



# **Annual Report**

# **2015**

## CEL-SCI Corporation

CEL-SCI is focused on finding the best way to activate the immune system to fight cancer and infectious diseases. CEL-SCI believes that the best results can be achieved by giving its cancer immunotherapy drug before surgery, radiation and chemotherapy, at a time when the immune system is thought to be much stronger. Other cancer immunotherapies are typically given after these conventional treatments.

CEL-SCI's lead investigational therapy Multikine® (Leukocyte Interleukin, Injection) is currently in a pivotal Phase 3 clinical trial against advanced primary (not yet treated) head and neck cancer, for which CEL-SCI has received Orphan Drug Status from the U.S. Food and Drug Administration, or FDA. If the primary endpoint of the FDA study is achieved, the results will be used to support applications to regulatory agencies around the world for worldwide commercial marketing approvals as a first line cancer therapy. Additional clinical indications for Multikine include cervical dysplasia in HIV/HPV co-infected women, for which a Phase 1 study was successfully concluded; and the treatment of peri-anal warts in HIV/HPV co-infected men and women, for which a Phase 1 trial is now underway in conjunction with the U.S. Naval Medical Center, San Diego under a Cooperative Research and Development Agreement, or CRADA, and at the University of California, San Francisco, or UCSF.

CEL-SCI's immune therapy, Multikine, is designed to be used in a different way than immune therapy is normally used. It is designed to be administered locally to treat local tumors before any other therapy has been administered. For example, in the ongoing Phase 3 clinical trial, Multikine is injected locally at the site of the tumor and near the adjacent draining lymph nodes as a first line of treatment before surgery, radiation and/or chemotherapy because that is when the immune system is thought to be strongest. The goal is to help the intact immune system recognize and kill the micro metastases that usually cause recurrence of the cancer. In short, CEL-SCI believes that local administration and administration before weakening of the immune system by chemotherapy and radiation will result in a better anti-tumor response than if Multikine were administered as a second- or later-line therapy. In clinical studies of Multikine, administration of the investigational therapy to head and neck cancer patients has demonstrated the potential for less or no appreciable toxicity.

CEL-SCI's focus on HPV is not the development of an antiviral against HPV in the general population. Instead, it is on developing an immunotherapy product candidate designed to be administered to patients who are immune-suppressed by other diseases, such as HIV, and who are therefore less able or unable to control HPV and its resultant or co-morbid diseases. This group of patients has limited treatment options available to them. HPV is also relevant to the head and neck cancer Phase 3 study since it is now known that HPV is a cause of head and neck cancer. Multikine was shown to kill HPV in an earlier study of HIV infected women with cervical dysplasia.

CEL-SCI is also developing its pre-clinical L.E.A.P.S. (Ligand Epitope Antigen Presentation System) technology for the potential treatment of pandemic influenza in hospitalized patients (LEAPS-H1N1-DC) and as a potential vaccine for the treatment of rheumatoid arthritis (CEL-2000 and CEL-4000). The investigational immunotherapy LEAPS-H1N1-DC treatment involves non-changing regions of H1N1 Pandemic Flu ([www.jci.org/articles/view/67550](http://www.jci.org/articles/view/67550)), Avian Flu (H5N1), and the Spanish Flu, as CEL-SCI scientists are very concerned about the possible emergence of a new more virulent hybrid virus through the combination of H1N1 and Avian Flu, or possibly Spanish Flu.

CEL-SCI Corporation was formed as a Colorado corporation in 1983. CEL-SCI's principal office is located at 8229 Boone Boulevard, Suite 802, Vienna, VA 22182 with two facilities in/near Baltimore, Maryland. CEL-SCI's telephone number is 703-506-9460 and its website is [www.cel-sci.com](http://www.cel-sci.com). CEL-SCI does not incorporate the information on its website into this report, and you should not consider it part of this report.

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

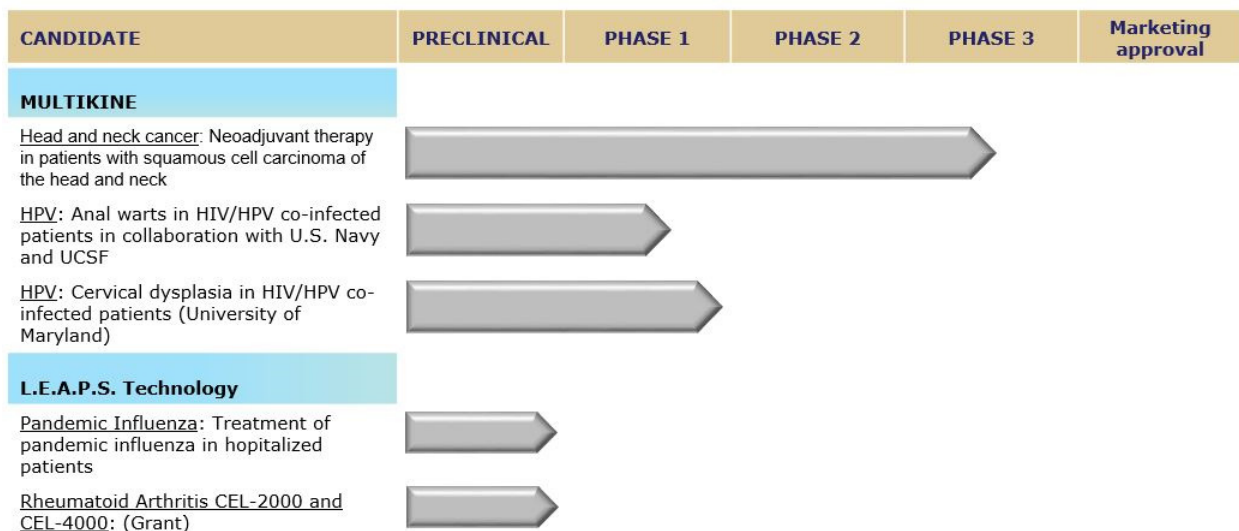
amendments to these reports available on its website free of charge as soon as practicable after they are filed or furnished to the SEC.

## CEL-SCI'S PRODUCTS

CEL-SCI is dedicated to research and development directed at improving the treatment of cancer and other diseases by using the immune system, the body's natural defense system. CEL-SCI is currently focused on the development of the following product candidates and technologies:

- 1) Multikine (an investigational immunotherapy under development for the potential treatment of certain head and neck cancers, and anal warts or cervical dysplasia in human immunodeficiency virus, or HIV, and human papillomavirus, or HPV, co-infected patients;
- 2) L.E.A.P.S. (Ligand Epitope Antigen Presentation System) technology, or LEAPS, with two investigational therapies, LEAPS-H1N1-DC, a product candidate under development for the potential treatment of pandemic influenza in hospitalized patients, and CEL-2000 and CEL-4000, vaccine product candidates under development for the potential treatment of rheumatoid arthritis.

The following chart depicts CEL-SCI's product candidates, their indications and their current stage of development:



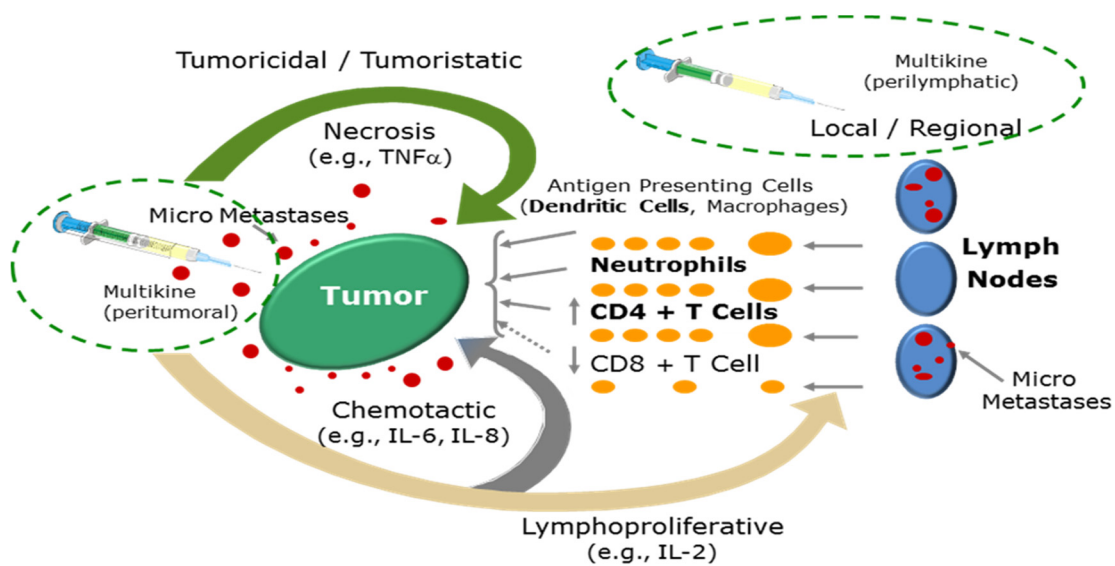
### MULTIKINE

CEL-SCI's lead investigational therapy, Multikine, 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 1 and Phase 2 clinical trials suggest that Multikine simulates the activities of a healthy person's immune system, enabling it to use the body's own anti-tumor immune response. Multikine is the trademark that CEL-SCI has registered for this investigational therapy, and this proprietary name is subject to review by the U.S. Food and Drug Administration, or FDA, in connection with CEL-SCI's future anticipated regulatory submission for approval. Multikine has not been licensed or approved for sale, barter or exchange by the FDA or any other regulatory agency, such as the European Medicine Agency, or EMA. Neither has its safety or efficacy been established for any use.

Multikine is an immunotherapy product candidate comprised of a patented defined mixture of 14 human natural cytokines and is manufactured in a proprietary manner in CEL-SCI's manufacturing facility. On the

manufacturing side alone, CEL-SCI spent over 10 years and more than \$80 million developing and validating the manufacturing process. The pro-inflammatory cytokine mixture includes interleukins, interferons, chemokines and colony-stimulating factors, which contain elements of the body's natural mix of defenses against cancer.

Multikine is designed to be used in a different way than immune therapy is normally used. It is designed to be administered locally to treat local tumors before any other therapy has been administered. For example, in the ongoing Phase 3 clinical trial, Multikine is injected locally at the site of the tumor and near the adjacent draining lymph nodes as a first line of treatment before surgery, radiation and/or chemotherapy because that is when the immune system is thought to be strongest. The goal is to help the intact immune system recognize and kill the micro metastases that usually cause recurrence of the cancer. In short, CEL-SCI believes that local administration and administration before weakening of the immune system by chemotherapy and radiation will result in better anti-tumor response than if Multikine were administered as a second- or later-line therapy. In clinical studies of Multikine, administration of the investigational therapy to head and neck cancer patients has demonstrated the potential for less or no appreciable toxicity.



Source: Adapted from Timar et al., Journal of Clinical Oncology 23(15) May 20, 2005

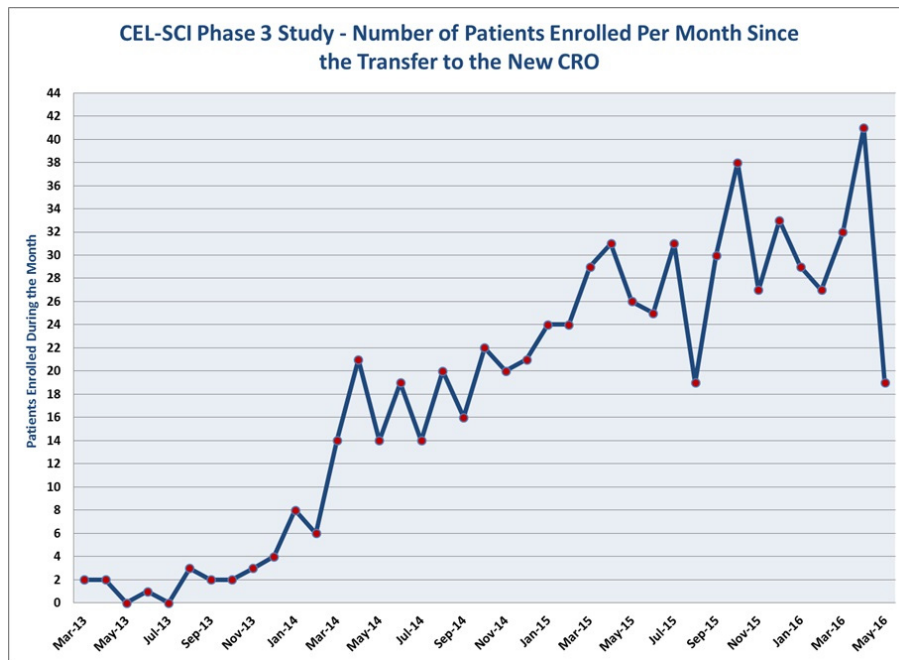
The first indication we are pursuing for our Multikine product candidate is an indication for neoadjuvant therapy in patients with squamous cell carcinoma of the head and neck, or SCCHN. Multikine investigational immunotherapy was granted Orphan Drug designation for neoadjuvant therapy in patients with SCCHN by the FDA in the United States. SCCHN is a type of head and neck cancer, and CEL-SCI believes that the head and neck cancer market, in the aggregate, represents a large, unmet medical need. The last FDA approval of a therapy for the treatment of advanced primary head and neck cancer was over 50 years ago. In the aggregate, head and neck cancer represents about 6% of the world's cancer cases, with over 650,000 patients diagnosed worldwide each year, and nearly 60,000 patients diagnosed annually in the United States.

#### Current Status of Ongoing Phase 3 Clinical Trial

Regulatory authorities in 24 countries around the world, including the FDA in the United States, have allowed Multikine to be studied in a global Phase 3 clinical trial as a potential neoadjuvant therapy in patients with SCCHN. This trial is currently primarily under the management of two clinical research

organizations, or CROs, ICON Inc. (formerly known as Aptiv Solutions, Inc.), or ICON, and Ergomed Clinical Research Limited, or Ergomed.

Ergomed is responsible for new patient enrollment. Enrollment has increased greatly since the transfer of the study to the new CROs. The following chart depicts the number of patients enrolled per month since the transfer to the new CROs.



The primary endpoint of the Phase 3 head and neck cancer study is achieved when a 10% increase is observed in overall survival in the investigational immunotherapy Multikine, including the administration of CIZ(1), plus Standard of Care (surgery + Radiotherapy or Chemoradiotherapy) Arm over the Control comparator (Standard of Care alone) Arm. The final determination whether this endpoint has been successfully reached can only be determined when 298 events (deaths) have occurred in the combined comparator arms of the study. CEL-SCI is currently aiming to enroll 880 patients in order to be able to have 784 evaluable patients for the per-protocol analysis. It should be noted that the total number of patients enrolled is not a key determinant in this study. Rather, the number of death events is, since the study derives its power solely from the death events in the study. If there is any change in the rate of death estimated from survival curves provided in the scientific literature, the number of patients in the study may be decreased or increased so that the number of events (deaths) in the study can be observed in a timely manner. In addition, if the death rate observed in the study is lower than that which was anticipated at the onset of the study, the study length may be affected. Currently, CEL-SCI is estimating that the enrollment of 880 patients will be completed in the summer of 2016.

- (1) CIZ = low dose (non-chemotherapeutic) of cyclophosphamide, indomethacin and Zinc-multivitamins) all of which are thought to enhance Multikine activity

A total of 816 patients have been enrolled in the study as of May 31, 2016. The former CRO had enrolled 117 patients, who are included in the number above. The Company may need to enroll additional patients to replace patients enrolled by the former CRO since the data from certain patients enrolled by the former CRO may not be usable, or for other reasons. If additional patients need to be enrolled, the timelines for the trial will also be affected.

CEL-SCI estimates that the total remaining cost of the Phase 3 clinical trial, excluding any costs that will be paid by CEL-SCI's partners, will be approximately \$17.2 million after March 31, 2016. This is in addition to the approximately \$29.4 million that CEL-SCI has spent on the trial as of March 31, 2016. This estimate is based on information currently available under the contracts with the CROs responsible for managing the Phase 3 clinical trial. This number may be affected by the rate of patient enrollment, rate and speed of deaths, foreign currency exchange rates and many other factors, some of which cannot be foreseen today. It is therefore possible that the cost of the Phase 3 clinical trial will be higher than currently estimated. The trial costs will also increase should CEL-SCI need to enroll additional patients to replace patients enrolled by the former CRO, since the data from certain patients enrolled by the former CRO may not be useable, or for other reasons.

The current standard of care, or SOC, treatment regimen for advanced primary head and neck cancer patients consist of surgical resection of the tumor and involved lymph nodes followed by either radiotherapy alone or radiotherapy and concurrent chemotherapy. Our ongoing Phase 3 clinical trial is testing the hypothesis that Multikine treatment, administered prior to such SOC treatment regimen, will extend overall survival, enhance the local/regional control of the disease and reduce the rate of disease progression in patients with squamous cell carcinoma of the head and neck.

The primary clinical endpoint in CEL-SCI's ongoing Phase 3 clinical trial is the achievement of a 10% improvement in overall survival in the Multikine plus SOC treatment arm over that which is achieved in the SOC treatment arm alone (all subjects in the Phase 3 study will receive SOC). 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 the FDA, to move forward, prepare and submit a Biologic License Application, or BLA, to the FDA for Multikine as neoadjuvant therapy in patients with SCCHN.

In the Phase 3 clinical trial, Multikine is administered to cancer patients 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, CEL-SCI believes 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 3 clinical trial.

#### Follow-Up Analysis of Overall Survival in Phase 2 Patients

Prior to starting the Phase 3 study, CEL-SCI had tested Multikine in over 200 patients. The following is a summary of results from CEL-SCI's last Phase 2 study conducted with Multikine. This study employed the same treatment protocol as is being followed in CEL-SCI's Phase 3 study:

- **Reported improved survival:** In a follow-up analysis of the Phase 2 clinical study population, which used the same dosage and treatment regimen as is being used in the Phase 3 study, head and neck cancer patients with locally advanced primary disease who received the investigational therapy Multikine as first-line investigational therapy followed by surgery and radiotherapy were reported by the clinical investigators to have had a 63.2% overall survival, or OS, rate at a median of 3.33 years from surgery. This percentage of OS was arrived at as follows: of the 21 subjects enrolled in the Phase 2 study, the consent for the survival follow-up portion of the study was received from 19 subjects. OS was calculated using the entire treatment population that consented to the follow-up portion of the study (19 subjects), including two subjects who, as later determined by three pathologists blinded to the study, did not have oral squamous cell carcinoma, or OSCC. These two subjects were thus not evaluable per the protocol and were not included in the pathology portion of the study for purposes of calculating complete response rate, as described below, but were included in the OS calculation. 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 7,294 patients studied), and 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 years from treatment. Therefore, the results of CEL-SCI's final Phase 2 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 Phase 3 clinical trial of this investigational therapy that is currently in progress. Subject to completion of that Phase 3 clinical trial and the 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 the Multikine product candidate to become a treatment for advanced primary head and neck cancer, if approved.

