



# **Annual Report**

**2016**

## CEL-SCI Corporation

CEL-SCI is focused on finding the best way to activate the immune system to fight cancer and infectious diseases. Its lead investigational therapy Multikine® (Leukocyte Interleukin, Injection) is currently in a pivotal Phase 3 clinical trial involving head and neck cancer, which remains on partial clinical hold. CEL-SCI has received Orphan Drug Status from the U.S. FDA for this indication. If the primary endpoint of this global 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.

CEL-SCI's immune therapy, Multikine, is being used in a different way than immune therapy is usually used. It is administered locally to treat local tumors or infections and it is given before any other therapy has been administered. For example, in the Phase 3 clinical trial, Multikine is given locally at the site of the tumor 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 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 higher efficacy with less or no toxicity.

CEL-SCI's focus on HPV is not the development of an antiviral against HPV in the general population. Instead it is the development of an immunotherapy to be used in patients who are immune-suppressed by diseases such as HIV and are therefore less able or unable to control HPV and its resultant diseases. This group of patients has no viable treatments available to them and there are, to CEL-SCI's knowledge, no competitors at the current time. 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 investigating a different peptide-based immunotherapy (LEAPS-H1N1-DC) as a possible treatment for H1N1 hospitalized patients and as a vaccine (CEL-2000 and CEL-4000) for Rheumatoid Arthritis (currently in preclinical testing) using its LEAPS technology platform. 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. 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.

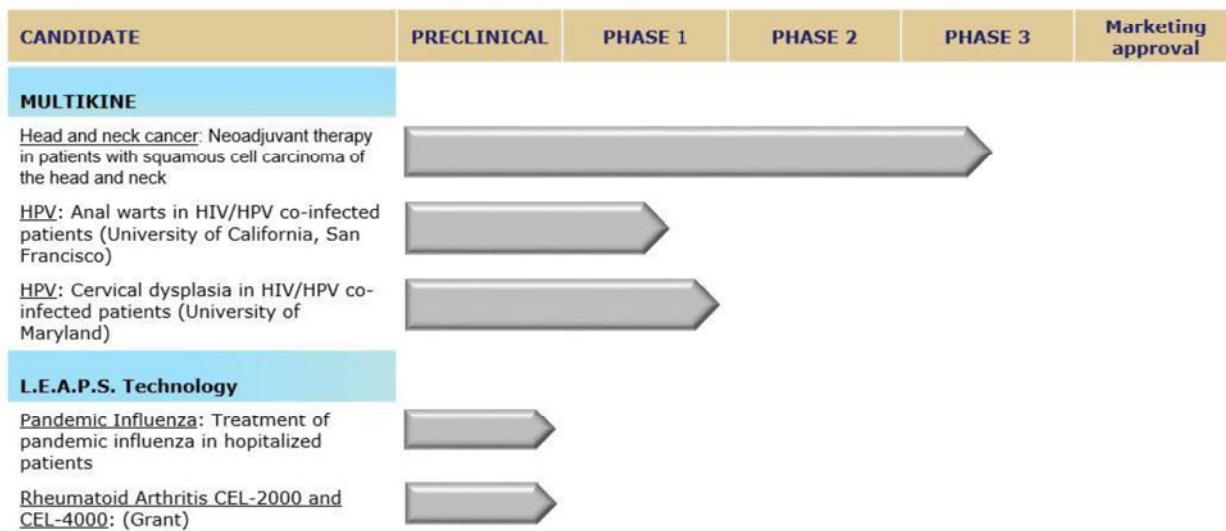
In this annual report, unless otherwise specified or the context requires otherwise, we use the terms "CEL-SCI," the "Company," "we," "us" and "our" to refer to CEL-SCI Corporation. Our fiscal year ends on September 30.

## 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 our product candidates, their indications and their current stage of development:



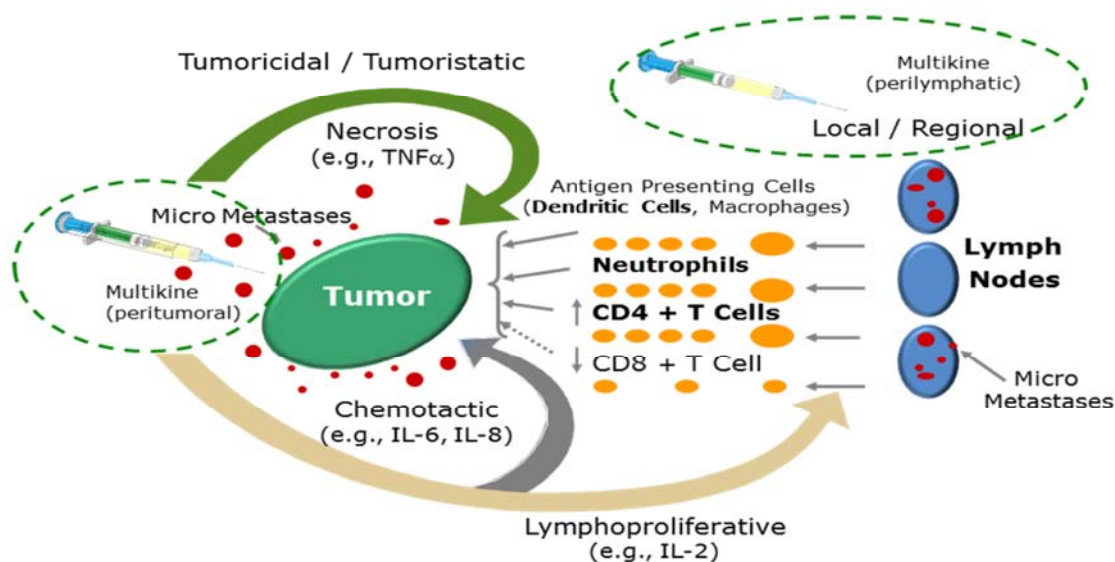
### MULTIKINE

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. CEL-SCI spent over 10 years and more than \$80 million developing and validating the manufacturing process for Multikine. 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 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 CEL-SCI is pursuing for its investigational drug product candidate Multikine is an indication for the neoadjuvant therapy in patients with squamous cell carcinoma of the head and neck, or SCCHN (hereafter also referred to as advanced primary head and neck cancer). As detailed below, the Phase 3 Clinical trial of the Multikine investigational drug as neoadjuvant therapy in SCCHN is currently on partial clinical hold by the U.S. FDA. SCCHN is a type of head and neck cancer, and CEL-SCI believes that, in the aggregate, there is a large, unmet medical need among head and neck cancer patients. CEL-SCI believes the last FDA approval of a therapy indicated 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 approximately over 650,000 patients diagnosed worldwide each year, and nearly 60,000 patients diagnosed annually in the United States. Multikine investigational immunotherapy was granted Orphan Drug designation for neoadjuvant therapy in patients with SCCHN by the FDA in the United States.

