should send the name, address and telephone number of the candidate, together with any relevant background or biographical information, to CEL-SCI's Chief Executive Officer, at the address shown on the cover page of this proxy statement. The Board has not established any specific qualifications or skills a nominee must meet to serve as a director. Although the Board does not have any process for identifying and evaluating director nominees, the Board does not believe there would be any differences in the manner in which the Board evaluates nominees submitted by shareholders as opposed to nominees submitted by any other person.

CEL-SCI does not have a policy with regard to Board member's attendance at annual meetings. All Board members, with the exception of Maximilian de Clara and Alexander Esterhazy, attended the last annual shareholder's meeting held on April 15, 2011.

Holders of CEL-SCI's common stock can send written communications to CEL-SCI's entire Board of Directors, or to one or more Board members, by addressing the communication to "the Board of Directors" or to one or more directors, specifying the director or directors by name, and sending the communication to CEL-SCI's offices in Vienna, Virginia. Communications addressed to the Board of Directors as whole will be delivered to each Board member. Communications addressed to a specific director (or directors) will be delivered to the director (or directors) specified.

Security holder communications not sent to the Board of Directors as a whole or to specified Board members are not relayed to Board members.

41

ITEM 11. EXECUTIVE COMPENSATION

Compensation Discussion and Analysis

This Compensation Discussion and Analysis (CD&A) outlines CEL-SCI's compensation philosophy, objectives and process for its executive officers. This CD&A includes information on how compensation decisions are made, the overall objectives of CEL-SCI's compensation program, a description of the various components of compensation that are provided, and additional information pertinent to understanding CEL-SCI's executive officer compensation program.

The Compensation Committee determines the compensation of CEL-SCI's Chief Executive Officer and President and delegates to the Chief Executive Officer the responsibility to determine the base salaries of all officers other than himself under the constraints of an overall limitation on the total amount of compensation to be paid to them.

Compensation Philosophy

CEL-SCI's compensation philosophy extends to all employees, including executive officers, and is designed to align employee and shareholder interests. The philosophy's objective is to pay fairly based upon the employee's position, experience and individual performance. Employees may be rewarded through additional compensation when CEL-SCI meets or exceeds targeted business objectives. Generally, under CEL-SCI's compensation philosophy, as an employee's level of responsibility increases, a greater portion of his or her total potential compensation becomes contingent upon annual performance.

A substantial portion of an executive's compensation incorporates performance criteria that support and reward achievement of CEL-SCI's long term business goals.

The fundamental principles of CEL-SCI's compensation philosophy are described below:

Market-driven. Compensation programs are structured to be competitive both in their design and in the total compensation that they offer.

Performance-based. Certain officers have some portion of their incentive compensation linked to CEL-SCI's performance. The application of performance measures as well as the form of the reward may vary depending on the employee's position and responsibilities.

Based on a review of its compensation programs, CEL-SCI does not believe that such programs encourage any of its employees to take risks that would be likely to have a material adverse effect on CEL-SCI. CEL-SCI reached this conclusion based on the following:

The salaries paid to employees are consistent with the employees' duties and responsibilities.
Employees who have high impact relative to the expectations of their job duties and functions are rewarded.
CEL-SCI retains employees who have skills critical to its long term success.

Review of Executive Officer Compensation

CEL-SCI's current policy is that the various elements of the compensation package are not interrelated in that gains or losses from past equity incentives are not factored into the determination of other compensation. For instance, if options that are granted in a previous year become underwater the next year, the Committee does not take that into consideration in determining the amount of the options or restricted stock to be granted the next year. Similarly, if the options or restricted shares granted in a previous year become extremely valuable, the Committee does not take that into consideration in determining the options or restricted stock to be awarded for the next year.

CEL-SCI does not have a policy with regard to the adjustment or recovery of awards or payments if relevant performance measures upon which they are based are restated or otherwise adjusted in a manner that would reduce the size of an award or payment.