- **Reported average of 50% reduction in tumor cells in Phase 2 trials (based on 19 patients evaluable by pathology, having OSCC):** The clinical investigators who administered the three week Multikine treatment regimen used in the Phase 2 study 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, which normally includes surgery, radiation and chemotherapy (Timar et al JCO 2005).
- **Reported 10.5% complete response in the final Phase 2 trial (based on 19 patients evaluable by pathology, having OSCC):** The clinical investigators who administered the three-week Multikine investigational treatment regimen used in the Phase 2 study reported that, as was determined in a controlled pathology study, the tumor apparently was no longer present (as determined by histopathology) in approximately 10.5% of evaluable patients with OSCC (Timar et al JCO 2005). In the original study, 21 subjects received Multikine, two of which were later excluded, as subsequent analysis by three pathologists blinded to the study revealed that these two patients did not have OSCC. Two subjects in this study had a complete response, leaving a reported complete response rate of two out of 19 assessable subjects with OSCC (or 10.5%) (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.

Subsequently, an analysis on the 21 subjects originally treated with Multikine in the study to evaluate overall survival was conducted, as described above. In connection with the follow-up portion of the study for overall survival, CEL-SCI also conducted an unreported post-hoc analysis of complete response rate in the study population, which included subjects who provided consent for the follow-up and who also had OSCC. Two out of the 21 subjects did not re-consent for follow-up, and two of the remaining 19 subjects were excluded from the post-hoc complete response rate analysis as they had previously been determined by pathology analysis to not have OSCC. The two complete responders with OSCC both consented to the follow-up study. Therefore, the post-hoc analysis of complete response was based on a calculation of the two complete responders out of 17 evaluable subjects who consented to the follow-up analysis and who also had OSCC (or 11.8%).

Furthermore, CEL-SCI reported an overall response rate of 42.1% based on the number of evaluable patients who experienced a favorable response to the treatment, including those who experienced minor,

major and complete responses. Out of the 19 evaluable patients, two experienced a complete response, two experienced a major response, and four experienced a minor response to treatment. Thus, CEL-SCI calculated the number of patients experiencing a favorable response as eight patients out of 19 (or 42.1%) (Timar et al, JCO 2005).

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.

#### Peri-Anal Warts and Cervical Dysplasia in HIV/HPV Co-Infected Patients

HPV is a very common sexually transmitted disease in the United States and other parts of the world. It can lead to cancer of the cervix, penis, anus, esophagus and head and neck. Our focus in HPV, however, is not on developing an antiviral for the potential treatment or prevention of HPV in the general population. Instead, the focus is on developing an immunotherapy product candidate designed to be administered to patients who are immune-suppressed by other diseases, such as HIV, and who are therefore less able or unable to control HPV and its resultant or co-morbid diseases. Such patients have limited treatment options available to them.

One condition that is commonly associated with both HIV and HPV is the occurrence of anal intraepithelial dysplasia, or AIN, and anal and genital warts. The incidence of AIN in HIV-infected people is estimated to be about 25%. The incidence of anal HPV infection in HIV-infected men who have sex with men, or MSM, is estimated to be as high as 95%. In the aggregate, the United States and Europe have about 875,000 HIV-infected patients with AIN (assuming AIN prevalence of approximately 25% of the aggregate HIV-infected population). Persistent HPV infection in the anal region is thought to be responsible for up to 80% of anal cancers, and men and women who are HIV positive have a 30-fold increase in their risk of anal cancer. Persistent HPV infection can also be a precursor to cervical cancer, as well as certain head and neck cancers.

In October 2013, CEL-SCI announced it signed a CRADA with the U.S. Naval Medical Center, San Diego, or the USNMC. Pursuant to this agreement, the USNMC will conduct a Phase 1 study, approved by the Human Subjects Institutional Review Board, of CEL-SCI's investigational immunotherapy, Multikine, in HIV/HPV co-infected men and women with peri-anal warts. The purpose of this study is to evaluate the safety and clinical impact of Multikine as a potential treatment of peri-anal warts and assess its effect on AIN in HIV/HPV co-infected men and women.

Pursuant to the CRADA, CEL-SCI is contributing Multikine for use in this Phase 1 study, and CEL-SCI will retain all rights to any currently-owned technology and will have the right to exclusively license any new technology developed from the collaboration. In October 2013, CEL-SCI also entered into a co-development and profit sharing agreement with Ergomed for development of Multikine as a potential treatment of HIV/HPV co-infected men and women with peri-anal warts. This agreement will initially be in support of the development with the USNMC.

In September 2014, CEL-SCI announced that the first volunteer patient had been enrolled and administered Multikine in this Phase 1 study, which is currently ongoing. In July 2015, CEL-SCI added an additional site and Key Opinion Leader, or KOL, to the ongoing Phase 1 study.

The treatment regimen for this Phase 1 study of up to 15 HIV/HPV co-infected patient volunteers with peri-anal warts, being conducted by doctors at the USNMC and at the UCSF, is identical to the regimen that was used in an earlier Institutional Review Board-approved Multikine Phase 1 study in HIV/HPV co-infected patients, which was conducted at the University of Maryland. In that study, the Multikine investigational therapy was administered to HIV/HPV co-infected women with cervical dysplasia, resulting in visual and histological evidence of clearance of lesions in three out of the eight subjects.



Furthermore, in this earlier Phase 1 study, the number of HPV viral sub-types in three volunteer subjects tested were reduced post-treatment with Multikine, as opposed to pre-treatment, as determined by in situ polymerase chain reaction performed on tissue biopsy collected before and after Multikine treatment. As reported by the investigators in the earlier study, the study volunteers all appeared to tolerate the treatment with no reported serious adverse events.

#### Development Agreements for Multikine

In August 2008, CEL-SCI signed an agreement with Teva Pharmaceutical Industries Ltd., or Teva, that gives Teva the exclusive right and license to market, distribute and sell Multikine in Israel and Turkey for treatment of head and neck cancer, if approved. The agreement terminates on a country-by-country basis 10 years after the product launch in each country or upon a material breach or upon bankruptcy of either party. The agreement will automatically extend for additional two year terms unless either party gives notice of its intent not to extend the agreement. If CEL-SCI develops Multikine for other oncology indications and Teva indicates a desire to participate, the parties have agreed to negotiate in good faith with respect to Teva's participation and contribution in future clinical trials.

Teva has agreed to use all reasonable efforts to obtain regulatory approval to market and sell Multikine in its territory at its own cost and expense. Pursuant to the agreement, it is CEL-SCI's responsibility to supply Multikine and Teva's responsibility to sell Multikine, if approved. Net sales will be divided 50/50 between the two parties. Teva also initially agreed to fund certain activities relating to the conduct of a clinical trial in Israel as part of the global Phase III trial for Multikine. In January 2012, pursuant to an assignment and assumption agreement between CEL-SCI, Teva and GCP Clinical Studies Ltd., or GCP, Teva transferred all of its rights and obligations concerning the Phase III trial in Israel to GCP. GCP is now operating the Phase III trial in Israel pursuant to a service agreement with CEL-SCI.

In July 2011, Serbia and Croatia were added to Teva's territory, pursuant to a joinder agreement between CEL-SCI and PLIVA Hrvatska d.o.o., or PLIVA, an affiliate of Teva's, subject to similar terms as described above.

In consideration for the rights granted by CEL-SCI to PLIVA under the joinder agreement, CEL-SCI will be paid by PLIVA (in U.S. dollars):

- \$100,000 upon European Medicines Agency ("EMA") grant of Marketing Authorization for Multikine;
- \$50,000 upon Croatia's grant of reimbursement status for Multikine in Croatia; and
- \$50,000 upon Serbia's grant of reimbursement status for Multikine in Serbia.

In November 2000, CEL-SCI signed an agreement with Orient Europharma Co., Ltd., or Orient Europharma, of Taiwan, which agreement was amended in October 2008 and again in June 2010. Pursuant to this agreement, as amended, Orient Europharma has the exclusive marketing and distribution rights to Multikine, if approved, for head and neck cancer, naso-pharyngeal cancer and potentially cervical cancer indications in Taiwan, Singapore, Malaysia, Hong Kong, the Philippines, South Korea, Australia and New Zealand. CEL-SCI has granted Orient Europharma the first right of negotiation with respect to Thailand and China.

The agreement requires Orient Europharma to fund 10% of the cost of the clinical trials needed to obtain marketing approvals in these countries for head and neck cancer, naso-pharyngeal cancer and potentially cervical cancer. Orient Europharma has signed nine centers in Taiwan where it has enrolled patients as part of the ongoing Phase 3 Multikine clinical trial and has made further financial contributions towards the cost of the ongoing Phase 3 clinical trial. If Multikine is approved for sale, Orient Europharma will purchase Multikine from CEL-SCI for 35% of the gross selling price in each country. Orient Europharma is obligated

to use the same diligent efforts to develop, register, market, sell and distribute Multikine in the territory as with its own products or other licensed products.

The agreement will terminate on a country-by-country basis 15 years after the product approval for Multikine in each country, at which point the agreement will be automatically extended for successive two year periods, unless either party gives notice of its intent not to extend the agreement. The agreement may also be terminated upon bankruptcy of either party or material misrepresentations that are not cured within 60 days. If the agreement ends before the 15 year term through no fault of either party, CEL-SCI will reimburse Orient Europharma for a prorated part of Orient Europharma's costs towards the clinical trials of Multikine. If Orient Europharma fails to make certain minimum purchases of Multikine during the term of the agreement, Orient Europharma's rights to the territory will become non-exclusive.

CEL-SCI has a licensing agreement with Byron Biopharma LLC, or Byron, under which CEL-SCI granted Byron an exclusive license to market and distribute Multikine in the Republic of South Africa, if approved. This license will terminate 20 years after marketing approval in South Africa or after bankruptcy or uncured material breach. After the 20-year period has expired, the agreement will be automatically extended for successive two year periods, unless either party gives notice of its intent not to extend the agreement.

Pursuant to the agreement, Byron will be responsible for registering Multikine in South Africa. If Multikine is approved for sale in South Africa, CEL-SCI will be responsible for manufacturing the product, while Byron will be responsible for sales in South Africa. Sales revenues will be divided equally between CEL-SCI and Byron.

### **INTELLECTUAL PROPERTY**

Patents and other proprietary rights are essential to CEL-SCI's business. CEL-SCI files patent applications to protect its technologies, inventions and improvements to its inventions that CEL-SCI considers important to the development of its business. CEL-SCI files for patent registration in the United States and in key foreign markets. CEL-SCI'S intellectual property portfolio covers its proprietary technologies, including Multikine and LEAPS, by multiple issued patents and pending patent applications.

Multikine is protected by a U.S. patent, which is a composition-of-matter patent issued in May 2005 that, in its current format, expires in 2024. Additional composition-of-matter patents for Multikine have been issued in Germany (issued in June 2011 and currently set to expire in 2025), China (issued in May 2011 and currently set to expire in 2024), Japan (issued in November 2012 and currently set to expire in 2025), and Europe (issued in September 2015 and currently set to expire in 2025).

CEL-SCI has two patent applications pending in Europe for Multikine, which, if issued, would extend protection through 2026, subject to any potential patent term extensions. In addition to the patents and applications that offer certain protections for Multikine, the method of manufacture for Multikine, a complex biological product, is held by CEL-SCI as trade secret.

LEAPS is protected by patents in the United States issued in February 2006, April 2007, and August 2007. The LEAPS patents, which expire in 2021, 2022 and 2021, respectively, include overlapping claims, with composition of both matter (new chemical entity), process and methods-of-use, to maximize and extend the coverage in their current format. Additional patent applications are pending in the United States and Europe that could offer protection through 2034.

CEL-SCI has six patent applications pending in the United States and one in Europe for LEAPS, which, if issued, would extend protection through 2034, subject to any potential patent term extensions. One pending U.S. application is a joint application with Northeast Ohio Medical University ("Neoucom"). If granted, CEL-SCI will share the ability to use the patent, unless CEL-SCI licenses the rights to the patent application and any ensuing patent from Neoucom.

As of May 31, 2016, there were no contested proceedings and/or third party claims with respect to CEL-SCI's patents or patent applications.

### **MANUFACTURING FACILITY**

Before starting the Phase 3 clinical trial, CEL-SCI needed to build a dedicated manufacturing facility to produce Multikine. This facility has been completed and validated, and has produced multiple clinical lots for the Phase 3 clinical trial. The facility has also passed review by a European Union Qualified Person on several occasions.

CEL-SCI's lease on the manufacturing facility expires on October 31, 2028. 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 3 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). 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. However, priority will always be given to Multikine as management considers the Multikine supply to the clinical studies and preparation for a final marketing approval to be more important than offering fill and finish services.

### **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 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 a vaccine, 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.

On July 15, 2014 CEL-SCI announced that it has been awarded a Phase 1 Small Business Innovation Research (SBIR) grant in the amount of \$225,000 from the National Institute of Arthritis Musculoskeletal and Skin Diseases, which is part of the National Institutes of Health. The grant is funding the further development of CEL-SCI's LEAPS technology as a potential treatment for rheumatoid arthritis, an autoimmune disease of the joints. The work is being conducted at Rush University Medical Center in Chicago, Illinois in the laboratories of Tibor Glant, MD, Ph.D., The Jorge O. Galante Professor of Orthopedic Surgery; Katalin Mikecz, MD, Ph.D. Professor of Orthopedic Surgery & Biochemistry; and Allison Finnegan, Ph.D. Professor of Medicine.

With the support of the SBIR grant, CEL-SCI is developing two new drug candidates, CEL-2000 and CEL-4000, as potential rheumatoid arthritis therapeutic vaccines. The data from animal studies using the CEL-2000 treatment vaccine demonstrated that it could be used as an effective treatment against rheumatoid arthritis with fewer administrations than those required by other anti-rheumatoid arthritis treatments currently on the market for arthritic conditions associated with the Th17 signature cytokine TNF- $\alpha$ . The data for CEL-4000 indicates it could be effective against rheumatoid arthritis cases where a Th1 signature cytokine (IFN- $\gamma$ ) is dominant. CEL-4000 and CEL-2000 have the potential to be a more disease-specific therapy, significantly less expensive, act at an earlier step in the disease process than current therapies and

may be useful in patients not responding to existing rheumatoid arthritis therapies. CEL-SCI believes this represents a large unmet medical need in the rheumatoid arthritis market.

In March 2015, CEL-SCI and its collaborators published a review article on vaccine therapies for rheumatoid arthritis based in part on work supported by the SBIR grant. The article is entitled “Rheumatoid arthritis vaccine therapies: perspectives and lessons from therapeutic Ligand Epitope Antigen Presentation System vaccines for models of rheumatoid arthritis” and was published in *Expert Rev. Vaccines* 1 - 18 and can be found at <http://www.ncbi.nlm.nih.gov/pubmed/25787143>.

In August 2012, Dr. Zimmerman, CEL-SCI’s Senior Vice President of Research, Cellular Immunology, gave a Keynote presentation at the OMICS 2nd International Conference on Vaccines and Vaccinations in Chicago. This presentation showed how the LEAPS peptides administered altered only select cytokines specific for each disease model, thereby improving the status of the test animals and even preventing death and morbidity. These results support the growing body of evidence that provides for its mode of action by a common format in these unrelated conditions by regulation of Th1 (e.g., IL12 and IFN- $\gamma$ ) and their action on reducing TNF- $\alpha$  and other inflammatory cytokines as well regulation of antibodies to these disease associated antigens. This was also illustrated by a schematic model showing how these pathways interact and result in the overall effect of protection and regulation of cytokines in a beneficial manner.

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, where a Th17 signature cytokine (TNF- $\alpha$ ) is dominant. 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” *Int Immunopharmacol.* 2010 Apr; 10(4):412-21 <http://www.ncbi.nlm.nih.gov/pubmed/20074669>.

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 potential pandemic flu treatment. CEL-SCI’s LEAPS flu treatment contains epitopes known to be associated with immune protection against influenza in animal models.

In September 2009, the U.S. FDA 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.

In November 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 was unable to complete the enrollment of patients.

Additional work on this treatment for the pandemic flu 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 LEAPS 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.D., Chief of the Emerging Respiratory Diseases Section in NIAID’s Division of Intramural Research, part of the National Institutes of Health, USA.

In July 2013, CEL-SCI announced the publication of the results of influenza studies by researchers from the NIAID in the Journal of Clinical Investigation ([www.jci.org/articles/view/67550](http://www.jci.org/articles/view/67550)). The studies described in the publication show that when CEL-SCI's investigational J-LEAPS Influenza Virus treatments were used "in vitro" to activate DCs, these activated DCs, when injected into influenza infected mice, arrested the progression of lethal influenza virus infection in these mice. The work was performed in the laboratory of Dr. Subbarao.

Even though the various LEAPS drug candidates have not yet been given to humans, they have been tested in vitro with human cells. They have induced similar cytokine responses that were seen in these animal models, which may indicate that the LEAPS technology might translate to humans. The LEAPS candidates have demonstrated protection against lethal herpes simplex virus (HSV1) and H1N1 influenza infection, as a prophylactic or therapeutic agent in animals. They have also shown efficacy in animals in two autoimmune conditions, curtailing and sometimes preventing disease progression in arthritis and myocarditis animal models. CEL-SCI's belief is that the LEAPS technology may be a significant alternative to the vaccines currently available on the market today for these diseases.

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 the 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.

### **MARKET FOR CEL-SCI'S COMMON EQUITY**

As of May 20, 2016 there were approximately 1,000 record holders of CEL-SCI's common stock. CEL-SCI's common stock is traded on the NYSE MKT under the symbol "CVM".

Shown below are the range of high and low quotations for CEL-SCI's common stock for the periods indicated as reported on the NYSE MKT. The market quotations reflect inter-dealer prices, without retail mark-up, mark-down or commissions and may not necessarily represent actual transactions.

<u>Quarter Ending</u>	<u>High</u>	<u>Low</u>
12/31/13	\$1.80	\$0.53
3/31/14	\$1.90	\$0.59
6/30/14	\$1.72	\$0.98
9/30/14	\$1.30	\$0.75
12/31/2014	\$0.91	\$0.54
3/31/2015	\$1.23	\$0.59
6/30/2015	\$1.09	\$0.59
9/30/2015	\$0.80	\$0.48
12/31/2015	\$0.75	\$0.36
3/31/2016	\$0.66	\$0.36

Holders of common stock are entitled to receive dividends as may be declared by CEL-SCI's 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

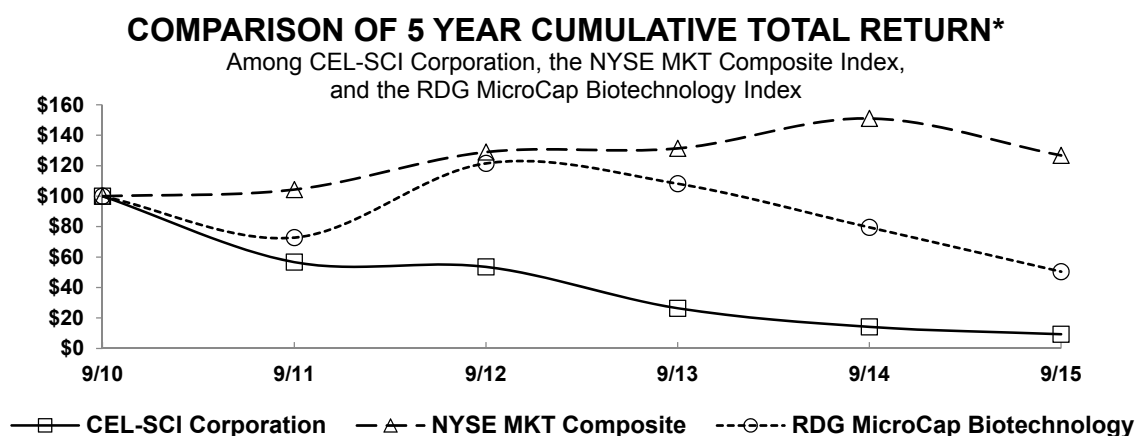
dividend. CEL-SCI has not paid any dividends on its common stock and CEL-SCI does not have any current plans to pay any common stock dividends.