#### Status of Phase 3 Clinical Trial

Following submissions to regulatory authorities in 24 countries around the world, including the FDA in the United States, a global Phase 3 clinical trial of the investigational Multikine therapy as a potential neoadjuvant therapy in patients with SCCHN was commenced in late 2010. This clinical trial is currently on partial clinical hold. In accordance with the partial clinical hold, we are continuing to follow the 928 patients enrolled in the study, and this includes following patients until the targeted 298 deaths between the 2 comparison groups is observed. This number of deaths is required to evaluate if the study's primary endpoint is achieved.

This trial is currently primarily under the management of two clinical research organizations, or CROs: ICON Inc. (who acquired Aptiv Solutions, Inc., one of the two CROs), or ICON, and Ergomed Clinical Research Limited, or Ergomed. Ergomed is responsible for new patient enrollment and the clinical study management of the various study sites, although enrollment of new patients has been on hold since we received verbal notice of FDA's partial clinical hold on September 26, 2016.

The Phase 3 study was designed with the objective that, if the study endpoint, which is an improvement in overall survival of the subjects treated with the Multikine treatment regimen plus the current standard of care (SOC) as compared to subjects treated with the current SOC only, is satisfied, the study results are expected to be used to support applications that we plan to submit to regulatory agencies in order to seek commercial marketing approvals

for Multikine in major markets around the world. This assessment can only be made when a certain number of deaths have occurred in these two main comparator groups of the study.

The primary endpoint for the original protocol for this Phase 3 head and neck cancer study required that a 10% increase in overall survival be obtained in the Multikine group which also is administered CIZ (CIZ = low dose (non-chemotherapeutic) of cyclophosphamide, indomethacin and Zinc-multivitamins) all of which are thought to enhance Multikine activity), plus Standard of Care (Surgery + Radiotherapy or Chemoradiotherapy) arm of the study over the Control comparator (Standard of Care alone) arm. As the study originally was designed, the final determination of whether this endpoint had been successfully reached could only be determined when 298 events (deaths) had occurred in the combined comparator arms of the study. Under the original study design, the plan was to enroll 880 patients in order to be able to have 784 evaluable patients for the per-protocol analysis.

In August 2016, we announced that the data available at that time from the Phase 3 clinical study reflected that the accumulation of deaths in the study was lower than that which was anticipated based on reported literature at the Phase 3 study's inception. If the number of deaths continued to be accumulated at the rate at that time, it had been determined that it would take longer than originally planned to complete the study. To minimize this eventuality, we decided it would be necessary to enroll additional patients. As required by law and in order to be able to implement the plan, we submitted an amendment to the existing Phase 3 protocol for our head and neck cancer study to the FDA and multiple regulatory agencies in the countries abroad where the Phase 3 study is being conducted to allow for this expansion in patient enrollment.

In April 2017, we announced that in light of new information we have decided to withdraw the study protocol amendment for additional patients that was submitted to the FDA and other regulatory agencies in the summer of 2016. It is now possible that we may not need to add more patients to the study or that only a smaller number of patients need to be added to the study to complete it in a reasonable period of time. Should additional patients be needed, we will submit a future study amendment to the FDA and other regulatory agencies to seek their clearance to proceed.

On September 26, 2016, we received verbal notice from FDA that the Phase 3 clinical trial in advanced primary head and neck cancer has been placed on partial clinical hold. At such time, enrollment in the Phase 3 study was 926 patients. Pursuant to this communication from FDA, patients currently receiving study treatments can continue to receive treatment, and patients already enrolled in the study will continue to be followed.

On October 21, 2016, we received a partial clinical hold letter from FDA and, on November 18, 2016, we submitted a response to FDA's partial clinical hold letter.

In its partial clinical hold letter, a) FDA stated that there is an unreasonable and significant risk of illness or injury to human subjects and cited among other things the absence of prompt reports by us to the FDA of Independent Data Monitoring (IDMC) recommendations to close the study entirely (made in spring of 2014) or at least to close it to accrual of new patients (made in spring of 2016); b) FDA stated that the investigator brochure is misleading, erroneous, and materially incomplete; and c) FDA stated that the plan or protocol is deficient in design to meet its stated objectives. In its partial clinical hold letter, FDA also identified the information needed to resolve these deficiencies. In addition, FDA's partial clinical hold letter included two requests relating to quality information regarding our investigational final drug product, which were noted by FDA as non-hold issues. We believe that our response submitted to FDA on November 18, 2016, addressed each of the deficiencies identified by FDA including detailing our belief that, under the applicable FDA guidance, there was no obligation to report the cited IDMC recommendations to the FDA at the time they were issued, and it also requested a face-to-face meeting with FDA, and outlined our commitment to diligently work with FDA in an effort to have the partial clinical hold for the study lifted.

On December 8, 2016, FDA advised us that the Agency was denying our request for a meeting at that time because FDA's review of our November 18, 2016 response was ongoing. We also were advised that we would be receiving a letter addressing its November 18, 2016 response by December 18, 2016.