Components of Compensation—Executive Officers

CEL-SCI's executive officers are compensated through the following three components:

Base Salary
Long-Term Incentives (stock options and/or grants of stock)
Benefits

These components provide a balanced mix of base compensation and compensation that is contingent upon each executive officer's individual performance. A goal of the compensation program is to provide executive officers with a reasonable level of security through base salary and benefits. CEL-SCI wants to ensure that the compensation programs are appropriately designed to encourage executive officer retention and motivation to create shareholder value. The Compensation Committee believes that CEL-SCI's stockholders are best served when CEL-SCI can attract and retain talented executives by providing compensation packages that are competitive but fair.

In past years, base salaries, benefits and incentive compensation opportunities were generally targeted near the median of general survey market data derived from indices covering similar biotech/pharmaceutical companies. The companies included Achillion Pharmaceuticals, Inc., Acura Pharmaceutical, Inc., Alimera Sciences, Inc., Agenus Inc., ARCA biopharma (ARCA Discovery), Cadence Pharmaceuticals, Inc., Chelsea Therapeutics, Inc., Cortex Pharmaceuticals, Inc., EpiCept Corp., IGI Laboratories Inc., Inhibitex, Inc., Medicis Technologies Corp., NeurogesX, Inc., Orexigen Therapeutics Inc., Pharmacyclics, Inc., Resverlogix Corp., SCOLR Pharma, Inc., StemCells, Inc., Psychemedics Corporation, Molecular Insight Pharmaceuticals, Inc., Nabi Biopharmaceuticals, NuPathe Inc. and POZEN, Inc. CEL-SCI has not used third party consultants to provide it with recommendations or reports.

Base Salaries

Base salaries generally have been targeted to be competitive when compared to the salary levels of persons holding similar positions in other pharmaceutical companies and other publicly traded companies of comparable size. Each executive officer's respective responsibilities, experience, expertise and individual performance are considered.

A further consideration in establishing compensation for the senior employees is their long term history with CEL-SCI. Taken into consideration are factors that have helped CEL-SCI survive in times when it was financially extremely weak, such as: willingness to accept salary cuts, willingness not to be paid at all for extended time periods, and in general an attitude that helped CEL-SCI survive during financially difficult times. For example, Geert Kersten, Maximilian de Clara and Patricia Prichep were without any salary between September 2008 and June 2009. Other senior members took substantial salary cuts, all geared towards helping CEL-SCI survive. In all of these cases the officers continued to work without any guarantee of payment.

Long-Term Incentives

Stock grants and option grants help to align the interests of CEL-SCI's employees with those of its shareholders. Options and stock grants are made under CEL-SCI's Stock Option, Stock Bonus and Stock Compensation Plans. Options are granted with exercise prices equal to the closing price of CEL-SCI's common stock on the day immediately preceding the date of grant, with pro rata vesting at the end of each of the following three years.

CEL-SCI believes that grants of equity-based compensation:

Enhance the link between the creation of shareholder value and long-term executive incentive compensation;
Provide focus, motivation and retention incentive; and
Provide competitive levels of total compensation.

CEL-SCI's management believes that the pricing for biotechnology stocks is highly inefficient until the time of product sales. As such any long term compensation tied to progress as measured by share price is not as efficient as it should be. However, CEL-SCI's Compensation Committee has not been able to substitute a better measurement and therefore continues to believe that stock grants and option grants best align the needs of the corporation and the employee with those of the shareholders.

Benefits

In addition to cash and equity compensation programs, executive officers participate in the health and welfare benefit programs available to other employees. In a few limited circumstances, CEL-SCI provides other benefits to certain executive officers, such as car allowances.

All executive officers are eligible to participate in CEL-SCI's 401(k) plan on the same basis as its other employees. CEL-SCI matches 100% of each employee's contribution up to the first 6% of his or her salary.