The provisions in CEL-SCI's Articles of Incorporation relating to CEL-SCI's preferred stock 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 which may be 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 MTK 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 September 30, 2010 and tracks it through September 30, 2015.

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



\*\$100 invested on 9/30/10 in stock or index, including reinvestment of dividends.  
Fiscal year ending September 30.

	9/10	9/11	9/12	9/13	9/14	9/15
CEL-SCI Corporation	100.00	56.68	53.57	26.40	14.16	9.32
NYSE MKT Composite	100.00	104.37	129.03	131.42	151.13	126.81
RDG MicroCap Biotechnology	100.00	72.80	121.61	108.23	79.54	50.43

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

## **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.

<u>Statements of Operations</u>	2015	2014	2013	2012	2011
Grant income and other	\$ 657,377	\$ 264,033	\$ 159,583	\$ 254,610	\$ 956,154
Operating expenses:					
Research and development	20,949,208	17,000,145	12,681,049	10,368,695	11,745,629
Depreciation & amortization	206,750	231,752	364,124	533,468	531,316
General and administrative	13,797,964	10,606,248	6,982,686	6,595,287	6,664,883
Gain on derivative instruments	282,616	248,767	10,750,666	1,911,683	4,432,148
Other expenses (3)	(641,276)	-	-	-	(12,000,000)
Interest income	110,544	122,854	117,086	116,061	164,163
Interest expense	(129,985)	(163,774)	(170,423)	(262,214)	(322,980)
Net loss	(34,674,646)	(27,366,265)	(9,170,947)	(15,477,310)	(25,712,343)
Issuance of additional shares due to reset provision		(1,117,447)	-	(250,000)	-
Modification of warrants			(59,531)	(325,620)	(1,068,369)
Inducement warrants				(1,593,000)	-
Net loss available to common shareholders	\$ (34,674,646)	\$ (28,483,712)	\$ (9,230,478)	\$ (17,645,930)	\$ (26,780,712)
Net loss per common share (1)					
Basic	(\$0.42)	(\$0.48)	(\$0.30)	(\$0.70)	(\$1.28)
Diluted	(\$0.42)	(\$0.49)	(\$0.66)	(\$0.78)	(\$1.50)
Weighted average common shares outstanding					
Basic and diluted	82,519,027	58,804,622	30,279,442	25,183,654	20,848,899
<u>Balance Sheets</u>	2015	2014	2013	2012	2011
Working capital (deficit)	\$ 1,982,589	\$ 8,496,076	\$ (1,033,370)	\$ 5,529,438	\$ 1,796,349
Total assets	\$ 5,447,603	\$ 19,230,434	\$ 10,838,572	\$ 16,067,450	\$ 18,625,440
Derivative instruments - current (2)	\$ -	\$ 18,105	\$ -	\$ -	\$ 5,068,552
Total liabilities	\$ 20,677,846	\$ 8,787,034	\$ 4,138,482	\$ 9,040,018	\$ 9,546,616
Stockholders' (deficit) equity	\$ (5,230,243)	\$ 10,443,400	\$ 6,700,090	\$ 7,027,432	\$ 9,078,824

- (1) The calculation of diluted earnings per share for the five years in the period ended September 30, 2015 excluded potentially dilutive shares because their effect would have been anti-dilutive.

- (2) Included in total liabilities.
- (3) The \$641,276 loss on debt extinguishment related to the renegotiation of terms on the note payable and is disclosed in the notes to the financial statements for the year ended September 30, 2015. The \$12 million other expense in 2011 was the cost of the lawsuit settlement. The detailed terms of the lawsuit settlement and the related agreements and documents were filed as exhibits to CEL-SCI's report on Form 10-Q for the three months ended March 31, 2011.

CEL-SCI's net loss available to common shareholders for each fiscal quarter during the two years ended September 30, 2015 were:

<u>Quarter</u>	<u>Net loss</u>	<u>Net loss per share</u>	
		<u>Basic</u>	<u>Diluted</u>
12/31/2014	\$ (7,845,318)	\$(0.11)	\$(0.14)
3/31/2015	\$ (12,556,236)	\$(0.17)	\$(0.17)
6/30/2015	\$ (4,429,137)	\$(0.05)	\$(0.06)
9/30/2015	\$ (9,843,955)	\$(0.10)	\$(0.10)
12/31/2013	\$ (5,451,865)	\$(0.11)	\$(0.15)
3/31/2014	\$(13,365,580)	\$(0.24)	\$(0.24)
6/30/2014	\$ (2,444,480)	\$(0.04)	\$(0.11)
9/30/2014	\$ (7,221,787)	\$(0.11)	\$(0.13)

Variances in quarterly gains and losses for the quarters presented are caused by the changes in the fair value outstanding warrants accounted for as derivatives each quarter. These changes in the fair value of the convertible debt and warrants are recorded on the statements of operations.

### **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 3 clinical trial in advanced primary head and neck cancer. It has received a go-ahead by the U.S. FDA as well as twenty-three other countries.

CEL-SCI also owns and is developing a pre-clinical technology called LEAPS.

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 2015**

During the year ended September 30, 2015, grant and other income increased by \$393,344 compared to the year ended September 30, 2014. The increase is primarily due to the timing of drug shipments to supply the Company's partner in Taiwan and the grant income earned by the Company's Small Business Innovation Research (SBIR) grant during fiscal year 2015 compared to fiscal year 2014.

During the year ended September 30, 2015, research and development expenses increased by \$3,949,063 compared to the year ended September 30, 2014. CEL-SCI is continuing the Phase 3 clinical trial and research and development fluctuates based on the activity level of the clinical trial. In fiscal year 2015, CEL-SCI received clearance from seven new countries for the Phase 3 clinical trial, and enrolled 305 patients in FY 2015 versus 142 in FY 2014.

During the year ended September 30, 2015, general and administrative expenses increased by \$3,191,746, compared to the year ended September 30, 2014. This increase is primarily due to an increase of approximately \$1,977,000 of equity based compensation costs for restricted stock granted, increased legal fees of approximately \$1,778,000 relating to arbitration with the Company's former CRO, and an increase of \$220,000 in professional services. These increases were offset by a decrease of approximately \$788,000 in employee compensation primarily due to a decrease in the number of stock options issued and vested in 2015 compared to 2014.

During the years ended September 30, 2015 and 2014, CEL-SCI recorded a derivative gain of \$282,616 and \$248,767, respectively. This variation was the result of the change in fair value of the derivative liabilities during the period which was caused by fluctuations in the share price of CEL-SCI's common stock.

Interest expense decreased \$33,789 during the year ended September 30, 2015 compared to the year ended September 30, 2014, and consisted primarily of interest expense on the loan from CEL-SCI's president and interest on a capital lease. Effective July 7, 2015, the interest rate on the related party loan was reduced from 15% to 9%, resulting in approximately \$11,000 less in interest expense during 2015 than in 2014. Additionally, the modifications of the loan from de Clara Trust were determined to be substantive, resulting in an extinguishment loss of \$641,276 and a premium on the note payable of \$165,943. The premium is being amortized as a reduction of interest expense over the term of the note. Amortization of the debt premium was \$20,819 for the year ended September 30, 2015.

### **Fiscal 2014**

During the year ended September 30, 2014, grant and other income increased by \$104,450 compared to the year ended September 30, 2013. The increase is primarily due to the timing of drug shipments to supply the Company's partner in Taiwan during fiscal year 2014 compared to fiscal year 2013.

During the year ended September 30, 2014, research and development expenses increased by \$4,319,096 compared to the year ended September 30, 2013. CEL-SCI is continuing the Phase 3 clinical trial and research and development fluctuates based on the activity level of the clinical trial. In fiscal year 2014, CEL-SCI received clearance from seven new countries for the Phase 3 trial, added approximately thirty sites and set multiple record breaking months for enrolling patients.

During the year ended September 30, 2014, general and administrative expenses increased by \$3,623,562, compared to the year ended September 30, 2013. This increase is primarily due to \$1,477,954 of equity based compensation costs for restricted stock issued, increased public relations costs of \$443,596 and legal

fees of \$1,668,780. Public relations costs increased to support the progression of the products through clinical trials. Legal fees increased primarily as a result of arbitration with the Company's former CRO.

During the year ended September 30, 2014, CEL-SCI recorded a derivative gain of \$248,767. For the year ended September 30, 2013, CEL-SCI recorded a derivative gain of \$10,750,666. This variation was the result of the change in fair value of the derivative liabilities during the period which was caused by fluctuations in the share price of CEL-SCI's common stock.

Interest expense decreased \$6,649 during the year ended September 30, 2014 compared to the year ended September 30, 2013, and consisted primarily of interest expense on the loan from CEL-SCI's president of \$165,609 and interest on a capital lease.

### **Research and Development Expenses**

During the five years ended September 30, 2015, 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.

	<u>2015</u>	<u>2014</u>	<u>2013</u>	<u>2012</u>	<u>2011</u>
MULTIKINE	\$20,455,398	\$16,625,367	\$12,303,564	\$ 9,977,617	\$11,257,157
LEAPS	<u>493,810</u>	<u>374,778</u>	<u>377,485</u>	<u>391,078</u>	<u>488,472</u>
TOTAL	<u>\$20,949,208</u>	<u>\$17,000,145</u>	<u>\$12,681,049</u>	<u>\$10,368,695</u>	<u>\$11,745,629</u>

In January 2007, CEL-SCI received a "no objection" letter from the FDA indicating that it could proceed with Phase 3 trials with Multikine in head and 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 3 clinical trial in Canada. Subsequently, CEL-SCI received similar authorizations from twenty-three other regulators.

CEL-SCI's Phase 3 clinical trial began in December 2010 after the completion and validation of CEL-SCI's dedicated manufacturing facility.

As explained previously, as of May 31, 2016, CEL-SCI was involved in 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, warrants 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 and for clinical trials. 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. During fiscal year 2015 and 2014, CEL-SCI raised net proceeds of approximately \$21,148,000 and \$31,546,000, respectively, through the sale of stock and exercise of outstanding warrants.

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 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 estimates the total cash cost of the Phase 3 clinical trial, with the exception of the parts that will be paid by its licensees, Teva Pharmaceuticals and Orient Europharma, to be approximately \$21.6 million after September 30, 2015.

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 required annual base rent payments of approximately \$1,573,000 during the twelve months ended September 30, 2015.

In August 2008, CEL-SCI sold 138,339 shares of common stock and 207,508 Series N warrants in a private financing for \$1,037,500. In June 2009, an additional 116,667 shares and 181,570 Series N warrants were issued to the investors. In October 2011, an additional 83,333 shares and 129,693 Series N warrants were issued to the investors. In October 2013, an additional 764,602 shares and 1,189,961 Series N warrants were issued to the investors. In December 2013, an additional 798,481 shares and 1,242,688 Series N warrants were issued to the investors. The additional shares and warrants were issued due to a reset provision included in the private financing. In January 2014, CEL-SCI offered to the investors to extend the Series N warrants by one year and allow for cashless exercise in exchange for cancelling the reset provision in the warrant agreement. One of the investors accepted this offer. In March 2014, 106,793 Series N Warrants were exercised. On October 28, 2014, the remaining Series N warrants were transferred to the de Clara Trust, of which the Company's CEO, Geert Kersten, is the trustee and a beneficiary. On June 29, 2015, concurrently with the modification of the note payable held by the de Clara Trust, CEL-SCI extended the expiration date of the Series N warrants to August 18, 2017. As of September 30, 2015, the remaining 2,844,627 Series N warrants entitle the holders to purchase one share of CEL-SCI's common stock at a price of \$0.52731 per share at any time prior to August 18, 2017.

Between June 23 and July 8, 2009, CEL-SCI sold 1,534,935 shares of its common stock at a price of \$4.00 per share totaling \$6,139,739. The investors in this offering also received 1,028,406 Series A warrants which may be exercised at any time prior to December 24, 2014 and January 8, 2015. As of September 30, 2014, 881,309 Series A warrants had been exercised. Between December 24, 2014 and January 8, 2015, 147,097 Series A warrants expired.

Between December 2008 and June 2009, Maximilian de Clara, CEL-SCI's President and a director, loaned CEL-SCI \$1,104,057 under a note payable. The original loan from Mr. de Clara bore interest at 15% per year and was secured by a lien on substantially all of CEL-SCI's assets. At Mr. de Clara's option, the note

could be converted into shares of CEL-SCI's common stock. The number of shares which would be issued upon any conversion would be determined by dividing the amount to be converted by \$4.00. In accordance with the note agreement, CEL-SCI issued Mr. de Clara warrants to purchase 164,824 shares of CEL-SCI's common stock at a price of \$4.00 per share. These warrants expired on December 24, 2014. In consideration for an extension of the due date, Mr. de Clara received warrants to purchase 184,930 shares of CEL-SCI's common stock at a price of \$5.00 per share. These warrants expired on January 6, 2015. In consideration of Mr. de Clara's agreement to subordinate his note to the convertible preferred shares and convertible debt as part of a prior year settlement agreement, CEL-SCI extended the maturity date of the note to July 6, 2015. In August 2014, the loan and warrants were transferred to the de Clara Trust, of which CEL-SCI's CEO, Geert Kersten, is the trustee and a beneficiary. Mr. de Clara will continue to receive the interest payments. On June 29, 2015, CEL-SCI extended the maturity date of the note to July 6, 2017, lowered the interest rate to 9% per year and changed the conversion price to \$0.59. The new terms were effective July 7, 2015. On October 11, 2015, the maturity date of the note was extended for one year to July 6, 2018. The extension was made at the request of Lake Whillans Vehicle I, LLC, which agreed to provide CEL-SCI with up to \$5,000,000 in funding for litigation expenses to support CEL-SCI's \$50,000,000 arbitration claims against CEL-SCI's former clinical research organization.

CEL-SCI does not have the right to prepay the loan without the consent of the Trust. The de Clara Trust may demand payment upon giving CEL-SCI a minimum 10 day notice. As of September 30, 2015, the full amount of the note was outstanding. On January 12, 2016, the Company owed the de Clara Trust \$1,105,989, which amount included accrued and unpaid interest. On January 13, 2016, the de Clara Trust demanded payment on the note payable. At the same time the Company sold 3,000,000 shares of its common stock and 3,000,000 Series X warrants to the de Clara Trust for \$1,110,000. Each warrant allows the de Clara Trust to purchase one share of the Company's common stock at a price of \$0.37 per share at any time on or before January 13, 2021.

On August 20, 2009, CEL-SCI sold 1,078,444 shares of its common stock to a group of private investors for \$4,852,995 or \$4.50 per share. The investors also received 539,220 Series C warrants which may be exercised at any time prior to February 20, 2015. As of September 30, 2014, 75,733 Series C warrants had been exercised. On February 20, 2015, the remaining 463,487 Series C warrants expired.

On January 25, 2012, CEL-SCI sold 1,600,000 shares of its common stock to institutional investors for \$5,760,000 or \$3.60 per share. The investors also received Series H warrants which may be exercised at any time prior to August 1, 2015. The Series H warrants entitle the holders to purchase 1,200,000 shares of CEL-SCI's common stock at a price of \$5.00 per share. As of September 30, 2015, none of the Series H Warrants had been exercised.

In February 2012, CEL-SCI received \$1,475,000 as a result of the exercise of the remaining Series O warrants. The Series O warrants were exercisable at any time on or prior to March 6, 2016. As an inducement for the early exercise of the Series O warrants, CEL-SCI issued Series P warrants to the former holder of the Series O warrants. The Series P warrants are exercisable at any time prior to March 7, 2017. The Series P warrants entitle the holders to purchase 590,001 shares of CEL-SCI's common stock at a price of \$4.50 per share. As of September 30, 2015, none of the Series P Warrants had been exercised.

In June 2012, CEL-SCI sold 1,600,000 shares of its common stock for \$5,600,000, or \$3.50 per share, in a registered direct offering. The investors in this offering also received Series Q warrants which may be exercised at any time on or before December 22, 2015. The Series Q warrants entitle the holders to purchase 1,200,000 shares of CEL-SCI's common stock at a price of \$5.00 per share. As of September 30, 2015, none of the Series Q Warrants had been exercised.

In December 2012, CEL-SCI sold 3,500,000 shares of its common stock to institutional investors for \$10,500,000 or \$3.00 per share. The investors also received Series R warrants which may be exercised at any time prior to December 7, 2016. The Series R warrants entitle the holders to purchase 2,625,000 shares

of CEL-SCI's common stock at a price of \$4.00 per share. As of September 30, 2015, none of the Series R Warrants had been exercised.

In October 2013, CEL-SCI sold 17,826,087 shares of its common stock, plus 20,475,000 Series S warrants, in an underwritten offering. The net proceeds to CEL-SCI from the sale of the shares and warrants were approximately \$16,424,000, after deducting the underwriting discount. The Series S warrants may be exercised at any time on or before October 11, 2018 at a price of \$1.25 per share.

In December 2013, CEL-SCI sold 5,238,095 shares of its common stock and Series S warrants in an underwritten offering. The net proceeds to CEL-SCI from the sale of the shares and Series S warrants were approximately \$2,710,000, after deducting the underwriting discount. The Series S warrants may be exercised at any time on or before October 11, 2018 at a price of \$1.25 per share.

In February 2014, the Series S warrants began trading on the NYSE MKT under the ticker symbol "CVM WS". As of September 30, 2015, 2,088,769 Series S Warrants had been exercised. The remaining 25,928,010 Series S warrants entitle the holders to purchase one share of CEL-SCI's common stock at a price of \$1.25 per share.

In April 2014, CEL-SCI sold 7,128,229 shares of common stock, plus 1,782,057 Series T warrants, in an underwritten offering. The net proceeds to CEL-SCI from the sale of the stock and warrants were approximately \$9.23 million. The Series T warrants had an exercise price of \$1.58 and expired on October 17, 2014. CEL-SCI also issued 445,514 Series U warrants to the underwriters for this offering. The Series U warrants may be exercised beginning October 17, 2014 at a price of \$1.75 per share and expire on October 17, 2017. As of September 30, 2015, none of the Series U warrants had been exercised.

In October 2014, CEL-SCI sold 7,894,737 shares of common stock, plus 1,973,684 Series S warrants in an underwritten public offering. The net proceeds to CEL-SCI from the sale of the stock and warrants were approximately \$5.5 million. The warrants are immediately exercisable, expire October 11, 2018 and have an exercise price of \$1.25.