On December 16, 2016, FDA issued an Incomplete Response To Hold letter to us indicating that based on the Agency's preliminary review of our November 18, 2016 submission, FDA has determined that it is not a complete

response to all of the issues listed in FDA's clinical hold letter. In its letter a) FDA stated that we did not provide the information identified as necessary to address FDA's statement that patients enrolled in the study are exposed to unreasonable and significant risk of illness or injury to human subjects; b) FDA stated that we did not provide the information identified as necessary to address FDA's statement that continued enrollment of patients in the study exposes the patients to unreasonable risks and the FDA furthermore stated that the study is unlikely to demonstrate that the addition of our investigational drug Multikine to the standard of care is superior to standard of care and thus should be terminated for futility; (c) FDA stated that we did not provide the information identified as necessary to address FDA's statement that the investigator brochure is misleading, erroneous, and materially incomplete; (d) FDA stated that we did not provide the information identified as necessary to address FDA's statement that the proposed revised clinical protocol is inadequate in design to meet its stated objectives and FDA furthermore stated that this deficiency cannot be addressed by further revisions to the protocol. In its incomplete response to hold letter, FDA also identified the steps we must take to address these deficiencies. In addition, FDA's Incomplete Response to Hold letter noted with respect to FDA's two requests relating to quality information regarding our investigational final drug product, which we had been instructed by FDA to submit separately from the response to the partial clinical hold, which again were noted by FDA as non-hold issues, that our November 18, 2016, submission had not included the information addressing these two requests.

In early January 2017, in preparation for the request for a Type A meeting with FDA and resolution of the partial clinical hold issues, we prepared a comprehensive submission to FDA detailing our belief, accompanied by what we believe to be appropriate supporting data, records, and information reflecting that we have taken the steps necessary to address the specific deficiencies identified by FDA, including: a) demonstrating that patients enrolled in the study are not exposed to unreasonable and significant risk of illness or injury; b) demonstrating that continued enrollment of patients in the study does not expose the patients to unreasonable risks and that the study should not be terminated for futility; (c) demonstrating that a supplemented investigator brochure is not misleading, erroneous, or materially incomplete; (d) demonstrating that the proposed revised clinical protocol is adequate in design to meet its stated objectives and that this deficiency can be addressed by the proposed revisions to the protocol.

On February 8, 2017, we met with the FDA to allow an open and frank discussion of the clinical hold issues raised by the FDA and to secure the FDA's input and clarification on how to address the partial hold issues. On March 1, 2017 CEL-SCI received the written minutes of this meeting from FDA. The Action Items for CEL-SCI to pursue per the minutes from the FDA were the following: 1) provide an updated Investigator's Brochure and current procedures for compliance with requirements under 21 CFR 312 Subpart D to address the partial clinical hold, and 2) provide a list of major protocol deviations, which CEL-SCI believes will affect study results, and provide a plan to identify major protocol deviations across all patients enrolled in the Phase 3 protocol.

We are diligently continuing to work with the FDA to have the partial clinical hold lifted. We have been in a continuing dialogue with them to try to resolve their questions and to supply them with supplemental information. We have supplied our response to those Action Items to the FDA. In accordance with the partial clinical hold, we are continuing to follow the 928 patients enrolled in the study, and this includes following patients until the targeted 298 deaths between the 2 comparison groups is observed. This number of deaths is required to evaluate if the study's primary endpoint is achieved.

Subject to the partial clinical hold, we estimate that the total remaining cash cost of the Phase 3 clinical trial, excluding any costs that will be paid by our partners, would be approximately \$13.5 million. This is in addition to the approximately \$36.0 million that we already had spent on the trial as of December 31, 2016. This number may be affected by the rate of any future patient enrollment, if needed, rate of death accumulation in the study, 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. If FDA will only lift the partial clinical hold with termination of the current study and initiation of a new clinical trial, any such new trial can only be initiated if permitted by FDA and, as appropriate, other regulatory authorities around the world after the requisite submissions are made to them, and the additional duration and costs of the Phase 3 clinical program would likely exceed those already incurred in connection with the Phase 3 clinical trial. If there is a need to conduct an additional Phase 3 clinical trial, any such requirement would have significant and severe material consequences for us and could impact our ability to continue as a going concern.

Currently we are not looking to enroll any more patients. We will not be able to enroll any additional patients in the Phase 3 study unless FDA lifts the partial clinical hold. In addition, in the spring of 2016, the IDMC recommended to us that new patient enrollment should stop in the Phase 3 study, but patients already on study should continue to be treated and followed. Although we had expected to work through the concerns raised by the IDMC while we worked through the partial clinical hold with FDA, the IDMC informed us on December 13, 2016, that because the study is on partial clinical hold imposed by FDA, the IDMC has no formal recommendation regarding continuation of the trial at that time. Another IDMC meeting was held on February 6, 2017. Due to the fact that the study is still on partial clinical hold imposed by the FDA, the IDMC had no formal recommendation regarding continuation of the trial at that time. If the partial clinical hold is not lifted by FDA or if it is determined by FDA that the study has been compromised, the study may be terminated, or if the partial clinical hold is lifted by FDA but the IDMC continues to recommend that enrollment not be allowed to continue, the study may be terminated by us.

If the partial clinical hold is not lifted, the Phase 3 study may not be able to be completed to its prespecified endpoints in a timely manner, if at all, and, if the Phase 3 study cannot be completed to its prespecified endpoints, the study would not be able to be used as the pivotal study supporting a marketing application in the United States, and at least one entirely new Phase 3 clinical trial would need to be conducted to support a marketing application in the United States. Even if the partial clinical hold is lifted, if it is not lifted in a timely fashion, the nature and duration of the partial clinical hold could irreparably harm the data from the Phase 3 study such that it may no longer be able to be used to support a marketing application in the United States. Even if the partial clinical hold is lifted in a timely fashion, it remains possible that the regulatory authorities could determine that the Phase 3 study is not sufficient to be used as a single pivotal study supporting a marketing application in the United States.