The following table sets forth in summary form the compensation received by (i) the Chief Executive Officer of CEL-SCI and (ii) by each other executive officer of CEL-SCI who received in excess of $100,000 during the three fiscal years ended September 30, 2011.

Name and Principal Position	Fiscal Year	Salary (1) $	Bonus (2) $	Restricted Stock Awards (3) $	Option Awards (4) $	All Other Annual Compensation (5) $	Total $
Maximilian de Clara,	2011	363,000	--	--	176,709	105,226	644,935
President	2010	363,000	--	--	107,424	102,186	572,610
	2009	334,720	--	205,000	531,236	83,274	1,154,230
Geert R. Kersten,	2011	464,005	--	14,700	207,314	57,656	743,675
Chief Executive Officer and Treasurer	2010	454,009	220,995	11,025	128,909	55,309	870,247
	2009	408,691	--	5,000	1,735,284	34,892	2,183,867
Patricia B. Prichep	2011	204,013	--	12,541	99,141	6,031	321,726
Senior Vice President of Operations and Secretary	2010	199,898	--	11,790	64,455	6,027	282,170
	2009	174,913	--	--	1,142,155	4,225	1,321,293
Eyal Talor, Ph.D.	2011	251,861	--	9,600	100,362	6,031	367,854
Chief Scientific Officer	2010	239,868	--	15,623	64,455	6,027	325,973
	2009	212,265	--	--	1,044,566	4,225	1,261,056
Daniel Zimmerman, Ph.D.	2011	193,260	--	11,896	98,948	6,031	310,135
Senior Vice President of Research. Cellular Immunology (6)	2010	165,800	--	9,233	64,455	5,027	244,515
	2009	47,124	--	--	--	875	47,999
John Cipriano	2011	178,870	--	--	91,815	31	270,716
	2010	175,952	--	--	240,711	27	416,690

Senior Vice President of Regulatory Affairs (7)							
	2009	48,594	--	--	--	25	48,619

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(1) The dollar value of base salary (cash and non-cash) earned.

(2) The dollar value of bonus (cash and non-cash) earned.

(3) During the periods covered by the table, the value of the shares of restricted stock issued as compensation for services to the persons listed in the table. In the case of Mr. de Clara, during three years ended September 30, 2011, 2010, and 2009, $0, $0 and $200,000, respectively, were paid in restricted shares of CEL-SCI's common stock which cannot be sold in the public market for a period of three years after the date of issuance. In the case of all other persons listed in the table, the shares were issued as CEL-SCI's contribution on behalf of the named officer to CEL-SCI's 401(k) retirement plan and restricted shares issued at the market price from the Stock Compensation Plan. The value of all stock awarded during the periods covered by the table are calculated according to ASC 718-10-30-3 which represented the grant date fair value.

(4) The greatest part of the value in FY 2009 was derived from options awarded to employees who did not collect a salary, or reduced or deferred their salary between September 15, 2008 and June 30, 2009. For example, Mr. de Clara, Mr. Kersten and Ms. Prichep did not collect any salary between September 30, 2008 and June 30, 2009. The fair value of all stock options granted during the periods covered by the table are calculated on the grant date in accordance with ASC 718-10-30-3 which represented the grant date fair value

(5) All other compensation received that CEL-SCI could not properly report in any other column of the table including annual contributions or other allocations to vested and unvested defined contribution plans, and the dollar value of any insurance premiums paid by, or on behalf of, CEL-SCI with respect to term life insurance for the benefit of the named executive officer, and the full dollar value of the remainder of the premiums paid by, or on behalf of, CEL-SCI and car allowances paid by CEL-SCI. Includes board of directors fees for Mr. de Clara and Mr. Kersten.

(6) Dr. Zimmerman was CEL-SCI's Senior Vice President of Research, Cellular Immunology between January 1996 and December 2008 and since November 2009.

(7) Mr. Cipriano was CEL-SCI's Senior Vice President of Regulatory Affairs between March 2004 and December 2008 and since October 2009.