Additionally, in October 2014, CEL-SCI sold 1,320,000 shares of common stock, plus 330,000 Series S warrants in a registered direct offering. The net proceeds to CEL-SCI from the sale of the stock and warrants were approximately \$941,000. The warrants are immediately exercisable, expire October 11, 2018 and have an exercise price of \$1.25.

On May 28, 2015, CEL-SCI sold 20,253,164 shares of common stock, plus 20,253,164 Series V warrants, in an underwritten public offering. The common stock and Series V warrants were sold at a combined per unit price of \$0.79 for net proceeds of approximately \$14.7 million. The Series V warrants are immediately exercisable at a price of \$0.79 and expire on May 28, 2020. As of September 30, 2015, none of the Series V warrants had been exercised.

Inventory decreased by approximately \$50,000 at September 30, 2015 as compared to September 30, 2014, due to the timing of supplies purchased and used in the manufacturing of Multikine for the Phase 3 clinical trial. In addition, prepaid expenses increased by approximately \$72,000. The increase was primarily due to the Company making advance payments to cover future expenses related to its ongoing Phase 3 clinical trial.

During the year ended September 30, 2015, CEL-SCI's cash decreased by \$2,786,938. Significant components of this decrease include: 1) net cash used in operating activities of \$23,833,333, 2) expenditures for equipment and patents of \$93,531, and 3) the repayment of \$8,452 in capital lease obligations offset by \$21,148,378 in proceeds from the sale of stock and warrants.

## Future Capital Requirements

Other than funding operating losses, funding its research and development program, and making required lease payments, CEL-SCI does not have any material capital commitments. Material contractual obligations as of September 30, 2015 are as follows:

	Years Ending September 30,						
	Total	2016	2017	2018	2019	2020	2021 & thereafter
Operating Leases	\$ 27,117,710	\$ 1,861,154	\$ 1,844,807	\$ 1,848,235	\$ 1,912,779	\$ 1,951,756	\$ 17,698,979
Related Party Note & Interest	1,393,872	107,646	99,365	1,186,861	-	-	-
Total Contractual Obligations	\$ 28,511,582	\$ 1,968,800	\$ 1,944,172	\$ 3,035,096	\$ 1,912,779	\$ 1,951,756	\$ 17,698,979

Further, CEL-SCI has contingent obligations with vendors for work that will be completed in relation to the Phase 3 trial. The timing of these obligations cannot be determined at this time. The estimated remaining cash cost of these obligations for the Phase 3 clinical trial is approximately \$21.6 million.

CEL-SCI will need to raise additional funds, either through the exercise of outstanding warrants/options, through a debt or equity financing or a partnering arrangement, to complete the Phase 3 trial and bring Multikine to market. If CEL-SCI is able to raise additional funds, then CEL-SCI believes that it has enough capital to support its operations for more than the next twelve months. If CEL-SCI cannot raise the needed funds, CEL-SCI may have to end the Phase 3 clinical trial before its completion.

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.

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 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 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 – Compensation cost 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 ASC 505-50, “Equity-Based Payments to Non-Employees.” Accordingly, compensation cost 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-- Prepaid expenses are payments for future services to be rendered and are expensed over the time period for which the service is rendered. Prepaid expenses may also include payment for goods to be received within one year of the payment date. Inventory consists of bulk purchases of laboratory supplies to be consumed in the manufacturing of CEL-SCI’s drug candidates for clinical studies and for quality control and bioassay use. Inventories are stated at the lower of cost or market, where cost is determined using the first-in, first out method applied on a consistent basis.

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 ASC 815, “Accounting for Derivative Instruments and Hedging Activities, 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 CEL-SCI’s balance sheet 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.

## **Market Risks**

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 the financial statements. The fair value of these instruments is affected primarily by volatility of the trading prices of CEL-SCI's common stock. For the three years ended September 30, 2015, CEL-SCI recognized a gain of \$282,616, \$248,767, and \$10,750,666, 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 3 trial are transacted in a foreign currency. The interest risk on investments on September 30, 2015 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.



**CEL-SCI CORPORATION**

**Financial Statements for the Years  
Ended September 30, 2015, 2014 and 2013, and  
Report of Independent Registered Public Accounting Firm**

# CEL-SCI CORPORATION

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## Report of Independent Registered Public Accounting Firm

Board of Directors and Stockholders  
CEL-SCI Corporation  
Vienna, Virginia

We have audited the accompanying balance sheets of CEL-SCI Corporation as of September 30, 2015 and 2014 and the related statements of operations, stockholders' (deficit) equity, and cash flows for each of the three years in the period ended September 30, 2015. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of CEL-SCI Corporation at September 30, 2015 and 2014, and the results of its operations and its cash flows for each of the three years in the period ended September 30, 2015, in conformity with accounting principles generally accepted in the United States of America.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), CEL-SCI Corporation's internal control over financial reporting as of September 30, 2015 based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) and our report dated December 11, 2015 expressed an unqualified opinion thereon.

/s/ BDO USA, LLP

McLean, Virginia  
December 11, 2015

CEL-SCI CORPORATION  
BALANCE SHEETS  
SEPTEMBER 30, 2015 and 2014

ASSETS	2015	2014
CURRENT ASSETS:		
Cash and cash equivalents	\$ 5,726,682	\$ 8,513,620
Receivables	87,214	81,820
Prepaid expenses	979,655	907,526
Deposits - current portion	150,000	150,000
Inventory used for R&D and manufacturing	1,401,839	1,452,020
Deferred rent - current portion	487,793	544,074
Total current assets	8,833,183	11,649,060
RESEARCH AND OFFICE EQUIPMENT, net	307,466	403,004
PATENT COSTS, net	291,564	323,588
DEFERRED RENT - net of current portion	4,044,473	4,733,865
DEPOSITS	1,970,917	2,120,917
TOTAL ASSETS	\$ 15,447,603	\$ 19,230,434
LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY		
CURRENT LIABILITIES:		
Accounts payable	\$ 5,128,682	\$ 1,160,783
Accrued expenses	88,575	547,208
Due to employees	365,131	307,961
Related party loan	1,249,181	1,104,057
Deferred rent - current portion	9,997	6,375
Lease obligation - current portion	9,028	8,495
Derivative instruments - current portion	-	18,105
Total current liabilities	6,850,594	3,152,984
Derivative instruments - net of current portion	13,686,587	5,487,141
Deferred revenue	126,639	126,591
Deferred rent - net of current portion	9,026	6,290
Lease obligation - net of current portion	-	9,028
Deposits held	5,000	5,000
Total liabilities	20,677,846	8,787,034
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' (DEFICIT) EQUITY		
Preferred stock, \$.01 par value-200,000 shares authorized; -0- shares issued and outstanding	-	-
Common stock, \$.01 par value - 600,000,000 shares authorized; 112,360,568 and 81,902,471 shares issued and outstanding at September 30, 2015 and 2014, respectively	1,123,606	819,025
Additional paid-in capital	267,847,630	249,151,208
Accumulated deficit	(274,201,479)	(239,526,833)
Total stockholders' (deficit) equity	(5,230,243)	10,443,400
TOTAL LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY	\$ 15,447,603	\$ 19,230,434

See notes to financial statements.

CEL-SCI CORPORATION  
STATEMENTS OF OPERATIONS  
YEARS ENDED SEPTEMBER 30, 2015, 2014 and 2013

	<u>2015</u>	<u>2014</u>	<u>2013</u>
GRANT INCOME AND OTHER	\$ 657,377	\$ 264,033	\$ 159,583
OPERATING EXPENSES:			
Research and development (excluding R&D depreciation of \$148,939, \$172,442 and \$253,072 respectively, included below)	20,949,208	17,000,145	12,681,049
Depreciation and amortization	206,750	231,752	364,124
General & administrative	<u>13,797,964</u>	<u>10,606,248</u>	<u>6,982,686</u>
Total operating expenses	<u>34,953,922</u>	<u>27,838,145</u>	<u>20,027,859</u>
OPERATING LOSS	(34,296,545)	(27,574,112)	(19,868,276)
GAIN ON DERIVATIVE INSTRUMENTS	282,616	248,767	10,750,666
LOSS ON DEBT EXTINGUISHMENT	(641,276)	-	-
INTEREST INCOME	110,544	122,854	117,086
INTEREST EXPENSE	<u>(129,985)</u>	<u>(163,774)</u>	<u>(170,423)</u>
NET LOSS	(34,674,646)	(27,366,265)	(9,170,947)
ISSUANCE OF ADDITIONAL SHARES DUE TO RESET PROVISIONS	-	(1,117,447)	-
MODIFICATION OF WARRANTS	<u>-</u>	<u>-</u>	<u>(59,531)</u>
NET LOSS AVAILABLE TO COMMON SHAREHOLDERS	<u>\$ (34,674,646)</u>	<u>\$ (28,483,712)</u>	<u>\$ (9,230,478)</u>
NET LOSS PER COMMON SHARE			
BASIC	\$ (0.42)	\$ (0.48)	\$ (0.30)
DILUTED	\$ (0.42)	\$ (0.49)	\$ (0.66)
WEIGHTED AVERAGE COMMON SHARES OUTSTANDING			
BASIC and DILUTED	82,519,027	58,804,622	30,279,442

See notes to financial statements.

CEL-SCI CORPORATION  
STATEMENTS OF STOCKHOLDERS' (DEFICIT) EQUITY  
YEARS ENDED SEPTEMBER 30, 2015, 2014 and 2013

	Common Shares	Stock Amount	Additional Paid-In Capital	Accumulated Deficit	Total
BALANCE, OCTOBER 1, 2012	27,312,492	273,125	209,743,928	(202,989,621)	7,027,432
Sale of stock	3,500,000	35,000	9,753,769	-	9,788,769
Issuance of warrants in connection with sale of common stock	-	-	(4,200,000)	-	(4,200,000)
401(k) contributions paid in common stock	74,230	742	158,114	-	158,856
Stock issued to nonemployees for service	138,297	1,383	359,542	-	360,925
Equity based compensation - employees	-	-	2,636,905	-	2,636,905
Equity based compensation - non-employees	-	-	98,150	-	98,150
Net loss	-	-	-	(9,170,947)	(9,170,947)
BALANCE, SEPTEMBER 30, 2013	31,025,019	310,250	218,550,408	(212,160,568)	6,700,090
Sale of stock	31,755,494	317,555	28,129,691	-	28,447,246
Issuance of warrants in connection with sale of common stock	-	-	(7,791,448)	-	(7,791,448)
401(k) contributions paid in common stock	164,787	1,647	153,787	-	155,434
Exercise of warrants	2,668,508	26,686	4,253,632	-	4,280,318
Conversion of warrant liability to equity	-	-	1,308,528	-	1,308,528
Stock issued to nonemployees for service	579,968	5,800	621,318	-	627,118
Stock issued for patents	8,695	87	9,912	-	9,999
Modification of options issued to consultants	-	-	76,991	-	76,991
Issuance of restricted stock	15,700,000	157,000	(157,000)	-	-
Equity based compensation - employees	-	-	3,958,637	-	3,958,637
Equity based compensation - non-employees	-	-	36,752	-	36,752
Net loss	-	-	-	(27,366,265)	(27,366,265)
BALANCE, SEPTEMBER 30, 2014	81,902,471	819,025	249,151,208	(239,526,833)	10,443,400
Sale of stock	29,467,901	294,679	20,853,699	-	21,148,378
Issuance of warrants in connection with sale of common stock	-	-	(8,463,957)	-	(8,463,957)
401(k) contributions paid in common stock	243,178	2,432	163,214	-	165,646
Stock issued to nonemployees for service	739,968	7,400	526,576	-	533,976
Modification of warrants	-	-	475,333	-	475,333
Forfeiture of unvested restricted stock	(100,000)	(1,000)	1,000	-	-
Equity based compensation - employees	107,050	1,070	5,104,757	-	5,105,827
Equity based compensation - non-employees	-	-	35,800	-	35,800
Net loss	-	-	-	(34,674,646)	(34,674,646)
BALANCE, SEPTEMBER 30, 2015	<u>112,360,568</u>	<u>\$ 1,123,606</u>	<u>\$ 267,847,630</u>	<u>\$ (274,201,479)</u>	<u>\$ (5,230,243)</u>

See notes to financial statements.

CEL-SCI CORPORATION  
STATEMENTS OF CASH FLOWS  
YEARS ENDED SEPTEMBER 30, 2015, 2014 and 2013

	2015	2014	2013
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>			
Net loss	\$ (34,674,646)	\$ (27,366,265)	\$ (9,170,947)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	206,750	231,752	364,124
Amortization of debt premium	(20,819)	-	-
Issuance of common stock, warrants and options for services	565,915	694,955	454,855
Modification of warrants issued to consultants	-	76,991	-
Equity based compensation	5,105,827	3,958,637	2,636,905
Common stock contributed to 401(k) plan	165,646	155,434	158,856
Impairment loss on abandonment of patents	-	1,182	22,628
Loss on retired equipment	313	268	4,350
Gain on derivative instruments	(282,616)	(248,767)	(10,750,666)
Loss on debt extinguishment	641,276	-	-
(Increase)/decrease in assets:			
Receivables	(5,394)	(7,557)	84,351
Deferred rent	745,673	769,159	544,028
Prepaid expenses	(68,268)	(158,088)	529,738
Inventory used for R&D and manufacturing	50,181	(435,392)	367,856
Deposits	150,000	(200,000)	(400,000)
Increase/(decrease) in liabilities:			
Accounts payable	3,981,886	(751,971)	1,316,964
Accrued expenses	(458,633)	433,712	101,995
Deferred revenue	48	46	45
Due to employees	57,170	(78,376)	186,446
Deferred rent liability	6,358	(3,739)	(108)
Net cash used in operating activities	<u>(23,833,333)</u>	<u>(22,928,019)</u>	<u>(13,548,580)</u>
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>			
Purchases of equipment	(73,399)	(103,977)	(102,033)
Expenditures for patent costs	(20,132)	(34,887)	(30,728)
Net cash used in investing activities	<u>(93,531)</u>	<u>(138,864)</u>	<u>(132,761)</u>
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>			
Proceeds from issuance of common stock and warrants	21,148,378	28,428,641	9,788,769
Proceeds from exercise of warrants	-	3,118,387	-
Payments on obligations under capital lease	(8,452)	(8,137)	(6,858)
Net cash provided by financing activities	<u>21,139,926</u>	<u>31,538,891</u>	<u>9,781,911</u>
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(2,786,938)	8,472,008	(3,899,430)
CASH AND CASH EQUIVALENTS, BEGINNING OF YEAR	<u>8,513,620</u>	<u>41,612</u>	<u>3,941,042</u>
CASH AND CASH EQUIVALENTS, END OF YEAR	<u>\$ 5,726,682</u>	<u>\$ 8,513,620</u>	<u>\$ 41,612</u>

See notes to financial statements.

CEL-SCI CORPORATION  
STATEMENTS OF CASH FLOWS  
YEARS ENDED SEPTEMBER 30, 2015, 2014 and 2013

	2015	2014	2013
<b>ACCOUNTS PAYABLE</b>			
(Decrease) Increase in research and office equipment	\$ (2,345)	\$ (1,074)	\$ 36,622
Decrease (increase) in capital lease obligation	43	3,477	(35,995)
(Decrease) increase in patent costs	(11,685)	4,474	14,024
Decrease (increase) in accounts payable	13,987	(6,877)	(14,651)
	\$ -	\$ -	\$ -
<b>ADDITIONAL PAID IN CAPITAL</b>			
(Increase) in derivative liabilities	\$ (8,463,957)	\$ (5,320,989)	\$ (4,200,000)
Decrease (Increase) in common stock	1,000	(16,375)	-
Increase in prepaid services	3,861	31,085	57,553
Increase in patent costs	-	9,999	-
Decrease in additional paid in capital	8,459,096	5,296,280	4,142,447
	\$ -	\$ -	\$ -
<b>SUPPLEMENTAL DISCLOSURE OF CASH FLOWS INFORMATION:</b>			
Cash paid for interest expense	\$ 147,166	\$ 180,654	\$ 156,225

See notes to financial statements.



**CEL-SCI CORPORATION**  
**NOTES TO FINANCIAL STATEMENTS**

**1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

CEL-SCI Corporation (the Company) was incorporated on March 22, 1983, in the state of Colorado, to finance research and development in biomedical science and ultimately to engage in marketing and selling products.

CEL-SCI's work is focused on finding the best way to activate the immune system to fight cancer and infectious diseases. The Company believes that the best results can be achieved by giving its cancer immunotherapy drug before surgery, radiation and chemotherapy, at a time when the immune system is much stronger. Other cancer immunotherapies are typically given after these conventional treatments. The Company's lead investigational therapy, Multikine (Leukocyte Interleukin, Injection), is currently being tested in a Phase 3 clinical trial as a potential therapeutic agent directed at using the immune system to produce an anti-tumor immune response for advanced primary head and neck cancer. Data from Phase 1 and Phase 2 clinical trials suggest Multikine has the potential to directly affect 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 the Company has registered for this investigational therapy, and this proprietary name is subject to FDA review in connection with the Company's 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.

Multikine has been cleared by the regulators in twenty four countries around the world, including the U.S. FDA, for a global Phase III clinical trial in advanced primary (not yet treated) head and neck cancer patients. Multikine is also being used in a Phase 1 study at the Naval Medical Center, San Diego under a Cooperative Research and Development Agreement (CRADA) and at the University of California, San Francisco (UCSF) in HIV/HPV co-infected men and women with peri-anal warts.

On June 25, 2013, CEL-SCI's shareholders approved a reverse split of the Company's common stock. The reverse split became effective on the NYSE MKT on September 25, 2013. On that date, every ten issued and outstanding shares of the Company's common stock automatically converted into one outstanding share. As a result of the reverse stock split, the number of the Company's outstanding shares of common stock decreased from 310,005,272 (pre-split) shares to 31,001,686 (post-split) shares. In addition, by reducing the number of CEL-SCI's outstanding shares, CEL-SCI's loss per share in all prior periods will increase by a factor of ten. The reverse stock split affected all stockholders of the Company's common stock uniformly, and did not affect any stockholder's percentage of ownership interest. The par value of the Company's stock remained unchanged at \$0.01 per share and the number of authorized shares of common stock remained the same after the reverse stock split.

As the par value per share of the Company's common stock remained unchanged at \$0.01 per share, a total of \$2,790,036 was reclassified from common stock to additional paid-in capital. In connection with this reverse stock split, the number of shares of common stock reserved for issuance under the Company's incentive and non-qualified stock option plans (Note 7) as well as the shares of common stock underlying outstanding stock options, and warrants were also proportionately reduced while the exercise prices of such stock options and warrants were proportionately increased. All references to shares of common stock and per share data for all periods presented in the accompanying financial statements and notes thereto have been adjusted to reflect the reverse stock split on a retroactive basis.

*Summary of Significant Accounting Policies:*

Cash and Cash Equivalents – For purposes of the statements of cash flows, cash and cash equivalents consist principally of unrestricted cash on deposit and short-term money market funds. The Company considers all highly liquid investments with a maturity when purchased of less than three months as cash and cash equivalents.