Throughout the course of the Phase 3 study, an Independent Data Monitoring Committee, or IDMC, has met periodically to review safety data from the Phase 3 study, and the IDMC is expected to continue doing so throughout the remainder of the Phase 3 study. At various points in the study at which the IDMC has completed review of the safety data and has issued recommendations, it has recommended that the Phase 3 study may continue, although on two occasions the IDMC has issued recommendations that would have closed the study entirely (spring of 2014) or at least closed it to accrual of new patients (spring of 2016). On one occasion, in the spring of 2014, the IDMC made a recommendation that the study be closed for safety and efficacy reasons. However, following review of additional information submitted by us, the IDMC recommended that the study may continue. In the spring of 2016, with close to 800 patients enrolled, the IDMC made a recommendation that enrollment in the Phase 3 study should stop, but that patients already enrolled in the study should continue treatment and follow-up. We responded to this letter and indicated it would address the remaining three requests (generally relating to study design considerations) that were not part of the IDMC recommendation in a follow-up correspondence.

However, before CEL-SCI could provide our follow-up response to the remaining three requests, the IDMC sent another letter (a) indicating that our initial letter responding to the IDMC recommendation was unresponsive and (b) also indicating that the IDMC was deeply concerned about patient safety in the trial based on its review of cumulative data. The IDMC's initial letter in the spring of 2016 did not mention that the IDMC was concerned about safety. Instead, the initial letter in the spring of 2016 noted that the study should be closed to further accrual, and that patients who had been randomized may continue treatment and should be followed. The statement that patients who had been randomized may continue treatment suggested to us that safety was not an issue. Because no safety concern had been raised by the IDMC since the spring of 2014, when, after further communications with CEL-SCI, the IDMC issued its recommendation that the study should proceed, CEL-SCI believed based on the entirety of the course of correspondence with the IDMC that acute safety was not an issue underlying the IDMC's recommendation to halt accrual in the spring of 2016. As noted above, all other correspondence to CEL-SCI from the IDMC from study initiation through September 2015, with the exception of the recommendation in spring 2014, stated that the IDMC recommends "the study may continue". CEL-SCI responded to the IDMC's recommendation in spring of 2016 with a statistical analysis showing that more patients were needed in order to complete the study in a reasonable amount of follow-up time, since the observed death rate in the study was lower than that which was predicted from the literature at the onset of the study. Subsequently a protocol amendment was prepared based on the analysis provided to the IDMC and submitted to FDA in July 2016, and a copy was then sent to the IDMC in response to its request for a copy of the submission. To date, CEL-SCI has not received a response from the IDMC regarding this protocol amendment. However, two months after the amendment was submitted to FDA, FDA placed the protocol on partial clinical hold. CEL-SCI expects to work through the concerns raised by the IDMC while CEL-SCI works through the partial hold with FDA. Ultimately, the decision as to whether CEL-SCI's drug product candidate is safe and effective

can only be made by FDA and/or by other regulatory authorities based upon an assessment of all of the data from an entire drug development program submitted as part of an application for marketing approval. As detailed elsewhere in this prospectus supplement, whether the partial clinical hold is lifted or not, the current Phase 3 clinical study for CEL-SCI's investigational drug may or may not be able to be used as the pivotal study supporting a marketing application in the United States, and, if not, at least one entirely new Phase 3 pivotal study would need to be conducted to support a marketing application in the United States.

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

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

- **Reported potential for 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 CEL-SCI's 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 our entire data set on this investigational therapy, we believe that these early-stage clinical trial results indicate the potential for our 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, we 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 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, we 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, we 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, our 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 signed a cooperative research and development agreement, or CRADA, with the U.S. Naval Medical Center, San Diego, or the USNMC. Pursuant to this agreement, the USNMC was to conduct a Phase 1 study, approved by the Human Subjects Institutional Review Board, of our investigational immunotherapy, Multikine, in HIV/HPV co-infected men and women with peri-anal warts. The purpose of this study was 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.

In July 2015, CEL-SCI added a clinical site at the University of California, San Francisco, or UCSF, and Key Opinion Leader, or KOL, to the ongoing Phase 1 study. In August 2016, the U.S. Navy discontinued this Phase 1 study because of difficulties in enrolling patients. UCSF is continuing with the study.

In October 2013, we 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 is supporting the development of Multikine with UCSF.

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 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, except one subject volunteer, 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 3 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 3 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 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 ten centers in Taiwan, four centers in Malaysia, three centers in Philippines and one center in Thailand to enroll patients as part of the Phase 3 Multikine clinical trial and has made further financial contributions towards the cost of the 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 between CEL-SCI and Byron. CEL-SCI will be paid fifty (50%) percent of the net sales of Multikine.

### **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 US 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 two in Europe (issued in September 2015 and May 2016 both currently set to expire in 2025).

CEL-SCI has one 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 December 1, 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**

Our 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-2000 and CEL-4000 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 February 2017 and November 2016, CEL-SCI announced new preclinical data that demonstrate its investigational new drug candidate CEL-4000 has the potential for use as a therapeutic vaccine to treat rheumatoid arthritis. This

efficacy study was supported in part by the SBIR Phase I Grant and was conducted in collaboration with Drs. Katalin Mikecz and Tibor Glant, and their research team at Rush University Medical Center in Chicago, IL.

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* (<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 some level of 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 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 AND RELATED STOCKHOLDER MATTERS**

As of September 30, 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>
12/31/2014	\$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
6/30/2016	\$0.60	\$0.44
9/30/2016	\$0.54	\$0.24

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. CEL-SCI's 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.