(8) In 2009, CEL-SCI made performance share awards to the senior management which entitles these employees to receive a specified number of options to purchase the Company's common stock provided that certain milestones are met. One third of the options can be exercised when the first 400 patients are enrolled in CEL-SCI's Phase III head and neck cancer clinical trial. One third of the options can be exercised when all of the patients have been enrolled in the Phase III clinical trial. One third of the options can be exercised when the Phase III trial is completed. The grant-date fair value of these options awarded to the senior management of the Company amounts to $3.3 million in total. A major consideration in the valuation of these options is the likelihood of the CEL-SCI reaching these milestones. CEL-SCI's management has assumed the likelihood of these milestones being reached to be 100%.

Employee Pension, Profit Sharing or Other Retirement Plans

CEL-SCI has a defined contribution retirement plan, qualifying under Section 401(k) of the Internal Revenue Code and covering substantially all CEL-SCI's employees. CEL-SCI's contribution to the plan is made in shares of CEL-SCI's common stock. Each participant's contribution is matched by CEL-SCI with shares of common stock which have a value equal to 100% of the participant's contribution, not to exceed the lesser of $1,000 or 6% of the participant's total compensation. CEL-SCI's contribution of common stock is valued each quarter based upon the closing price of its common stock. The fiscal 2011 expenses for this plan were $154,100. Other than the 401(k) Plan, CEL-SCI does not have a defined benefit, pension plan, profit sharing or other retirement plan.

Compensation of Directors During Year Ended September 30, 2011

Name	Paid in Cash	Stock Awards (1)	Option Awards (2)	Total
Maximilian de Clara	$40, 000	$-	$176,709	$216,709
Geert Kersten	$40, 000	$-	$207,314	$247,314
Alexander Esterhazy	$44, 000	$-	$91,815	$135,815
C. Richard Kinsolving	$44, 000	$-	$91,815	$135,815
Peter R. Young	$44, 000	$-	$91,815	$135,815

(1) The fair value of stock issued for services.

(2) The fair value of options granted computed in accordance with ASC 718-10-30-3 on the date of grant which represents their grant date fair value.

Directors' fees paid to Maximilian de Clara and Geert Kersten are also included in the Executive Compensation table.

46

Employment Contracts.

Maximilian de Clara

In April 2005, CEL-SCI entered into a three-year employment agreement with Maximilian de Clara, CEL-SCI's President. The employment agreement provided that CEL-SCI would pay Mr. de Clara an annual salary of $363,000 during the term of the agreement. On September 8, 2006 Mr. de Clara's Employment Agreement was amended and extended to April 30, 2010. The terms of the amendment to Mr. de Clara's employment agreement are referenced in a report on Form 8-K filed with the Securities and Exchange Commission on September 8, 2006. On August 30, 2010, Mr. de Clara's employment agreement, as amended on September 8, 2006, was extended to August 30, 2013.

In the event that there is a material reduction in Mr. de Clara's authority, duties or activities, or in the event there is a change in the control of CEL-SCI, the agreement allows Mr. de Clara to resign from his position at CEL-SCI and receive a lump-sum payment from CEL-SCI equal to 18 months salary ($544,500) and the unvested portion of any stock options would vest immediately ($308,779). For purposes of the employment agreement, a change in the control of CEL-SCI means the sale of more than 50% of the outstanding shares of CEL-SCI's common stock, or a change in a majority of CEL-SCI's directors.

The employment agreement will also terminate upon the death of Mr. de Clara, Mr. de Clara's physical or mental disability, the conviction of Mr. de Clara for any crime involving fraud, moral turpitude, or CEL-SCI's property, or a breach of the employment agreement by Mr. de Clara. If the employment agreement is terminated for any of these reasons, Mr. de Clara, or his legal representatives, as the case may be, will be paid the salary provided by the employment agreement through the date of termination.

Geert Kersten