Prepaid Expenses – Prepaid expenses are payments for future services to be rendered and are expensed over the time period for which the service is rendered. Prepaid expenses may also include payment for goods to be received within one year of the payment date.

Inventory – Inventory consists of manufacturing production advances and bulk purchases of laboratory supplies to be consumed in the manufacturing of the Company's product for clinical studies. Inventories are stated at the lower of cost or market, where cost is determined using the first-in, first out method applied on a consistent basis.

Deposits – The deposits are required by the lease agreement for the manufacturing facility and by the clinical research organization (CRO) agreements.

Research and Office Equipment and Leasehold Improvements – Research and office equipment is recorded at cost and depreciated using the straight-line method over estimated useful lives of five to seven years. Leasehold improvements are depreciated over the shorter of the estimated useful life of the asset or the term of the lease. Repairs and maintenance which do not extend the life of the asset are expensed when incurred. The fixed assets are reviewed on a quarterly basis to assess impairment, if any.

Patents – Patent expenditures are capitalized and amortized using the straight-line method over the shorter of the expected useful life or the legal life of the patent (17 years). In the event changes in technology or other circumstances impair the value or life of the patent, appropriate adjustment to 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 would be the difference between the estimated fair value of the asset and its carrying value.

Deferred Rent (Asset) – Consideration paid, including deposits, related to operating leases is recorded as a deferred rent asset and amortized as rent expense over the lease term. Interest on the

deferred rent is calculated at 3% on the funds deposited on the manufacturing facility and is included in deferred rent. This interest income will be used to offset future rent.

Deferred Rent (Liability) – Certain of the Company’s operating leases provide for minimum annual payments that adjust over the life of the lease. The aggregate minimum annual payments are expensed on a straight-line basis over the minimum lease term. The Company recognizes a deferred rent liability for rent escalations when the amount of straight-line rent exceeds the lease payments, and reduces the deferred rent liability when the lease payments exceed the straight-line rent expense. For tenant improvement allowances and rent holidays, the Company records a deferred rent liability and amortizes the deferred rent over the lease term as a reduction to rent expense.

Derivative Instruments - The Company has entered into financing arrangements that consist of freestanding derivative instruments that contain embedded derivative features. The Company accounts for these arrangements in accordance with Accounting Standards Codification (ASC) 815, “Accounting for Derivative Instruments and Hedging Activities”. In accordance with accounting principles generally accepted in the United States (U.S.GAAP), derivative instruments and hybrid instruments are recognized as either assets or liabilities on the balance sheet 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. The Company 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. The derivative liabilities are remeasured at fair value at the end of each reporting period as long as they are outstanding.

Grant Income – The Company's grant arrangements are handled on a reimbursement basis. Grant income under the arrangements is recognized when costs are incurred.

Research and Development Costs – Research and development expenditures are expensed as incurred.

Net Loss Per Common Share – The Company calculates net loss per common share in accordance with ASC 260 “Earnings Per Share” (ASC 260). Basic and diluted net loss per common share was determined by dividing net loss applicable to common shareholders by the weighted average number of common shares outstanding during the period. The Company’s potentially dilutive shares, which include outstanding common stock options, restricted stock units, convertible preferred stock and common stock warrants, have not been included in the computation of diluted net loss per share for all periods as the result would be anti-dilutive.

Concentration of Credit Risk – Financial instruments, which potentially subject the Company to concentrations of credit risk, consist of cash and cash equivalents. The Company maintains its cash and cash equivalents with high quality financial institutions. At times, these accounts may exceed federally insured limits. The Company has not experienced any losses in such bank accounts. The Company believes it is not exposed to significant credit risk related to cash and cash equivalents. All non-interest bearing cash balances were fully insured up to \$250,000 at September 30, 2015.

Income Taxes – The Company uses the asset and liability method of accounting for income taxes. Under the asset and liability method, deferred tax assets and liabilities are recognized for future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating and tax loss carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. The Company records a valuation allowance to reduce the deferred tax assets to the amount that is more likely than not to be recognized.

Use of Estimates – The preparation of financial statements in conformity U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and the accompanying disclosures. These estimates are based on management’s best knowledge of current events and actions the Company may undertake in the future. Estimates are used in accounting for, among other items, inventory obsolescence, accruals, stock options, useful lives for depreciation and amortization of long-lived assets, deferred tax assets and the valuation of derivative liabilities. Actual results could differ from estimates, although management does not generally believe such differences would materially affect the financial statements in any given year. However, in regard to the valuation of derivative liabilities determined using various valuation techniques including the Black-Scholes and binomial pricing methodologies, significant fluctuations may materially affect the financial statements in a given year. The Company considers such valuations to be significant estimates.

Fair Value Measurements – The Company evaluates financial assets and liabilities subject to fair value measurements in accordance with a fair value hierarchy to prioritize the inputs used to measure fair value. A financial instrument’s level within the fair value hierarchy is based on the lowest level of input significant to the fair value measurement, where Level 1 is the highest and Level 3 is the lowest. See Note 12 for the definition of levels and the classification of assets and liabilities in those levels.

Stock-Based Compensation – Compensation cost for all stock-based awards is measured at fair value as of the grant date in accordance with the provisions of ASC 718, “Compensation – Stock Compensation.” The fair value of stock options is calculated using the Black-Scholes option pricing model. The Black-Scholes model requires various judgmental assumptions including volatility and expected option life. The stock-based compensation cost is recognized on the straight line allocation method as expense over the requisite service or vesting period.

Equity instruments issued to non-employees are accounted for in accordance with ASC 505-50, “Equity-Based Payments to Non-Employees.” Accordingly, compensation is recognized when goods or services are received and may be measured using the Black-Scholes valuation model, based on the type of award. The Black-Scholes model requires various judgmental assumptions regarding the fair value of the equity instruments at the measurement date and the expected life of the options.

The Company has Incentive Stock Option Plans, Non-Qualified Stock Options Plans, Stock Compensation Plans, Stock Bonus Plans and an Incentive Stock Bonus Plan. In some cases, these Plans are collectively referred to as the “Plans.” All Plans have been approved by the Company’s stockholders.

The Company’s stock options are not transferable, and the actual value of the stock options that an employee may realize, if any, will depend on the excess of the market price on the date of exercise over the exercise price. The Company has based its assumption for stock price volatility on the variance of daily closing prices of the Company’s stock. The risk-free interest rate assumption was based on the U.S. Treasury rate at date of the grant with term equal to the expected life of the option. Historical data was used to estimate option exercise and employee termination within the valuation model. The expected term of options represents the period of time that options granted are expected to be outstanding and has been determined based on an analysis of historical exercise behavior. If any of the assumptions used in the Black-Scholes model change significantly, stock-based compensation expense for new awards may differ materially in the future from that recorded in the current period.

Vesting of restricted stock granted under the Incentive Stock Bonus Plan is subject to service, performance or market conditions and meets the classification of equity awards. These awards were measured at fair market value on the grant-dates for issuances where the attainment of performance criteria is probable and at fair value on the grant-dates, using a Monte Carlo simulation for issuances where the attainment of performance criteria is uncertain. The total compensation cost will be expensed over the estimated requisite service period.

Recent Accounting Pronouncements – In April 2015, the FASB issued ASU 2015-03 to simplify the presentation of debt issuance costs. The amendments in this ASU require that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. The recognition and measurement guidance for debt issuance costs are not affected by these amendments. For public business entities, the amendments are effective for financial statements issued for fiscal years beginning after December 15, 2015, and interim periods within those fiscal years. Management does not expect this amendment to have a material effect on the financial statements.

In July 2015, the FASB issued ASU 2015-11 to simplify the accounting for inventory measured using FIFO or average cost. The amendments in this ASU require that inventory be measured at the lower of cost or net realizable value instead of the lower of cost or market value. For public business entities, the amendment is effective for financial statements issued for fiscal years beginning after December 15, 2016, and interim periods within those fiscal years. Management does not expect this amendment to have a material effect on the financial statements.

The Company has considered all other recently issued accounting pronouncements and does not believe the adoption of such pronouncements will have a material impact on its financial statements.

## 2. DERIVATIVES LIABILITIES, WARRANTS AND OTHER OPTIONS

Below is a chart presenting the derivative liabilities, warrants and other options outstanding at September 30, 2015:

<u>Warrants</u>	<u>Issue Date</u>	Shares Issuable upon <u>Exercise of</u> <u>Warrants</u>	<u>Exercise</u> <u>Price</u>	<u>Expiration</u> <u>Date</u>	<u>Refer</u> <u>-ence</u>
Series N	8/18/08	2,844,627	0.53	8/18/17	1
Series Q	6/21/12	1,200,000	5.00	12/22/15	1
Series R	12/6/12	2,625,000	4.00	12/6/16	1
Series S	10/11/13- 10/24/14	25,928,010	1.25	10/11/18	1
Series U	4/17/14	445,514	1.75	10/17/17	1
Series V	5/28/15	20,253,164	0.79	5/28/20	1
Series P	2/10/12	590,001	4.50	3/6/17	2
Consultants	10/14/05 – 7/1/15	238,000	0.66 – 20.00	10/14/15 - 6/30/18	3

### 1. Derivative Liabilities

The table below presents the derivative instruments and their respective balances at September 30.

	<u>2015</u>	<u>2014</u>
Series A through E warrants	\$ -	\$ 6,105
Series H warrants	-	12,000
Series Q warrants	-	12,000
Series R warrants	-	157,500
Series S warrants	7,363,555	5,197,352
Series U warrants	44,551	120,289
Series V warrants	<u>6,278,481</u>	<u>-</u>
Total derivative liabilities	<u>\$ 13,686,587</u>	<u>\$ 5,505,246</u>

The table below presents the gains and (losses) on the derivative instruments for the years ended September 30:

<u>Warrant Series</u>	<u>2015</u>	<u>2014</u>	<u>2013</u>
Series A - E	\$ 6,105	\$ 1	\$ 780,883
Series F and G	-	12,667	1,634,000
Series H	12,000	24,000	1,764,000
Series N	-	(1,404,027)	788,533
Series Q	12,000	36,000	1,872,000

Series R	157,500	131,250	3,911,250
Series S	(1,705,466)	1,098,787	-
Series T	-	276,122	-
Series U	75,738	73,967	-
Series V	<u>1,724,739</u>	<u>-</u>	<u>-</u>
Net gain	<u>\$ 282,616</u>	<u>\$ 248,767</u>	<u>\$ 10,750,666</u>

The Company reviews all outstanding warrants in accordance with the requirements of ASC 815. This topic provides that an entity should use a two-step approach to evaluate whether an equity-linked financial instrument (or embedded feature) is indexed to its own stock, including evaluating the instrument's contingent exercise and settlement provisions. The warrant agreements provide for adjustments to the exercise price for certain dilutive events. Under the provisions of ASC 815, the warrants are not considered indexed to the Company's stock because future equity offerings or sales of the Company's stock are not an input to the fair value of a "fixed-for-fixed" option on equity shares, and equity classification is therefore precluded.

In accordance with ASC 815, derivative liabilities must be measured at fair value upon issuance and re-valued at the end of each reporting period through expiration. Any change in fair value between the respective reporting periods is recognized as a gain or loss in the statement of operations.

#### *Series A through E Warrants*

As of September 30, 2015, all Series A through E warrants had expired. The Company accounted for the Series A through E Warrants as derivative liabilities in accordance with ASC 815. These warrants did not qualify for equity accounting and were accounted for as derivative liabilities because the warrant agreements provided the holders the right to require a cash settlement of the warrants in the event of a Fundamental Transaction, as defined in the warrant agreement. Since the occurrence of a Fundamental Transaction is not entirely within the Company's control, circumstances existed that would require net-cash settlement of the warrants while holders of shares would not receive a cash settlement.

On December 24, 2014, 130,347 Series A warrants, with an exercise price of \$5.00, expired. The fair value of the warrants on the date of expiration was \$1,303. As of September 30, 2014, all of these warrants were outstanding and the fair value of these derivative liabilities was \$1,303. On January 8, 2015, 16,750 Series A warrants, with an exercise price of \$5.00, expired. The fair value of the Series A warrants was \$0 on the date of expiration. As of September 30, 2014, all of these warrants were outstanding and the fair value of these derivative liabilities was \$167.

In connection with a loan received and fully repaid in a prior period, the Company issued 50,000 Series B warrants with an exercise price of \$6.80 per share. On September 4, 2014, all outstanding Series B warrants expired. As of September 30, 2014, no Series B warrants remained outstanding.

On February 20, 2015, 463,487 Series C warrants, with an exercise price of \$5.50, expired. The fair value of the Series C warrants was \$0 on the date of expiration. As of September 30,

2014, all of these warrants were outstanding. As of September 30, 2014, the fair value of the Series C warrants was \$4,635.

On August 12, 2014, all 71,428 outstanding Series E warrants, with an exercise price of \$17.50, expired. As of September 30, 2014, no Series E warrants remained outstanding.

#### *Series F and G warrants*

In October 2011, in connection with a financing, the Company issued 1,200,000 Series F warrants exercisable at \$4.00 per share at any time prior to October 6, 2014. The Company also issued 66,667 Series G warrants exercisable at \$4.00 per share to the placement agent for this offering. On August 12, 2014, all outstanding Series G warrants expired. The fair value of the Series G warrants on the date of expiration was \$0. On October 6, 2014, all outstanding Series F warrants expired. The fair value of the Series F warrants on the date of expiration was \$0. As of September 30, 2014, the fair value of the Series F warrants was \$0.

#### *Series H Warrants*

In January 2012, in connection with a financing, the Company issued 1,200,000 Series H warrants exercisable at \$5.00 per share at any time prior to August 1, 2015. On August 1, 2015, all outstanding Series H warrants expired. The fair value of the Series H warrants was \$0 on the date of expiration.

#### *Series Q Warrants*

In June 2012, in connection with a financing, the Company issued 1,200,000 Series Q warrants exercisable at \$5.00 per share at any time prior to December 22, 2015. The initial cost of the warrants of \$2,160,000 was recorded as a debit to additional paid-in capital and a credit to derivative liabilities. As of September 30, 2015, 1,200,000 Series Q warrants remained outstanding.

#### *Series R Warrants*

On December 4, 2012, the Company sold 3,500,000 shares of its common stock for \$10,500,000, or \$3.00 per share, in a registered direct offering. The investors in this offering also received Series R warrants which entitle the investors to purchase up to 2,625,000 shares of the Company's common stock. The Series R warrants may be exercised at any time before December 6, 2016 at a price of \$4.00 per share. The initial cost of the warrants of \$4,200,000 was recorded as a debit to additional paid-in capital and a credit to derivative liabilities. As of September 30, 2015, 2,625,000 Series R warrants remained outstanding.

#### *Series S Warrants*

On October 11, 2013, the Company closed a public offering of 17,826,087 units of common stock and warrants at a price of \$1.00 per unit for net proceeds of \$16,400,000, net of underwriting discounts and commissions and offering expenses of the Company. Each unit



consisted of one share of common stock and one Series S warrant to purchase one share of common stock. The Series S warrants were immediately exercisable, expire on October 11, 2018, and have an exercise price of \$1.25. In November 2013, the underwriters purchased an additional 2,648,913 warrants pursuant to the overallotment option, for which the Company received net proceeds of \$24,370. The initial cost of the Series S warrants of \$6,142,500 was recorded as a debit to additional paid-in capital and a credit to derivative liabilities.

On December 24, 2013, the Company closed a public offering of 4,761,905 units of common stock and warrants at a price of \$0.63 per unit for net proceeds of \$2,790,000, net of underwriting discounts and commissions and offering expenses of the Company. Each unit consisted of one share of common stock and one Series S warrant to purchase one share of common stock. The underwriters purchased an additional 476,190 units of common stock and warrants pursuant to the overallotment option, for which the Company received net proceeds of approximately \$279,000. The initial cost of the Series S warrants of \$1,178,571 was recorded as a debit to additional paid-in capital and a credit to derivative liabilities. On February 7, 2014, the Series S warrants began trading on the NYSE MKT under the symbol CVM WS.

On October 24, 2014, the Company closed an underwritten public offering of 7,894,737 shares of common stock and 1,973,684 Series S warrants to purchase shares of common stock. Additionally, on October 21, 2014, the Company sold 1,320,000 shares of common stock and 330,000 Series S warrants to purchase shares of common stock in a private offering. The common stock and Series S warrants were sold at a combined per unit price of \$0.76 for net proceeds of approximately \$6.4 million, net of underwriting discounts and commissions and offering expenses. The initial cost of the Series S warrants of \$460,737 was added to the existing Series S warrant liability.

During the year ended September 30, 2015, no Series S warrants were exercised. During the year ended September 30, 2014, 2,088,769 Series S Warrants were exercised, and the Company received proceeds of \$2,610,961. The total fair value of the Series S warrants on the dates of exercise was \$1,024,932.

As of September 30, 2015, the remaining 25,928,010 Series S warrants entitle the holders to purchase one share of the Company's common stock at a price of \$1.25 per share.

#### *Series T and U Warrants*

On April 17, 2014, the Company closed a public offering of 7,128,229 shares of common stock at a price of \$1.40 and 1,782,057 Series T warrants to purchase one share of common stock for net proceeds of \$9,230,000, net of underwriting commissions and offering expenses. The Series T warrants were immediately exercisable and had an exercise price of \$1.58. On October 17, 2014, all of the Series T warrants expired. The fair value of the Series T warrants was \$0 on the date of expiration. The underwriters received 445,514 Series U warrants to purchase one share of common stock. The Series U warrants were exercisable beginning October 17, 2014, expire on October 17, 2017, and have an exercise price of \$1.75. The initial cost of the Series T and U warrants of \$470,377 was recorded as a debit to additional paid-in capital and

a credit to derivative liabilities. As of September 30, 2015, 445,514 Series U warrants remained outstanding.

### *Series V Warrants*

On May 28, 2015, the Company closed an underwritten public offering of 20,253,164 shares of common stock and 20,253,164 Series V warrants to purchase shares of common stock. The common stock and Series V warrants were sold at a combined per unit price of \$0.79 for net proceeds of approximately \$14.7 million, net of underwriting discounts and commissions and offering expenses. The Series V warrants were immediately exercisable at a price of \$0.79 and expire on May 28, 2020. The initial cost of the Series V warrants of \$8,003,220 was recorded as derivative liability. As of September 30, 2015, 20,253,164 Series V warrants remained outstanding.

## 2. Equity Warrants

### *Series N Warrants*

Series N warrants were previously issued in connection with a financing. On October 11, 2013 and December 24, 2013, in connection with public offerings of common stock on those dates, the Company reset the exercise price of the 518,771 outstanding Series N warrants from \$3.00 to \$0.53 and issued the Series N warrant holders 2,432,649 additional warrants exercisable at \$0.53, as required by the warrant agreements. In January 2014, the Company offered the investors the option to extend the Series N warrants by one year and allow for cashless exercise in exchange for cancelling the reset provision in the warrant agreement. One investor, holding 2,844,627 Series N warrants accepted this offer. Accordingly, these warrants are no longer considered a derivative liability due to the cancelation of the reset provision. The fair value of the warrants on that date totaled \$1,308,528 and was reclassified from derivative liabilities to additional paid-in capital. On March 21, 2014, the other investor exercised 106,793 Series N warrants. The Company received cash proceeds of \$7,424 for 14,078 of the warrants exercised. The remaining 92,715 warrants were exercised in a cashless exercise. The fair value of the warrants on the date of exercise was \$137,000 and was reclassified from derivative liabilities to additional paid-in capital.