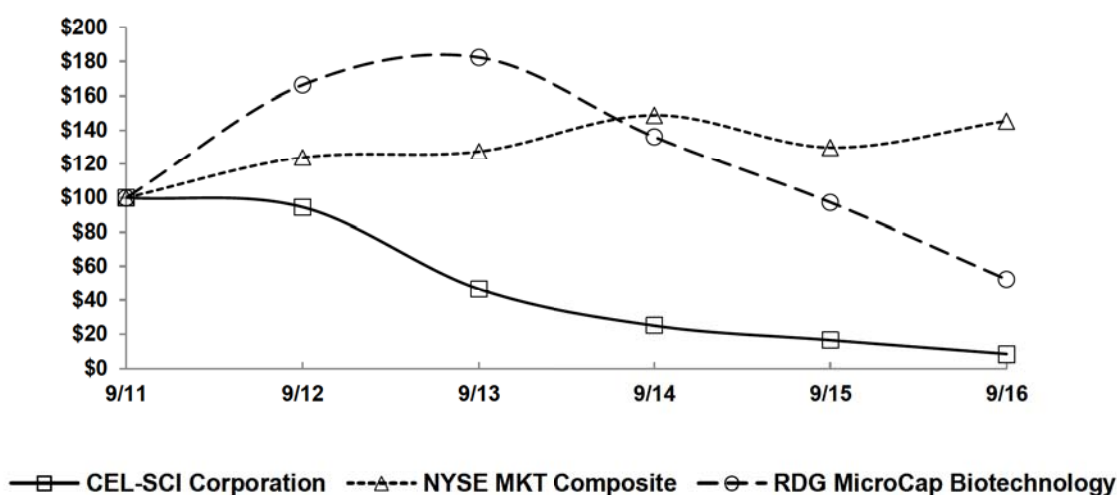
Factors such as fluctuations in CEL-SCI's operating results, announcements of technological innovations or new therapeutic products by CEL-SCI or its competitors, governmental regulation, developments in patent or other proprietary rights, public concern as to the safety of products which may be developed 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, 2011 and tracks it through September 30, 2016.

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

### COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN\*

Among CEL-SCI Corporation, the NYSE MKT Composite Index and the RDG MicroCap Biotechnology Index



\*\$100 invested on 9/30/11 in stock or index, including reinvestment of dividends.  
Fiscal year ending September 30.

	9/11	9/12	9/13	9/14	9/15	9/16
<b>CEL-SCI Corporation</b>	<b>100.00</b>	<b>94.52</b>	<b>46.58</b>	<b>24.98</b>	<b>16.44</b>	<b>8.36</b>
<b>NYSE MKT Composite</b>	<b>100.00</b>	<b>123.99</b>	<b>127.59</b>	<b>148.86</b>	<b>129.94</b>	<b>145.53</b>
<b>RDG MicroCap Biotechnology</b>	<b>100.00</b>	<b>166.25</b>	<b>182.33</b>	<b>136.22</b>	<b>97.34</b>	<b>52.30</b>

### SELECTED FINANCIAL DATA

The following selected historical consolidated financial data are qualified by reference to, and should be read in conjunction with the financial statements and the related notes thereto, appearing elsewhere in this report, as well as Management's Discussion and Analysis of Financial Condition and Results of Operations of this report.

<u>Statements of Operations</u>	2016	2015	2014	2013	2012
Grant revenue and other	\$285,055	\$657,377	\$264,033	\$159,583	\$254,610
Operating expenses:					
Research and development	19,351,779	21,098,147	17,172,587	12,934,121	10,814,405

General and administrative	6,486,501	13,855,775	10,665,558	7,093,738	6,683,045
Gain on derivative instruments	14,013,726	282,616	248,767	10,750,666	1,911,683
Loss on debt extinguishment	-	(620,457)	-	-	-
Interest income (expense), net	73,001	(40,260)	(40,920)	(53,337)	(146,153)
Net loss	(11,466,498)	(34,674,646)	(27,366,265)	(9,170,947)	(15,477,310)
Issuance of additional shares due to reset provision			(1,117,447)	-	(250,000)
Modification of warrants				(59,531)	(325,620)
Inducement warrants	-	-	-	-	(1,593,000)
Net loss available to common shareholders	<u>\$(11,466,498)</u>	<u>\$(34,674,646)</u>	<u>\$(28,483,712)</u>	<u>\$(9,230,478)</u>	<u>\$(17,645,930)</u>
Net loss per common share					
Basic	(\$0.09)	(\$0.42)	(\$0.48)	(\$0.30)	(\$0.70)
Diluted	(\$0.09)	(\$0.42)	(\$0.49)	(\$0.66)	(\$0.78)
Weighted average common shares outstanding					
Basic and diluted	121,655,108	82,519,027	58,804,622	30,279,442	25,183,654
<u>Balance Sheets</u>	<u>2016</u>	<u>2015</u>	<u>2014</u>	<u>2013</u>	<u>2012</u>
Working capital (deficit)	\$1,875,874	\$2,127,718	\$8,496,076	\$(1,033,370)	\$5,529,438
Total assets	\$11,598,247	\$15,447,603	\$19,230,434	\$10,838,572	\$16,067,450
Derivative instruments (a)	\$8,394,934	\$13,686,587	\$5,505,246	\$433,024	\$6,983,690
Total liabilities	\$12,554,315	\$20,532,722	\$8,787,034	\$4,138,482	\$9,040,018
Stockholders' (deficit) equity	\$(956,068)	\$(5,085,119)	\$10,443,400	\$6,700,090	\$7,027,432

(a) Included in total liabilities.

CEL-SCI's net loss available to common shareholders for each fiscal quarter during the two years ended September 30, 2016 were:

<u>Quarter</u>	<u>Net income (loss)</u>	<u>Net income (loss) per share</u>	
		<u>Basic</u>	<u>Diluted</u>
12/31/2015	\$ 2,341,813	\$ 0.02	\$0.02
3/31/2016	\$ (8,844,855)	\$(0.07)	\$(0.07)
6/30/2016	\$ (3,849,324)	\$(0.03)	\$(0.03)
9/30/2016	\$ (1,114,132)	\$(0.01)	\$(0.01)
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)

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

On September 26, 2016, CEL-SCI received verbal notice from the FDA that the Phase 3 clinical trial in advanced primary head and neck cancer has been placed on clinical hold. Pursuant to this communication from FDA, patients currently receiving study treatments can continue to receive treatment, and patients already enrolled in the study will continue to be followed.

On October 21, 2016, CEL-SCI issued a press release stating the following: "following up on our press release issued on September 26, 2016, we have received the Partial Clinical Hold letter from the U.S. Food and Drug Administration (FDA). On November 21, 2016, CEL-SCI announced that it had submitted a response to FDA's Partial Clinical Hold letter referenced above.

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 2016**

During the year ended September 30, 2016, grant and other income decreased by approximately \$372,000 compared to the year ended September 30, 2015. The decrease 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 2016 compared to fiscal year 2015.

During the year ended September 30, 2016, research and development expenses decreased by approximately \$1.7 million compared to the year ended September 30, 2015. The Company is continuing the Phase 3 clinical trial subject to the partial clinical hold and research and development fluctuates based on the activity level of the clinical trial.

During the year ended September 30, 2016, general and administrative expenses decreased by approximately \$7.4 million, compared to the year ended September 30, 2015. Major components of the decrease are 1) Lake Whillans Litigation Finance took over payment of legal fees which were about \$4.4 million in fiscal year 2015 in the arbitration against the former CRO that used to run the Company's Phase 3 trial, 2) a \$2.8 million decrease in share-based employee compensation costs, which relates to the timing vesting for the incentive stock bonus plan and 3) other miscellaneous decreases netting to approximately \$200,000.

During the years ended September 30, 2016 and 2015, CEL-SCI recorded a derivative gain of approximately \$14.0 million and \$283,000, 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.

Net interest income (expense) decreased approximately \$113,000 during the year ended September 30, 2016 compared to the year ended September 30, 2015, primarily due to an approximate \$124,000 reduction in interest

expense on the related party loan, which was paid off in January 2016, offset by an approximate \$9,000 reduction in interest income due to lower cash balances.

### Fiscal 2015

During the year ended September 30, 2015, grant and other income increased by approximately \$393,000 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 approximately \$3.9 million 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 fiscal year 2015 vs 142 in fiscal year 2014.

During the year ended September 30, 2015, general and administrative expenses increased by approximately \$3.1 million, compared to the year ended September 30, 2014. This increase is primarily due to an increase of approximately \$2.0 million of equity based compensation costs for restricted stock granted, increased legal fees of approximately \$1.8 million relating to arbitration with the Company's former CRO, and an increase of approximately \$220,000 in fees for professional services. These increases were offset by a decrease of approximately \$788,000 in employe 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 approximately \$283,000 and \$249,000, respectively. This variation was the result of the change in fair value of the derivative liabilities during the period which resulted from relative inconsistencies in the share price of CEL-SCI's common stock.

Interest expense decreased by approximately \$13,000 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 former 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 less 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 approximately \$620,000 during 2015.

### Research and Development Expenses

During the five years ended September 30, 2016, 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>2016</u>	<u>2015</u>	<u>2014</u>	<u>2013</u>	<u>2012</u>
MULTIKINE	\$ 18,960,871	\$ 20,604,337	\$ 16,797,809	\$ 12,556,636	\$ 10,423,327
LEAPS	<u>390,908</u>	<u>493,810</u>	<u>374,778</u>	<u>377,485</u>	<u>391,078</u>
TOTAL	<u>\$ 19,351,779</u>	<u>\$ 21,098,147</u>	<u>\$ 17,172,587</u>	<u>\$ 12,934,121</u>	<u>\$ 10,814,405</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 of November 30, 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.

On September 26, 2016, CEL-SCI received verbal notice from the FDA that the Phase 3 clinical trial in advanced primary head and neck cancer has been placed on clinical hold. Pursuant to this communication from FDA, patients currently receiving study treatments can continue to receive treatment, and patients already enrolled in the study will continue to be followed.

On October 21, 2016, CEL-SCI issued a press release stating the following: "following up on our press release issued on September 26, 2016, we have received the Partial Clinical Hold letter from the U.S. Food and Drug Administration (FDA). On November 21, 2016, CEL-SCI announced that it had submitted a response to FDA's Partial Clinical Hold letter referenced above.

### **Liquidity and Capital Resources**

CEL-SCI has had only limited revenues from operations since its inception in March 1983. CEL-SCI has relied upon capital generated from the public and private offerings of its common stock and convertible notes. In addition, CEL-SCI has utilized short-term loans to meet its capital requirements. Capital raised by CEL-SCI has been used 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 2016 and 2015, CEL-SCI raised net proceeds of approximately \$21.4 million and \$21.1 million, respectively, through the sale of stock.

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 12.1 million going forward.

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 \$1.6 million during the twelve months ended September 30, 2016.

In January 2014, CEL-SCI offered to the investors to extend the outstanding 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, 2016, 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.

On January 13, 2016, CEL-SCI repaid the note payable to the de Clara Trust, the balance of which was \$1,105,989, including principal and interest. 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.

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 \$16.4 million, 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 \$2.7 million, 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 S warrants began trading on the NYSE MKT under the ticker symbol "CVM WS". As of September 30, 2016, 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, 2016, 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, 2016, none of the Series V warrants had been exercised.

On October 28, 2015, the Company 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 per unit price of \$0.67 for net proceeds of approximately \$10.5 million, net of underwriting discounts and commissions and offering expenses. The Series W warrants are immediately exercisable at a price of \$0.67 and expire on October 28, 2020. As of September 30, 2016, none of the Series W warrants had been exercised.

In January 2016, the Company sold 3,000,000 shares of its common stock and 3,000,000 Series X warrants to the de Clara Trust for approximately \$1.1 million, as noted above. The de Clara Trust is controlled by Geert Kersten, the Company's Chief Executive Officer and a director. Each Series X 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. As of September 30, 2016, none of the Series X warrants had been exercised.

In February 2016, the Company sold 1,300,000 shares of its common stock and 650,000 Series Y warrants to a private investor for \$624,000. Each Series Y warrant allows the holder to purchase one share of the Company's

common stock at a price of \$0.48 per share at any time on or before February 15, 2021. As of September 30, 2016, none of the Series Y warrants had been exercised.