In addition, the October and December 2013 financings triggered the reset provision related to the initial Series N financing which resulted in the issuance of an additional 1,563,083 shares of common stock. The cost of additional shares issued was \$1,117,447. This cost was recorded as a debit and a credit to additional paid-in capital and was deemed a dividend.

On October 28, 2014, the outstanding 2,844,627 Series N Warrants were transferred to the de Clara Trust, of which the Company's CEO, Geert Kersten, is the trustee and a beneficiary. On June 29, 2015, the Company extended the expiration date of the Series N warrants to August 18, 2017. The incremental cost of this modification was \$475,333. The modification was concurrent with the extinguishment and reissuance of a note payable also held in the de Clara Trust, and was recorded as a loss on debt extinguishment.

As of September 30, 2015, the remaining 2,844,627 Series N warrants entitle the holders to purchase one share of the Company's common stock at a price of \$0.53 per share at any time prior to August 18, 2017. On September 30, 2015 and 2014, no derivative liability was recorded because the warrants no longer were considered a liability for accounting purposes.

#### *Series L and Series M Warrants*

Series L and Series M warrants were previously issued in connection with a financing. In April 2012, 25,000 Series L warrants exercisable at a price of \$7.50 per share were transferred to a consultant and were extended for two years from the current expiration date. The additional value of \$43,910 was accounted for as a credit to additional paid-in capital and a debit to general and administrative expense. On April 17, 2014, the 25,000 Series L warrants expired. In April 2013, 100,000 Series L warrants were repriced to \$2.50 per share and were extended for two years to April 2, 2015 in return for a reduction in outstanding warrants to 70,000. The additional cost of \$59,531 was recorded as a debit and a credit to additional paid-in capital and was a deemed dividend. This cost was included in modification of warrants and increased the net loss available to shareholders on the statements of operations. In April 2015, the remaining 70,000 of the Series L warrants, at an exercise price of \$2.50, expired. As of September 30, 2015, no Series L warrants remained outstanding.

In October 2013, the Company reduced the exercise prices of the Series M warrants from \$3.40 to \$1.00 in exchange for a reduction in the number of warrants from 600,000 to 500,000. The additional cost of \$76,991 was recorded as non-employee stock compensation expense. In March 2014, 500,000 Series M warrants were exercised at a price of \$1.00, and the Company received proceeds of \$500,000. As of September 30, 2014, no Series M warrants remained outstanding.

#### *Series O and P Warrants*

On February 10, 2012, the Company issued 590,001 Series P warrants to the former holder of the Series O warrants as an inducement for the early exercise of the Series O warrants. The Series P warrants allow the holder to purchase up to 590,001 shares of the Company's common stock at a price of \$4.50 per share. The Series P warrants are exercisable at any time prior to March 6, 2017. The warrants qualified for equity treatment in accordance with ASC 815 and were valued using the Black-Scholes method. As of September 30, 2015, 590,001 Series P warrants remained outstanding.

#### *Private Investor Warrants*

Between February and August 2014, 132,500 warrants held by a private investor, with exercise prices between \$5.60 and \$8.20, expired. On January 26, 2014, 608,438 warrants issued to the lessor of the Company's manufacturing facility, with an exercise price of \$7.50 per share, expired. As of September 30, 2014, no private investor warrants remained outstanding.

### *Warrants held by Officer and Director*

The Company's President and a director, Maximilian de Clara, loaned the Company \$1,104,057 under a note payable. In accordance with the loan agreement, the Company issued Mr. de Clara warrants to purchase 164,824 shares of the Company's common stock at a price of \$4.00 per share. In August 2014, the loan and warrants were transferred to the de Clara Trust, of which the Company's CEO, Geert Kersten, is the trustee and a beneficiary. The warrants expired on December 24, 2014. In consideration for an extension of the due date for the note, Mr. de Clara received warrants to purchase 184,930 shares of the Company's common stock at a price of \$5.00 per share. These warrants were also transferred to the de Clara Trust and expired on January 6, 2015.

### 3. Options and Shares Issued to Consultants

As of September 30, 2015, 238,000 options issued to consultants as payment for services remained outstanding, of which 230,000 options were issued from the Non-Qualified Stock Option plans.

During the year ended September 30, 2015, the Company entered into four new short-term agreements for consulting services. In accordance with these agreements, the Company issued 70,000 shares of restricted stock at an aggregate fair market value of \$54,850 and 90,000 fully vested options to purchase common stock at prices ranging from \$0.66 to \$1.02, at an aggregate fair value of \$35,800. The aggregate fair market values were recorded as prepaid expenses and are being charged to general and administrative expense over the period of service.

On December 15, 2014, the Company extended a one-year consulting agreement for services to be provided through December 15, 2015. In consideration for services provided under the original contract and the extension, the Company issued the consultant 100,000 shares of restricted common stock during each of the years ended September 30, 2015 and 2014. The shares were issued at the fair market value on the grant dates with an aggregate fair market value of \$66,900 and \$108,710 for shares issued during the year ended September 30, 2015 and 2014, respectively. The fair market value of the shares issued was recorded as a prepaid expense and is being charged to general and administrative expense over the period of service.

On October 20, 2013, the Company entered into a consulting agreement for services to be provided through October 19, 2016. In consideration for services provided, the Company agreed to issue the consultant 34,164 restricted shares each month of the agreement, with the first three months being issued in advance. During the years ended September 30, 2015 and 2014, the Company issued the consultant 409,968 shares of restricted stock at the fair market value of \$307,476 and \$439,008, respectively. The aggregate fair market value was recorded as a prepaid expense and is being charged to general and administrative expense over the period of service. In November 2014, the Company issued the same consultant 150,000 shares of common stock at the aggregate fair market value of \$97,500, in consideration for services provided.

The Company also engaged an additional consultant for services to be provided through November 30, 2014. During the year ended September 30, 2015, the Company issued the consultant 10,000 shares of restricted stock at the fair market value of \$7,250. During the year ended September 30, 2014, the Company issued the consultant 70,000 shares of restricted stock at the fair market value of \$79,400. The fair market value of the shares issued was recorded as a prepaid expense and was charged to general and administrative expense over the period of service.

During the years ended September 30, 2015 and 2014, the Company recorded total expense of \$565,915 and \$600,650 relating to these consulting agreements. In addition, \$94,305 was expensed during the year ended September 30, 2014 for other prior year consulting agreements. At September 30, 2015 and 2014, respectively, \$30,329 and \$26,468 relating to these consulting agreements is included in prepaid expenses.

### **3. OPERATIONS AND FINANCING**

The Company has incurred significant costs since its inception in connection with the acquisition of certain patented and unpatented proprietary technology and know-how relating to the human immunological defense system, patent applications, research and development, administrative costs, construction of laboratory facilities, and clinical trials. The Company has funded such costs with proceeds from loans and the public and private sale of its common and preferred stock. The Company will be required to raise additional capital or find additional long-term financing in order to continue with its research efforts. To date, the Company has not generated any revenue from product sales. The ability of the Company 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, the Company must complete the development of its products, obtain the appropriate regulatory approvals and obtain sufficient revenues to support its cost structure.

The Company is currently running a large multi-national Phase 3 clinical trial for head and neck cancer. The Company believes that it has enough capital to support its operations for more than the next twelve months as it believes that it has ready access to new equity capital should the need arise. During fiscal year 2015, the Company raised \$21.1 million net proceeds from public offerings. During fiscal year 2014, the Company raised approximately \$31.5 million in net proceeds through the sale of common stock and warrants in three public offerings and from the exercise of previously issued warrants. To finance the study beyond the next 12 months, the Company plans to raise additional capital in the form of corporate partnerships, debt and/or equity financings. In addition, the Company expects to receive proceeds from the arbitration against its former clinical research organization, Inventiv. The Company believes that it will be able to obtain additional financing because it has done so consistently in the past, and because Multikine is a product in the Phase 3 clinical trial stage. However, there can be no assurance that the Company will be successful in raising additional funds or that funds will be available to the Company on acceptable terms or at all. If the Company does not raise the necessary capital, the Company will either have to slow or delay the Phase 3 clinical trial or even significantly curtail its operations until such time as it is able to raise the required funding.

Since the Company launched its Phase 3 clinical trial for Multikine, the Company has spent approximately \$25 million as of September 30, 2015 on direct costs for the Phase 3 clinical trial. The total remaining cash cost of the clinical trial is estimated to be approximately \$21.6 million. It should be noted that this estimate is based only on the information currently available in the Company's contracts with the Clinical Research Organizations responsible for managing the Phase 3 clinical trial. This number can be affected by the speed of enrollment, foreign currency exchange rates and many other factors, some of which cannot be foreseen today. It is therefore possible that the cost of the Phase 3 clinical trial will be higher than currently estimated.

#### 4. RESEARCH AND OFFICE EQUIPMENT

Research and office equipment consisted of the following at September 30:

	<u>2015</u>	<u>2014</u>
Research equipment	\$3,268,757	\$3,230,882
Furniture and equipment	141,347	141,269
Leasehold improvements	<u>131,910</u>	<u>131,910</u>
	3,542,014	3,504,061
Accumulated depreciation and amortization	<u>(3,234,548)</u>	<u>(3,101,057)</u>
Net research and office equipment	<u>\$ 307,466</u>	<u>\$ 403,004</u>

Depreciation expense for the years ended September 30, 2015, 2014 and 2013 totaled \$166,279, \$188,967 and \$275,917, respectively. During the years ended September 30, 2015, 2014 and 2013, equipment with a net book value of \$313, \$268 and \$4,350, respectively, was retired. One asset is recorded under capital lease with a cost of \$33,203 at September 30, 2015 and 2014. Accumulated amortization on this asset is \$24,902 and \$16,660 at September 30, 2015 and 2014, respectively. Amortization of the capital lease asset is included in depreciation and amortization expense in the Statements of Operations.

#### 5. PATENTS

Patents consisted of the following at September 30:

	<u>2015</u>	<u>2014</u>
Patents	\$ 1,525,791	\$ 1,517,344
Accumulated amortization	<u>(1,234,227)</u>	<u>(1,193,756)</u>
Net Patents	<u>\$ 291,564</u>	<u>\$ 323,588</u>

During the years ended September 30, 2015, 2014 and 2013, the Company recorded patent impairment charges of \$0, \$1,182 and \$22,628, respectively, for the net book value of patents abandoned during the year. These amounts are included in general and administrative expenses. Amortization expense for the years ended September 30, 2015, 2014 and 2013 totaled \$40,471, \$42,785 and \$88,207, respectively. The total estimated future amortization is as follows:

<u>Years ending September 30,</u>	
2016	\$ 36,547
2017	36,547
2018	36,213
2019	34,510
2020	31,317
Thereafter	<u>116,430</u>
	<u>\$ 291,564</u>

## 6. INCOME TAXES

At September 30, 2015 and 2014, the Company had federal net operating loss carryforwards of approximately \$157.0 million and 141.0 million, respectively. The NOLs begin to expire during the fiscal year ended in 2018 and become fully expired by the end of the fiscal year ended 2035. In addition, the Company has a general business credit as a result of the credit for increasing research activities (“R&D credit”) of approximately \$1.2 million at September 30, 2015 and 2014. The R&D credit begins to expire during the fiscal year ended 2020 and is fully expired during the fiscal year ended 2029. Deferred taxes at September 30 consisted of the following:

	<u>2015</u>	<u>2014</u>
Net operating loss carryforwards	\$ 61,363,080	\$ 55,229,799
R&D credit	1,221,487	1,221,487
Stock-based compensation	5,854,794	4,054,450
Fixed assets and intangibles	41,018	26,329
Capitalized R&D	15,081,545	9,897,041
Vacation and other	114,625	108,891
Loan modification	<u>56,779</u>	<u>-</u>
Total deferred tax assets	83,733,328	70,537,997
Valuation allowance	<u>(83,733,328)</u>	<u>(70,537,997)</u>
Net deferred tax asset	<u>\$ -</u>	<u>\$ -</u>

In assessing the realization of deferred tax assets, management considered whether it was more likely than not that some, or all, of the deferred tax asset will be realized. The ultimate realization of the deferred tax assets is dependent upon the generation of future taxable income. Management has considered the history of the Company's operating losses and believes that the realization of the benefit of the deferred tax assets cannot be reasonably assured. In addition, under Internal Revenue Code Section 382, the Company's ability to utilize these net operating loss carryforwards may be limited or eliminated in the event of future changes in ownership.

The Company has no federal or state current or deferred tax expense or benefit. The Company's effective tax rate differs from the applicable federal statutory tax rate. The reconciliation of these rates for the three years ended September 30, 2015 is as follows:

	<u>2015</u>	<u>2014</u>	<u>2013</u>
Federal Rate	34.00%	34.00%	34.00%
State tax rate, net of federal benefit	5.12	5.15	4.97
State tax rate change	(0.15)	0.93	(3.77)
Other adjustments	(0.21)	0.00	0.00
Expired tax attributes	0.00	0.00	(87.87)
Adjustment to deferreds	0.00	19.13	14.30
Permanent differences	(0.71)	(0.43)	(1.59)
Change in valuation allowance	<u>(38.05)</u>	<u>(58.78)</u>	<u>39.96</u>
Effective tax rate	<u>0.00%</u>	<u>0.00%</u>	<u>0.00%</u>

The Company applies the provisions of ASC 740, "Accounting for Uncertainty in Income Taxes," which requires financial statement benefits to be recognized for positions taken for tax return purposes when it is more likely than not that the position will be sustained. The Company has elected to reflect any tax penalties or interest resulting from tax assessments on uncertain tax positions as a component of tax expense. The Company has generated federal net operating losses in tax years ending September 30, 1998 through 2014. These years remain open to examination by the major domestic taxing jurisdictions to which the Company is subject.

## 7. STOCK COMPENSATION

The Company recognized the following expenses for options issued or vested and restricted stock awarded during the year:

	<u>Year Ended September 30,</u>		
	<u>2015</u>	<u>2014</u>	<u>2013</u>
Employees	\$5,105,827	\$3,958,637	\$2,636,905
Non-employees	\$ 565,915	\$ 771,946	\$ 454,855



These expenses were recorded as general and administrative expense. During the years ended September 30, 2015, 2014 and 2013, non-employee compensation excluded \$30,329, \$26,468 and \$57,553, respectively, for future services to be performed (Note 11).

During the years ended September 30, 2015, 2014 and 2013, the fair value of each option grant was estimated on the date of grant using the Black-Scholes option-pricing model with the following assumptions.

	<u>2015</u>	<u>2014</u>	<u>2013</u>
Expected stock price volatility	73.38 – 86.19%	72.81 – 86.87%	84.41-92.28%
Risk-free interest rate	0.93 – 2.35%	0.59 – 2.65%	0.75-2.73%
Expected life of options	3.0 – 9.76 Years	3.0 – 9.76 Years	4.85-9.77
Expected dividend yield	-	-	-

Non-Qualified Stock Option Plans--At September 30, 2015, the Company has collectively authorized the issuance of 7,680,000 shares of common stock under its Non-Qualified Stock Option Plans. Options typically vest over a three-year period and expire no later than ten years after the grant date. Terms of the options are to be determined by the Company's Compensation Committee, which administers the plans. The Company's employees, directors, officers, and consultants or advisors are eligible to be granted options under the Non-Qualified Stock Option Plans.

Incentive Stock Option Plans--At September 30, 2015, the Company had collectively authorized the issuance of 1,960,000 shares of common stock under its Incentive Stock Option Plans. Options typically vest over a three-year period and expire no later than ten years after the grant date. Terms of the options were determined by the Company's Compensation Committee, which administers the plans. Only the Company's employees are eligible to be granted options under the Incentive Stock Option Plans.

Activity in the Company's Non-Qualified and Incentive Stock Option Plans for the two years ended September 30, 2015 is summarized as follows:

**Non-Qualified and Incentive Stock Option Plans**

	<u>Outstanding</u>				<u>Exercisable</u>			
	Number of Shares	Weighted Average Exercise Price	Weighted Ave Remaining Contractual Term (Years)	Aggregate Intrinsic Value	Number of Shares	Weighted Average Exercise Price	Weighted Ave Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding at October 1, 2013	5,188,141	\$3.62	6.53	\$133	2,422,997	\$4.00	4.95	\$133
Vested Granted (a) Exercised	1,723,240	\$1.09			1,094,803	\$2.14		
Forfeited	6,316	\$1.60						
Expired	73,916	\$4.29			73,916	\$4.29		

Cancelled

Outstanding at September 30, 2014	6,831,149	\$2.98	6.55	\$3,600	3,443,884	\$3.40	5.49	\$3,600
Vested					1,153,357	\$2.48		
Granted (b)	893,700	\$0.66						
Exercised								
Forfeited	116,665	\$1.87						
Expired	70,499	\$4.15			70,499	\$4.15		
Cancelled								
Outstanding at September 30, 2015	7,537,685	\$2.71	5.98	\$50	4,526,742	\$3.15	5.01	\$0

(a) Includes 80,000 stock options granted to consultants

(b) Includes 90,000 stock options granted to consultants

A summary of the status of the Company's non-vested options for the two years ended September 30, 2015 is presented below:

	<u>Number of Shares</u>	<u>Weighted Average Grant Date Fair Value</u>
Unvested at October 1, 2013	2,765,144	\$2.79
Vested	(1,094,803)	
Granted	1,723,240	
Forfeited	<u>(6,316)</u>	
Unvested at September 30, 2014	3,387,265	\$2.15
Vested	(1,153,357)	
Granted	893,700	
Forfeited	<u>(116,665)</u>	
Unvested at September 30, 2015	<u>3,010,943</u>	\$1.72

A summary of the status of the Company's restricted stock units issued from the Incentive Stock Bonus Plan for the two years ended September 30, 2015 is presented below:

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested at October 1, 2013	-	-
Vested	-	
Granted	15,700,000	
Forfeited	-	
Unvested at September 30, 2014	15,700,000	\$0.55
Vested	(500,000)	
Granted	-	
Forfeited	(100,000)	
Unvested at September 30, 2015	15,100,000	\$0.55

In December 2012, the Company offered employees and directors holding options that expire on April 1, 2013 the opportunity to forfeit these options and have new options issued with expiration dates of December 17, 2017. All twelve employees and directors eligible for this offer accepted the terms. This resulted in the cancellation of 387,466 options priced at \$2.20 per share and the concurrent issuance of the same number of options at \$2.80 per share. At the cancellation date, the incremental compensation cost was \$477,879 which was amortized over the remaining service period. As of September 30, 2015, all options remained outstanding.