On May 23, 2016, the Company closed a registered direct offering of 10,000,000 shares of common stock and 6,600,000 Series Z warrants to purchase shares of common stock. The common stock and warrants were sold at a combined per unit price of \$0.50 for net proceeds of approximately \$4.6 million, net of placement agent's commissions and offering expenses. The Series Z warrants may be exercised at any time on or after November 23, 2016 and on or before November 23, 2021 at a price of \$0.55 per share. The Company also issued 500,000 Series ZZ warrants to the placement agent as part of its compensation. The Series ZZ warrants may be exercised at any time on or after November 23, 2016 and on or before May 18, 2021 at a price of \$0.55 per share. As of September 30, 2016, none of the Series Z and ZZ warrants had been exercised.

On August 26, 2016, the Company closed a registered direct offering of 10,000,000 shares of common stock and Series AA warrants to purchase up to 5,000,000 shares of common stock. Each share of common stock was sold together with a Series AA warrant to purchase one-half of a share of common stock for the combined purchase price of \$0.50. Each warrant can be exercised at any time after February 22, 2017 and on or before February 22, 2022 at a price of \$0.55 per share. The Company also issued 400,000 Series BB warrants to the placement agent as part of its compensation. The Series BB warrants may be exercised at any time on or after February 22, 2017 and on or before August 22, 2021 at a price of \$0.55 per share. The Company received proceeds from the sale of Series AA and Series BB shares and warrants of approximately \$4.5 million, net of placement agent's commissions and offering expenses. As of September 30, 2016, none of the Series AA and BB warrants had been exercised.

On December 8, 2016, the Company sold 34,024,000 shares of common stock and warrants to purchase common stock at a price of \$0.125 in a public offering. The warrants consist of 17,012,000 Series CC warrants to purchase 17,012,000 shares of common stock, 34,024,000 Series DD warrants to purchase 34,024,000 shares of common stock and 34,024,000 Series EE warrants to purchase 34,024,000 shares of common stock. The Series CC warrants are immediately exercisable, expire in five-years and have an exercise price of \$0.20 per share. The Series DD warrants are immediately exercisable, expire in six-months and have an exercise price of \$0.18 per share. The Series EE warrants are immediately exercisable, expire in nine-months and have an exercise price of \$0.18 per share. In addition, the Company issued 1,701,000 Series FF warrants to purchase 1,701,000 shares of common stock to the placement agent. The FF warrants are exercisable at any time on or after June 8, 2017 and expire on December 1, 2021 and have an exercise price \$0.15625. The net proceeds to CEL-SCI from this offering was approximately \$3.8 million, excluding any future proceeds that may be received from the exercise of the warrants.

Inventory decreased by approximately \$393,000 at September 30, 2016 as compared to September 30, 2015, due to the timing of supplies purchased and used in the manufacturing of Multikine for the Phase 3 clinical trial. In addition, receivables increased by approximately \$307,000, primarily due to the timing of payments reimbursed under the litigation funding arrangement noted above.

During the year ended September 30, 2016, CEL-SCI's cash decreased by approximately \$2.8 million. Significant components of this decrease include: 1) net cash used in operating activities of approximately \$23.1 million, 2) expenditures for equipment and patents of approximately \$34,000, 3) the approximate \$1.1 million repayment of the related party loan, and 4) the payment of approximately \$8,000 in capital lease obligations offset by approximately \$21.4 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. As of September 30, 2016, material contractual obligations, consisting of operating lease payments are as follows:

2017	\$	1,930,244
2018		1,997,309
2019		2,066,329
2020		2,109,887
2021		2,099,785
Thereafter		15,830,794
	\$	<u>26,034,348</u>

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. CEL-SCI estimates that the total remaining cash cost of the Phase 3 clinical trial, excluding any costs that will be paid by CEL-SCI's partners, would be approximately \$12.1 million after September 30, 2016. This is based on the executed contract costs with the CROs only and does not include other related costs, e.g. the manufacturing of the drug.

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. 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. In general, CEL-SCI believes that it will be able to raise sufficient capital in fiscal year 2017 to continue operations through December 2017. However, it is possible that CEL-SCI will not be able to generate enough cash to continue operations at its current level. CEL-SCI's registered independent public accounting firm has issued an audit opinion that includes an explanatory paragraph that expresses substantial doubt about CEL-SCI's ability to continue as a going concern mainly due to continued losses from operations and future liquidity needs of CEL-SCI. CEL-SCI's management has engaged in fundraising for over 20 years and believes that the manner in which it is proceeding will produce the best possible outcome for the shareholders. There can be no assurances that CEL-SCI will be successful in raising additional funds.

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

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

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

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

### **Critical Accounting Policies**

CEL-SCI's significant accounting policies are more fully described in Note 1 to the financial statements included as part of this report. However, certain accounting policies are particularly important to the portrayal of CEL-SCI's 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:

*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.

*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 arrangements 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 the statement of financial position and are measured at fair value with gains or losses recognized in earnings or other comprehensive income depending on the nature of the derivative or hybrid instruments. Embedded derivatives that are not clearly and closely related to the host contract are bifurcated and recognized at fair value with changes in fair value recognized as either a gain or loss in earnings if they can be reliably measured. When the fair value of embedded derivative features cannot be reliably measured, CEL-SCI measures and reports the entire hybrid instrument at fair value with changes in fair value recognized as either a gain or loss in earnings. CEL-SCI determines the fair value of derivative instruments and hybrid instruments based on available market data using appropriate valuation models, giving consideration to all of the rights and obligations of each instrument and precluding the use of “blockage” discounts or premiums in determining the fair value of a large block of financial instruments. Fair value under these conditions does not necessarily represent fair value determined using valuation standards that give consideration to blockage discounts and other factors that may be considered by market participants in establishing fair value.