Stock Bonus Plans -- At September 30, 2015, the Company was authorized to issue up to 3,594,000 shares of common stock under its Stock Bonus Plans. All employees, directors, officers, consultants, and advisors are eligible to be granted shares. During the year ended September 30, 2015, 243,178 shares were issued to the Company's 401(k) plan for a cost of \$165,646. During the year ended September 30, 2014, 164,787 shares were issued to the Company's 401(k) plan for a cost of \$155,434. During the year ended September 30, 2013, 74,230 shares were issued to the Company's 401(k) plan for a cost of \$158,856. As of September 30, 2015, the Company has issued a total of 1,643,714 shares of common stock from the Stock Bonus Plans.

Stock Compensation Plans-- At September 30, 2015, 3,350,000 shares were authorized for use in the Company's . During the years ended September 30, 2015, 2014 and 2013, 218,328, 409,968 and 50,000 shares were issued from the Stock Compensation Plans to consultants for payment of services at a cost of \$146,696, \$439,008 and \$140,000, respectively. During the year ended September 30, 2015, 107,050 shares were issued to employees from the Stock Compensation Plans as part of their compensation at a cost of \$57,807. No shares were issued to employees from the Stock Compensation Plans during the years ended September 30, 2014 and 2013. As of September 30, 2015, the Company has issued 1,423,999 shares of common stock from the Stock Compensation Plans.

Incentive Stock Bonus Plan-- On July 22, 2014 the Company's shareholders approved the 2014 Incentive Stock Bonus Plan, authorizing the issuance of up to 16,000,000 shares in the Company's Incentive Stock Bonus Plan. During the year ended September 30, 2014, 15,700,000 shares were issued from the Incentive Stock Bonus Plan to officers and employees. During the year ended September 30, 2015, 100,000 shares were forfeited, 500,000 shares vested and were issued and the remaining 15,100,000 shares are unvested and are held in escrow. The shares will only be earned upon the achievement of certain milestones leading to the commercialization of the Company's Multikine technology, or specified increases in the market price of the Company's stock. If the performance or market criteria are not met as specified in the Incentive Stock Bonus Plan, all or a portion of the awarded shares will be forfeited. The fair value of the shares on the grant date was calculated using the market value on the grant-date for issuances where the attainment of performance criteria is likely and using a Monte Carlo simulation for issuances where the attainment of performance criteria is uncertain. The grant date fair value of shares issued that remain outstanding as of September 30, 2015 is \$8,609,679. The total value of the shares, if earned, is being expensed over the requisite service periods for each milestone, provided the requisite service periods are rendered, regardless of whether the market conditions are met. No compensation cost is recognized for awards where the requisite service period is not rendered. During the years

ended September 30, 2015 and 2014, the Company recorded expense relating to the issuance of restricted stock pursuant to the plan of \$3,396,771 and \$1,477,954, respectively. At September 30, 2015, the Company has unrecognized compensation expense of \$3,734,954 which is expected to be recognized over a weighted average period of 6.04 years.

## **8. EMPLOYEE BENEFIT PLAN**

The Company maintains a defined contribution retirement plan, qualifying under Section 401(k) of the Internal Revenue Code, subject to the Employee Retirement Income Security Act of 1974, as amended, and covering substantially all Company employees. Each participant's contribution is matched by the Company with shares of common stock that have a value equal to 100% of the participant's contribution, not to exceed the lesser of \$10,000 or 6% of the participant's total compensation. The Company's contribution of common stock is valued each quarter based upon the closing bid price of the Company's common stock. Total expense, including plan maintenance, for the years ended September 30, 2015, 2014 and 2013, in connection with this Plan was \$169,759, \$159,632 and \$162,865, respectively.

## **9. COMMITMENTS AND CONTINGENCIES**

### *Clinical Research Agreements*

In March 2013, the Company entered into an agreement with Aptiv Solutions to provide certain clinical research services in accordance with a master service agreement. The Company will reimburse Aptiv for costs incurred. In May 2013, CEL-SCI made an advance payment of \$400,000. In October 2013, the Company made the second and final advance payment of \$200,000. In November 2014, \$150,000 was credited against invoices received in accordance with the agreement. The remaining advances will be credited against future invoices in \$150,000 annual increments through December 2017. As of September 30, 2015, \$150,000 of the deposit is classified as a current asset.

In April 2013, the Company entered into a co-development and revenue sharing agreement with Ergomed. Under the agreement, Ergomed will contribute up to \$10 million towards the Phase III head and neck cancer study in the form of offering discounted clinical services in exchange for a single digit percentage of milestone and royalty payments, up to four times Ergomed's contribution amount. The Company accounted for the co-development and revenue sharing agreement in accordance with ASC 808 "Collaborative Arrangements". The Company determined the payments to Ergomed are within the scope of ASC 730 "Research and Development." Therefore, the Company records the discount on the clinical services as a credit to research and development expense on its Statements of Operations. Since the Company entered into the co-development and revenue sharing agreement with Ergomed it has incurred research and development expenses of approximately \$11,969,000 related to Ergomed's services. This amount is net of Ergomed's discount of approximately \$4,159,000. During the years ended September 30, 2015, 2014 and 2013, the Company recorded, approximately \$6,746,000, \$4,385,000 and \$838,000, respectively, as research and

development expense related to Ergomed's services. These amounts were net of Ergomed's discount of approximately \$2,364,000, \$1,513,000 and \$281,000, respectively, over the comparable periods.

In October 2013, the Company entered into two co-development and profit sharing agreements with Ergomed. One agreement supports the U.S. Navy with the development of Multikine as a potential treatment for peri-anal warts in HIV/HPV co-infected men and women. The other agreement focuses on the development of Multikine as a potential treatment for cervical dysplasia in HIV/HPV co-infected women. Ergomed will assume up to \$3 million in clinical and regulatory costs for each study.

In April 2013, the Company dismissed inVentiv Health Clinical, LLC (f/k/a PharmaNet LLC) and PharmaNet GmbH (f/k/a PharmaNet AG), the Company's former clinical research organization and replaced it with Aptiv Solutions, Inc. and Ergomed Clinical Research Ltd. On October 31, 2013, the Company initiated the proceedings against inVentiv Health Clinical, LLC, or inVentiv, the former third-party CRO, and is seeking payment for damages related to inVentiv's prior involvement in the ongoing Phase 3 clinical trial of Multikine. The arbitration claim, initiated under the Commercial Rules of the American Arbitration Association, alleges (i) breach of contract, (ii) fraud in the inducement, and (iii) common law fraud. Currently, CEL-SCI is seeking at least \$50 million in damages in its amended statement of claim. Based upon further analysis, however, CEL-SCI believes that its damages (direct and consequential) presently total over \$150 million.

On December 12, 2013, inVentiv filed a counterclaim, alleging breach of contract on the part of the Company and seeking at least \$2 million in damages. On December 20, 2013, inVentiv moved to dismiss certain claims. On June 24, 2014, the arbitrator denied inVentiv's motion to dismiss.

In an amended statement of claim, the Company asserted the claims set forth above as well as an additional claim for professional malpractice. The arbitrator subsequently granted inVentiv's motion to dismiss the professional malpractice claim based on the "economic loss doctrine" under New Jersey law, a legal doctrine that, under certain circumstances, prohibits bringing a negligence-based claim alongside a claim for breach of contract. The arbitrator denied the remainder of inVentiv's motion, which had sought to dismiss certain other aspects of the amended statement of claim. In particular, the arbitrator rejected inVentiv's argument that several aspects of the amended statement of claim were beyond the arbitrator's jurisdiction.

In connection with the pending arbitration proceedings, inVentiv has asserted counterclaims against the Company for (i) breach of contract, seeking at least \$2 million in damages for services allegedly performed by inVentiv; (ii) breach of contract, seeking at least \$1 million in damages for the Company's alleged use of inVentiv's name in connection with publications and promotions in violation of the parties' contract; (iii) opportunistic breach, restitution and unjust enrichment, seeking at least \$20 million in disgorgement of alleged unjust profits allegedly made by the Company as a result of the purported breaches referenced in subsection (ii); and (iv) defamation, seeking at least \$1 million in damages for allegedly defamatory

statements made about inVentiv. The Company believes inVentiv’s counterclaims are meritless and intends to vigorously defend against them. However, if such defense is unsuccessful, and inVentiv successfully asserts any of its counterclaims, such an adverse determination could have a material adverse effect on our business, results, financial condition and liquidity.

In October 2015 CEL-SCI signed a funding agreement with a company established by Lake Whillans Litigation Finance, LLC, a firm specializing in funding litigation expenses. Pursuant to the agreement, an affiliate of Lake Whillans will provide CEL-SCI with up to \$5,000,000 in funding for litigation expenses to support its \$50,000,000 arbitration claims against inVentiv. The funding will be available to CEL-SCI if and when needed to fund the expenses of the ongoing arbitration and will only be repaid when CEL-SCI receives proceeds from the arbitration.

The arbitration hearing on the merits (the “trial”) is expected to occur in the spring of 2016. The exact date has not yet been determined.

#### *Lease Agreements*

The future minimum annual rental payments due under non-cancelable operating leases for office and laboratory space are as follows:

#### Years Ending September 30,

2016	\$ 1,861,154
2017	1,844,807
2018	1,848,235
2019	1,912,779
2020	1,951,756
Thereafter	<u>17,698,979</u>
Total minimum lease payments:	<u>\$ 27,117,710</u>

Rent expense, including amortization of deferred rent, for the years ended September 30, 2015, 2014 and 2013, was \$2,651,638, \$2,650,829 and \$2,651,460, respectively. The Company’s three leases expire between February 2017 and October 2028.

In August 2007, the Company leased a building near Baltimore, Maryland. The building was remodeled in accordance with the Company’s specifications so that it can be used by the Company to manufacture Multikine for the Company’s Phase III clinical trial and sales of the drug if approved by the FDA. The lease is for a term of twenty years and requires annual base rent to escalate each year at 3%. The Company is required to pay all real estate and personal property taxes, insurance premiums, maintenance expenses, repair costs and utilities. The lease allows the Company, 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.

At September 30, 2015, the Company recorded a total deferred rent asset of \$4,532,266, of which \$4,044,473 is long term and the balance of \$487,793 is included in current assets. At September 30, 2014, the Company recorded a total deferred rent asset of \$5,277,939, of which \$4,733,865 is long term and the balance of \$544,074 is included in current assets. On September 30, 2015 and 2014, the Company has included in deferred rent the following: 1) deposit on the manufacturing facility (\$3,150,000); 2) the fair value of the warrants issued to lessor (\$1,403,654); 3) additional investment (\$2,995,541); 4) deposit on the cost of the leasehold improvements for the manufacturing facility (\$1,786,591). At September 30, 2015, the Company has also included accrued interest on deposit of \$127,927, and accumulated amortization of \$4,931,447. At September 30, 2014, the Company has also included accrued interest on deposit of \$329,525, and accumulated amortization of \$4,387,374.

The Company was required to deposit the equivalent of one year of base rent in accordance with the lease. When the Company meets the minimum cash balance required by the lease, the deposit will be returned to the Company. The \$1,670,917 is included in non-current assets on September 30, 2015 and 2014.

The Company subleases a portion of its rental space on a month to month term lease, which requires a 30 day notice for termination. The sublease rent for the years ended September 30, 2015, 2014 and 2013 was \$64,879, \$63,144 and \$61,305, respectively, and is recorded in grant income and other in the statements of operations.

The Company leases its research and development laboratory under a 60 month lease which expires February 28, 2017. The operating lease includes escalating rental payments. The Company is recognizing the related rent expense on a straight line basis over the full 60 month term of the lease at the rate of \$11,360 per month. As of September 30, 2015 and 2014, the Company has recorded a deferred rent liability of \$6,484 and \$6,387, respectively.

On July 1, 2015, the Company renewed the operating lease on the office headquarters under a 60 month lease which expires June 30, 2020. The operating lease includes escalating rental payments. The Company is recognizing the related rent expense on a straight line basis over the full 60 month term of the lease at the rate \$8,134 per month. Under the prior operating lease, rent expense was recognized at a rate of \$7,864. As of September 30, 2015 and 2014, the Company has recorded a deferred rent liability of \$12,539 and \$6,278, respectively.

The Company leases office equipment under a capital lease arrangement. The term of the capital lease is 48 months and expires on September 30, 2016. The monthly lease payment is \$1,025. The lease bears interest at approximately 6% per annum.

#### *Employment Contracts*

On August 30, 2013, the Company's employment agreement with Maximilian de Clara, the Company's President and a director, as amended on September 8, 2006 and extended on August 30, 2010, was further extended to August 30, 2016. The employment agreement provides that the Company will pay Mr. de Clara an annual salary of \$363,000 during the term of the agreement. In the event that there is a material reduction in his authority, duties or

activities, or in the event there is a change in the control of the Company, then the agreement allows him to resign from his position at the Company and receive a lump-sum payment from the Company equal to 18 months of salary. For purposes of the employment agreement, a change in the control of the Company means the sale of more than 50% of the outstanding shares of the Company's common stock, or a change in a majority of the Company's directors.

On September 1, 2011, the Company agreed to extend its employment agreement with Geert Kersten, the Company's Chief Executive Officer, to August 31, 2016. Mr. Kersten's annual salary for fiscal year 2015 was \$542,769. Mr. Kersten will receive at least the same salary increases each year as do other senior executives of the Company. Further increases, if any, will be made at the sole discretion of the Company's directors.

During the employment term, Mr. Kersten will be entitled to receive any other benefits which are provided to the Company's executive officers or other fulltime employees in accordance with the Company's policies and practices and subject to Mr. Kersten's satisfaction of any applicable condition of eligibility.

If Mr. Kersten resigns within ninety (90) days of the occurrence of any of the following events: (i) a relocation (or demand for relocation) of Mr. Kersten's place of employment to a location more than thirty-five (35) miles from his current place of employment, (ii) a significant and material reduction in Mr. Kersten's authority, job duties or level of responsibility or (iii) the imposition of significant and material limitations on the Mr. Kersten's autonomy in his position, the employment agreement will be terminated.

The employment agreement will also terminate upon the death of Mr. Kersten, Mr. Kersten's physical or mental disability, willful misconduct, an act of fraud against the Company, or a breach of the employment agreement by Mr. Kersten.

If the employment agreement is terminated for any of the foregoing, Mr. Kersten, or his legal representatives, as the case may be, will be paid the salary provided by the employment agreement through the date of termination, any options or bonus shares of the Company then held by Mr. Kersten will become fully vested and the expiration date of any options which would expire during the four year period following his termination of employment will be extended to the date which is four years after his termination of employment.

In the event there is a change in the control of the Company, the agreement allows Mr. Kersten to resign from his position at the Company and receive a lump-sum payment from the Company equal to 24 months of salary, based upon his salary then in effect on the date of his resignation. For purposes of the employment agreement a change in the control of the Company means: (1) the merger of the Company with another entity if after such merger the shareholders of the Company do not own at least 50% of voting capital stock of the surviving corporation; (2) the sale of substantially all of the assets of the Company; (3) the acquisition by any person of more than 50% of the Company's common stock; or (4) a change in a majority of the Company's directors which has not been approved by the incumbent directors.



On August 30, 2013, the Company amended certain sections of Mr. Kersten's employee agreement so that it would correspond with similar sections of the employment agreements discussed below.

On August 30, 2013, the Company extended its employment agreement with Patricia B. Prichep, the Company's Senior Vice President of Operations, through August 30, 2016. Ms. Prichep's annual salary for fiscal year 2015 was \$238,644.

On August 30, 2013, the Company extended its employment agreement with Eyal Talor, Ph.D., the Company's Chief Scientific Officer, through August 30, 2016. Dr. Talor's annual salary for fiscal year 2015 was \$294,615.

In the event there is a change in the control of the Company, the employment agreements with Ms. Prichep and Dr. Talor allow Ms. Prichep and/or Dr. Talor (as the case may be) to resign from her or his position at the Company and receive a lump-sum payment from the Company equal to 18 months of salary. For purposes of the employment agreements, a change in the control of the Company means: (1) the merger of the Company with another entity if after such merger the shareholders of the Company do not own at least 50% of voting capital stock of the surviving corporation; (2) the sale of substantially all of the assets of the Company; (3) the acquisition by any person of more than 50% of the Company's common stock; or (4) a change in a majority of the Company's directors which has not been approved by the incumbent directors.

The employment agreements with Ms. Prichep and Dr. Talor will also terminate upon the death of the employee, the employee's physical or mental disability, willful misconduct, an act of fraud against the Company, or a breach of the employment agreement by the employee. If the employment agreement is terminated for any of these reasons the employee, or her or his legal representatives, as the case may be, will be paid the salary provided by the employment agreement through the date of termination.

Further, the Company has contingent obligations with other 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 total remaining cash cost of these future obligations for the Phase III trial is estimated to be approximately \$21.6 million.

## **10. LOAN FROM OFFICER**

In 2009 the Company's President, and a director, Maximilian de Clara, loaned the Company \$1,104,057 under a note payable. The original loan from Mr. de Clara bore interest at 15% per year and was secured by a lien on substantially all of the Company's assets. At Mr. de Clara's option, the note may be converted into shares of the Company's common stock. The number of shares which will be issued upon any conversion will be determined by dividing the amount to be converted by \$4.00. The Company did not have the right to prepay the note without Mr. de Clara's consent. In accordance with the loan agreement, the Company issued Mr. de Clara warrants to purchase 164,824 shares of the Company's common stock at a price of \$4.00 per

share. These warrants expired on December 24, 2014. In consideration for an extension of the due date, Mr. de Clara received warrants to purchase 184,930 shares of the Company's common stock at a price of \$5.00 per share. These warrants expired on January 6, 2015. In consideration of Mr. de Clara's agreement to subordinate his note to the convertible preferred shares and convertible debt as part of a prior year settlement agreement the Company extended the maturity date of the note to July 6, 2015. In August 2014, the loan and warrants were transferred to the de Clara Trust, of which the Company's CEO, Geert Kersten, is the trustee and a beneficiary. Mr. de Clara receives the interest payments.

On June 29, 2015, the Company extended the maturity date of the note to July 6, 2017, lowered the interest rate to 9% per year and changed the conversion price to \$0.59, the closing stock price on the previous trading day. The de Clara Trust may demand payment upon giving the Company 10 days of notice. The new terms were effective July 7, 2015. The Company determined these modifications to be substantive and therefore accounted for the modifications as an extinguishment of the pre-modification note and issuance of the post-modification note. The Company recorded an extinguishment loss and a premium on the note payable of \$165,943. The premium increased the face value of the note to \$1,270,000 and will be amortized as a reduction of interest expense through the expiration date of the note. Concurrently, the Company extended the expiration date of the Series N warrants to August 18, 2017. The incremental cost of this modification was \$475,333 and was included in debt extinguishment loss on the note, for a total loss of \$641,276.

On October 11, 2015, the maturity date of the note was extended for one year to July 6, 2018. The extension was made at the request of Lake Whillans Vehicle I, LLC, which agreed to provide the Company with up to \$5,000,000 in funding for litigation expenses to support the Company's \$50,000,000 arbitration claims against the Company's former clinical research organization. As of September 30, 2015, the full amount of the note payable was outstanding.

During the years ended September 30, 2015, 2014 and 2013, the Company paid \$146,288, \$179,409 and \$151,808, respectively, in interest expense to Mr. de Clara. During the year ended September 30, 2015, \$20,816 was amortized as a reduction of interest expense, reducing the effective rate of the note payable to 6.98%.

## **11. STOCKHOLDERS' EQUITY**

During the year ended September 30, 2015, no warrants were exercised. During the year ended September 30, 2014, 2,695,562 Series M, N and S warrants were exercised. The Company issued 2,668,508 shares of common stock and received \$3,118,387 from the exercise of these warrants since 92,715 Series N warrants were exercised in a cashless exercise. During the year ended September 30, 2013, no warrants were exercised.

In December 2012, the Company sold 3,500,000 shares of its common stock for \$10,500,000, or \$3.00 per share, in a registered direct offering. The investors in this offering also received Series R warrants which entitle the investors to purchase up to 2,625,000 shares of the Company's common stock. The Series R warrants may be exercised at any time before

December 7, 2016 at a price of \$4.00 per share. The Company paid Chardan Capital Markets, LLC, the placement agent for this offering, a cash commission of \$682,500. The initial cost of the warrants was \$4,200,000 and was recorded as a debit to additional paid-in capital and a credit to derivative liabilities. As of September 30, 2015, all of the Series R warrants remained outstanding, with a fair value of \$0.

On October 11, 2013, the Company closed a public offering of units of common stock and Series S warrants at a price of \$1.00 per unit for net proceeds of \$16,400,000, net of underwriting discounts and commissions. Each unit consisted of one share of common stock and a warrant to purchase one share of common stock. The warrants were immediately exercisable and expire on October 11, 2018, and have an exercise price of \$1.25. In November 2013, the underwriters purchased an additional 2,648,913 warrants pursuant to the overallotment option, for which the Company received net proceeds of \$24,370.

On December 24, 2013, the Company closed a public offering of units of common stock and Series S warrants at a price of \$0.63 per unit for net proceeds of \$2,790,000, net of underwriting discounts and commissions. Each unit consisted of one share of common stock and a warrant to purchase one share of common stock. The warrants are immediately exercisable and expire on October 11, 2018, and have an exercise price of \$1.25. The underwriters exercised the option for the full 10% overallotment, for which the Company received net proceeds of approximately \$279,000.

The Company incurred \$189,188 in offering costs related to the October and December 2013 offerings which were charged to additional paid-in capital and netted against the cash proceeds in the Statement of Cash Flows.

The October and December 2013 financings triggered the reset provision from the August 2008 financing which resulted in the issuance of an additional 1,563,083 shares of common stock. The cost of additional shares issued was \$1,117,447. This cost was recorded as a debit and a credit to additional paid-in capital and was deemed a dividend.

On October 24, 2014, the Company closed an underwritten public offering of 7,894,737 shares of common stock and 1,973,684 Series S warrants to purchase shares of common stock. Additionally, in a related private offering on October 21, 2014, the Company sold 1,320,000 shares of common stock and 330,000 Series S warrants to purchase shares of common stock. The common stock and Series S warrants were sold at a combined price of \$0.76 for net proceeds of approximately \$6.4 million, net of underwriting discounts and commissions and \$85,335 in offering expenses.

The Series S warrants trade of the NYSE MKT under the symbol CVM WS. As of September 30, 2015, 25,928,010 Series S warrants remained outstanding, with a fair value of \$7,363,555, which is recorded as a derivative liability on the Company's balance sheet (Note 2).

On April 17, 2014, the Company closed a public offering of units consisting of an aggregate of 7,128,229 shares of common stock and Series T warrants to purchase an aggregate of 1,782,057 shares of common stock. The units were sold at a price of \$1.40 per unit. The

Company received net proceeds of approximately \$9,143,000, after deducting the underwriting commissions and offering expenses. The common stock and warrants separated immediately. The Series T warrants, with an exercise price of \$1.58 per share, expired on October 17, 2014. The fair value of the Series T warrants was \$0 on the date of expiration. The underwriters in the offering received 445,514 Series U warrants to purchase one share of common stock. The Series U warrants expire on October 17, 2017, and have an exercise price of \$1.75. As of September 30, 2015, all of the Series U warrants remain outstanding, and are recorded at a fair value of \$44,551, which is shown on the Company's balance sheet as a derivative liability (Note 2).

On May 28, 2015, the Company closed an underwritten public offering of 20,253,164 shares of common stock and 20,253,164 Series V warrants to purchase shares of common stock. The common stock and Series V warrants were sold at a combined per unit price of \$0.79 for net proceeds of approximately \$14.7 million, net of underwriting discounts and commissions and offering expenses. The Series V warrants are immediately exercisable at a price of \$0.79 and expire on May 28, 2020. The initial cost of the Series V warrants of \$8,003,220 was recorded as a warrant liability. As of September 30, 2015, the total Series V warrant liability was adjusted to fair value of \$6,278,481.

During the year ended September 30, 2014, the Company issued 15,700,000 restricted shares of its common stock from its Incentive Stock Bonus Plan to officers and employees. During the year ended September 30, 2015, 100,000 restricted shares were forfeited, 500,000 restricted shares vested and the remaining 15,100,000 restricted shares are unvested and held in escrow. The shares are only to be earned upon the achievement of certain milestones leading to the commercialization of the Company's Multikine technology, or specified increases in the market price of the Company's stock. If the performance or market criteria are not met as specified in the Incentive Stock Bonus Plan, all or a portion of the awarded shares will be forfeited. The fair value of the shares on the date of issuance was calculated by using the market value on the grant-date for issuances where the attainment of performance criteria is likely and using a Monte Carlo simulation for issuances where the attainment of performance criteria is uncertain. The total value of the shares, if earned, is calculated to be \$8,662,502 and will be expensed over the requisite service period for each milestone. At September 30, 2015, the Company had unrecognized compensation expense of \$3,734,954 relating to the restricted stock awards.

## **12. FAIR VALUE MEASUREMENTS**

In accordance with the provisions of ASC 820, "*Fair Value Measurements*," the Company determines fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The Company generally applies the income approach to determine fair value. This method uses valuation techniques to convert future amounts to a single present amount. The measurement is based on the value indicated by current market expectations about those future amounts.

ASC 820 establishes a fair value hierarchy that prioritizes the inputs used to measure fair value. The hierarchy gives the highest priority to active markets for identical assets and liabilities (Level 1 measurement) and the lowest priority to unobservable inputs (Level 3 measurement). The Company classifies fair value balances based on the observability of those inputs. The three levels of the fair value hierarchy are as follows:

- Level 1 – Observable inputs such as quoted prices in active markets for identical assets or liabilities
- Level 2 – Inputs other than quoted prices that are observable for the asset or liability, either directly or indirectly. These include quoted prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active and amounts derived from valuation models where all significant inputs are observable in active markets
- Level 3 – Unobservable inputs that reflect management’s assumptions

For disclosure purposes, assets and liabilities are classified in their entirety in the fair value hierarchy level based on the lowest level of input that is significant to the overall fair value measurement. The Company’s assessment of the significance of a particular input to the fair value measurement requires judgment and may affect the placement within the fair value hierarchy levels.

The table below sets forth the assets and liabilities measured at fair value on a recurring basis, by input level, on the balance sheet at September 30, 2015:

	<u>Quoted Prices in Active Markets for Identical Assets or Liabilities (Level 1)</u>	<u>Significant Other Observable Inputs (Level 2)</u>	<u>Significant Unobservable Inputs (Level 3)</u>	<u>Total</u>
Derivative Instruments	\$ <u>7,363,555</u>	\$ <u>-</u>	\$ <u>6,323,032</u>	\$ <u>13,686,587</u>

The table below sets forth the assets and liabilities measured at fair value on a recurring basis, by input level, in the balance sheet at September 30, 2014:

	<u>Quoted Prices in Active Markets for Identical Assets or Liabilities (Level 1)</u>	<u>Significant Other Observable Inputs (Level 2)</u>	<u>Significant Unobservable Inputs (Level 3)</u>	<u>Total</u>
Derivative Instruments	\$ <u>5,197,352</u>	\$ <u>-</u>	\$ <u>307,894</u>	\$ <u>5,505,246</u>

The following sets forth the reconciliation of beginning and ending balances related to fair value measurements using significant unobservable inputs (Level 3), as of September 30:

	<u>2015</u>	<u>2014</u>
Beginning balance	\$ 307,894	\$ 433,024
Issuances	8,003,220	7,791,448
Settlements	-	(1,445,528)
Transfers to Level 1	-	(7,321,071)
Net realized and unrealized derivative (gain)/loss	<u>(1,988,082)</u>	<u>850,021</u>
Ending balance	<u>\$ 6,323,032</u>	<u>\$ 307,894</u>

The fair values of the Company's derivative instruments disclosed above under Level 3 are primarily derived from valuation models where significant inputs such as historical price and volatility of the Company's stock as well as U.S. Treasury Bill rates are observable in active markets.

### 13. NET LOSS PER COMMON SHARE

Basic loss per share is computed by dividing net loss available to common shareholders by the weighted average number of common shares outstanding during the period. The Company's potentially dilutive shares, which include outstanding common stock options, common stock warrants, restricted stock and shares issuable on convertible debt, have not been included in the computation of diluted net loss per share for all periods presented, as the result would be anti-dilutive. For the years presented, the gain on derivative instruments is not included in net loss available to common shareholders for purposes of computing dilutive loss per share because its effect is anti-dilutive.

The following table provides a reconciliation of the numerators and denominators of the basic and diluted per-share computations:

	<u>2015</u>	<u>2014</u>	<u>2013</u>
Net loss available to common shareholders	\$ (34,674,646)	\$ (28,483,712)	\$ (9,230,478)
Less: Gain on derivative Instruments	<u>-</u>	<u>(248,767)</u>	<u>(10,750,666)</u>
Net loss - diluted	\$ (34,674,646)	\$ (28,732,479)	\$(19,981,144)
Weighted average number of shares - basic and diluted	82,519,027	58,804,622	30,279,442
Loss per share - basic	\$ <u>(0.42)</u>	\$ <u>(0.48)</u>	\$ <u>(0.30)</u>
Loss per share - diluted	\$ <u>(0.42)</u>	\$ <u>(0.49)</u>	\$ <u>(0.66)</u>

For the year ended September 30, 2015, the gain on derivatives is not excluded from the numerator in calculating diluted loss per share because the gain relates to derivative warrants that were priced higher than the average market price during the period.

In accordance with the contingently issuable shares guidance of FASB ASC Topic 260, *Earnings Per Share*, the calculation of diluted net loss per share excludes the following dilutive securities because their inclusion would have been anti-dilutive as of September 30:

	<u>2015</u>	<u>2014</u>	<u>2013</u>
Options and Warrants	58,421,058	39,994,707	12,350,633
Convertible Debt	1,871,283	276,014	276,014
Unvested Restricted Stock	15,100,000	15,700,000	-
Total	<u>75,392,341</u>	<u>55,970,721</u>	<u>12,626,647</u>

#### 14. SEGMENT REPORTING

ASC 280, “*Disclosure about Segments of an Enterprise and Related Information*” establishes standards for reporting information regarding operating segments in annual financial statements and requires selected information for those segments to be presented in interim financial reports issued to stockholders. This topic also establishes standards for related disclosures about products and services and geographic areas. Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker, or decision-making group, in making decisions how to allocate resources and assess performance. The Company’s chief decision maker, as defined under this topic, is the Chief Executive Officer. To date, the Company has viewed its operations as principally one segment, the research and development of certain drugs and vaccines. As a result, the financial information disclosed herein materially represents all of the financial information related to the Company’s principal operating segment.

#### 15. QUARTERLY INFORMATION (UNAUDITED)

The following quarterly data are derived from the Company’s statements of operations.

##### Financial Data

##### Fiscal 2015

	Three months ended December 31 <u>2014</u>	Three months ended March 31, <u>2015</u>	Three months ended June 30, <u>2015</u>	Three months Ended September 30, <u>2015</u>	Year ended September 30, <u>2015</u>
Grant income and other	\$ 136,838	\$ 197,620	\$ 389,223	\$ (66,304)	\$ 657,377
Operating expenses	10,132,579	7,956,963	8,590,698	8,273,682	34,953,922

Non-operating (expense) income, net	(12,547)	(14,097)	(15,166)	22,369	(19,441)
Gain (loss) on derivative instruments	<u>2,162,970</u>	<u>(4,782,796)</u>	<u>4,428,780</u>	<u>(1,526,338)</u>	<u>282,616</u>
Loss on debt extinguishment	<u>-</u>	<u>-</u>	<u>(641,276)</u>	<u>-</u>	<u>(641,276)</u>
Net loss available to common shareholders	<u>\$ (7,845,318)</u>	<u>\$ (12,556,236)</u>	<u>\$ (4,429,137)</u>	<u>\$ (9,843,955)</u>	<u>\$ (34,674,646)</u>
Net loss per share-basic	<u>\$ (0.11)</u>	<u>\$ (0.17)</u>	<u>\$ (0.05)</u>	<u>\$ (0.10)</u>	<u>\$ (0.42)</u>
Net loss per share-diluted	<u>\$ (0.14)</u>	<u>\$ (0.17)</u>	<u>\$ (0.06)</u>	<u>\$ (0.10)</u>	<u>\$ (0.42)</u>
Weighted average shares:					
Basic	73,260,783	75,847,869	83,796,311	97,040,004	82,519,027
Diluted	73,260,783	75,847,869	85,134,107	97,040,004	82,519,027

### **Fiscal 2014**

	Three months ended December 31 <u>2013</u>	Three months ended March 31, <u>2014</u>	Three months ended June 30, <u>2014</u>	Three months Ended September 30, <u>2014</u>	Year ended September 30, <u>2014</u>
Grant income and other	\$ 113,144	\$ 67,157	\$ 15,914	\$ 67,818	\$ 264,033
Operating expenses	6,047,454	6,293,592	6,917,243	8,579,856	27,838,145
Non-operating expenses, net	(10,925)	(6,797)	(10,927)	(12,271)	(40,920)
Gain (loss) on derivative instruments	1,610,817	(7,132,348)	4,467,776	1,302,522	248,767
Net loss	(4,334,418)	(13,365,580)	(2,444,480)	(7,221,787)	(27,366,265)
Issuance of shares due to reset provisions	<u>(1,117,447)</u>	<u>-</u>	<u>-</u>	<u>-</u>	<u>(1,117,447)</u>
Net loss available to common shareholders	<u>\$ (5,451,865)</u>	<u>\$ (13,365,580)</u>	<u>\$ (2,444,480)</u>	<u>\$ (7,221,787)</u>	<u>\$ (28,483,712)</u>
Net loss per share-basic	<u>\$ (0.11)</u>	<u>\$ (0.24)</u>	<u>\$ (0.04)</u>	<u>\$ (0.11)</u>	<u>\$ (0.48)</u>
Net loss per share-diluted	<u>\$ (0.15)</u>	<u>\$ (0.24)</u>	<u>\$ (0.11)</u>	<u>\$ (0.13)</u>	<u>\$ (0.49)</u>
Weighted average shares-basic and diluted	48,215,919	56,239,562	64,664,274	66,091,826	58,804,622

The Company has experienced large swings in its quarterly gains and losses in 2015 and 2014 caused by the changes in the fair value of warrants each quarter.



## 16. SUBSEQUENT EVENTS

In accordance with ASC 855, “*Subsequent Events*”, the Company has reviewed subsequent events through the date of the filing.

On October 5, 2015, the Company and its CRO Ergomed plc expanded their co-development agreement with increased activities to be undertaken by Ergomed. Pursuant to the expanded co-development agreement, Ergomed's contribution to the Phase 3 clinical trial will increase from \$10,000,000 to \$12,000,000.

On October 14, 2015, the Company entered into an agreement with a litigation firm to provide the Company with up to \$5,000,000 in funding for litigation expenses to support its \$50,000,000 arbitration claims against its former clinical research organization. The funding will be available to CEL-SCI if and when needed to fund the expenses of the ongoing arbitration and will only be repaid upon CEL-SCI receiving proceeds from the arbitration, subject to the terms and conditions of the agreement. As of September 30, 2015, the Company has recorded approximately \$1,104,000 in accounts payable that will be assumed by the litigation firm. On October 14, 2015, the Company will record the transfer of the liability to the litigation firm as a gain on the derecognition of legal costs. The gain will be included as a reduction of operating expenses on the Statement of Operations.

On October 28, 2015 the Company announced that it closed an underwritten public offering of 17,223,248 shares of common stock and 17,223,248 Series W warrants to purchase shares of common stock. The common stock and warrants were sold at a combined price of \$0.67 for net proceeds of approximately \$10.59 million, net of underwriting commissions and offering expenses. The warrants were immediately exercisable, expire October 28, 2020 and have an exercise price of \$0.67.

## **CORPORATE INFORMATION**

### **Board of Directors**

**Maximilian de Clara**  
Chairman and President  
CEL-SCI Corporation

**Geert R. Kersten**  
Chief Executive Officer  
CEL-SCI Corporation

**Alexander G. Esterhazy**  
Financial Advisor

**Peter Young, Ph.D.**  
President  
Agnus Dei, Inc.

**Bruno Baillavoine**  
Partner  
Globomass Holdings Limited

### **Corporate Officers**

**Maximilian de Clara**  
Director and President

**Geert R. Kersten**  
Chief Executive Officer  
Treasurer

**Eyal Talor, Ph.D.**  
Chief Scientific Officer

**John Cipriano**  
Senior Vice President of  
Regulatory Affairs

**Patricia B. Prichep**  
Senior Vice President of Operations  
Corporate Secretary

**Daniel Zimmerman, Ph.D.**  
Senior Vice President of  
Research, Cellular Immunology

### **Corporate Headquarters**

CEL-SCI Corporation  
8229 Boone Boulevard  
Suite 802  
Vienna, VA 22182  
USA

Telephone: (703) 506-9460  
Facsimile: (703) 506-9471  
[www.cel-sci.com](http://www.cel-sci.com)

### **Independent Auditors**

BDO USA, LLP  
McLean, VA

### **Counsel**

Hart & Hart  
Denver, CO

### **Transfer Agent and Registrar**

Computershare Investor Services  
350 Indiana Street, Suite 800  
Golden, CO 80401  
(303) 262-0600

Inquiries regarding transfer requirements, lost certificates and change of address should be directed to the transfer agent.

### **Stock Profile**

CEL-SCI Corporation's Common Stock is traded on the NYSE MKT exchange under the symbol **CVM**. CEL-SCI also trades on five German stock exchanges under the Symbol **LSR**, German Securities Code (Wertpapierkennnummer) 871006. CEL-SCI's Series S warrants trade on the NYSE MKT exchange under the symbol **CVM WS**

There are approximately 1,000 stockholders of record as of May 20, 2016. CEL-SCI has not paid cash dividends on its Common Stock since its inception.

### **SEC Form 10-K**

A copy of CEL-SCI's annual report to the Securities and Exchange Commission on Form 10-K is available without charge upon written request to:

Corporate Communications  
CEL-SCI Corporation  
8229 Boone Boulevard, Suite 802  
Vienna, VA 22182  
USA

**CEL-SCI Corporation**  
**8229 Boone Boulevard**  
**Suite 802**  
**Vienna, VA 22182**  
**USA**

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