## **QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT 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 three years ended September 30, 2016, CEL-SCI recognized gains of \$14,013,726, \$282,616, and \$248,767, 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, 2016 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, 2016, 2015 and 2014, and  
Report of Independent Registered Public Accounting Firm**



# CEL-SCI CORPORATION

## TABLE OF CONTENTS

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	<u>Page</u>
REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM	F- 2
FINANCIAL STATEMENTS FOR THE YEARS ENDED SEPTEMBER 30, 2016, 2015 and 2014:	
Balance Sheets	F- 3
Statements of Operations	F- 4
Statements of Stockholders' (Deficit) Equity	F- 5
Statements of Cash Flows	F- 6
Notes to Financial Statements	F- 8

## 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 (the “Company”) as of September 30, 2016 and 2015 and the related statements of operations, stockholders’ (deficit) equity, and cash flows for each of the three years in the period ended September 30, 2016. 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, 2016 and 2015, and the results of its operations and its cash flows for each of the three years in the period ended September 30, 2016, in conformity with accounting principles generally accepted in the United States of America.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has a history of net losses and expects to incur substantial losses for the foreseeable future that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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, 2016 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 14, 2016 expressed an unqualified opinion thereon.

/s/ BDO USA, LLP

McLean, Virginia  
December 14, 2016

CEL-SCI CORPORATION  
BALANCE SHEETS  
SEPTEMBER 30, 2016 and 2015

ASSETS	<u>2016</u>	<u>2015</u>
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 2,917,996	\$ 5,726,682
Receivables	394,515	87,214
Prepaid expenses	981,677	979,655
Deposits - current portion	154,995	150,000
Inventory used for R&D and manufacturing	1,008,642	1,401,839
Deferred rent - current portion	<u>429,821</u>	<u>487,793</u>
Total current assets	5,887,646	8,833,183
RESEARCH AND OFFICE EQUIPMENT, net	226,216	307,466
PATENT COSTS, net	256,547	291,564
DEFERRED RENT - net of current portion	3,406,921	4,044,473
DEPOSITS	<u>1,820,917</u>	<u>1,970,917</u>
<b>TOTAL ASSETS</b>	<b><u>\$ 11,598,247</u></b>	<b><u>\$ 15,447,603</u></b>
<b>LIABILITIES AND STOCKHOLDERS' DEFICIT</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable	\$ 3,091,512	\$ 5,128,682
Accrued expenses	378,672	88,575
Due to employees	538,278	365,131
Related party loan	-	1,104,057
Deferred rent - current portion	3,310	9,997
Lease obligation - current portion	<u>-</u>	<u>9,028</u>
Total current liabilities	4,011,772	6,705,470
Derivative instruments	8,394,934	13,686,587
Deferred revenue	125,000	126,639
Deferred rent - net of current portion	17,609	9,026
Deposits held	<u>5,000</u>	<u>5,000</u>
Total liabilities	<u>12,554,315</u>	<u>20,532,722</u>
<b>COMMITMENTS AND CONTINGENCIES</b>		
<b>STOCKHOLDERS' DEFICIT</b>		
Preferred stock, \$.01 par value-200,000 shares authorized; -0- shares issued and outstanding	-	-
Common stock, \$.01 par value - 600,000,000 shares authorized; 155,962,079 and 112,360,568 shares issued and outstanding at September 30, 2016 and 2015, respectively	1,559,621	1,123,606
Additional paid-in capital	283,152,288	267,992,754
Accumulated deficit	<u>(285,667,977)</u>	<u>(274,201,479)</u>
Total stockholders' deficit	<u>(956,068)</u>	<u>(5,085,119)</u>
<b>TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT</b>	<b><u>\$ 11,598,247</u></b>	<b><u>\$ 15,447,603</u></b>

See notes to financial statements.

CEL-SCI CORPORATION  
STATEMENTS OF OPERATIONS  
YEARS ENDED SEPTEMBER 30, 2016, 2015 and 2014

	2016	2015	2014
GRANT INCOME AND OTHER	\$ 285,055	\$ 657,377	\$ 264,033
OPERATING EXPENSES:			
Research and development	19,351,779	21,098,147	17,172,587
General & administrative	6,486,501	13,855,775	10,665,558
Total operating expenses	25,838,280	34,953,922	27,838,145
OPERATING LOSS	(25,553,225)	(34,296,545)	(27,574,112)
GAIN ON DERIVATIVE INSTRUMENTS	14,013,726	282,616	248,767
LOSS ON DEBT EXTINGUISHMENT	-	(620,457)	-
INTEREST INCOME (EXPENSE), NET	73,001	(40,260)	(40,920)
NET LOSS	(11,466,498)	(34,674,646)	(27,366,265)
ISSUANCE OF ADDITIONAL SHARES DUE TO RESET PROVISIONS	-	-	(1,117,447)
NET LOSS AVAILABLE TO COMMON SHAREHOLDERS	\$ (11,466,498)	\$ (34,674,646)	\$ (28,483,712)
NET LOSS PER COMMON SHARE			
BASIC	\$ (0.09)	\$ (0.42)	\$ (0.48)
DILUTED	\$ (0.09)	\$ (0.42)	\$ (0.49)
WEIGHTED AVERAGE COMMON SHARES OUTSTANDING			
BASIC and DILUTED	121,655,108	82,519,027	58,804,622

See notes to financial statements.

CEL-SCI CORPORATION  
STATEMENTS OF STOCKHOLDERS' (DEFICIT) EQUITY  
YEARS ENDED SEPTEMBER 30, 2016, 2015 and 2014

	Common Shares	Stock Amount	Additional Paid-In Capital	Accumulated Deficit	Total
BALANCE, OCTOBER 1, 2013	31,025,019	310,250	218,550,408	(212,160,568)	6,700,090
Sale of common 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 common 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 and extinguishment loss	-	-	620,457	-	620,457
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	112,360,568	1,123,606	267,992,754	(274,201,479)	(5,085,119)
Sale of common stock	41,523,248	415,232	20,958,464	-	21,373,696
Issuance of warrants in connection with					
sale of common stock	-	-	(8,722,073)	-	(8,722,073)
401(k) contributions paid					
in common stock	408,497	4,085	157,486	-	161,571
Stock issued to nonemployees for service	1,248,831	12,489	677,824	-	690,313
Equity based compensation - employees	420,935	4,209	2,008,474	-	2,012,683
Equity based compensation - non-employees	-	-	79,359	-	79,359
Net loss	-	-	-	(11,466,498)	(11,466,498)
BALANCE, SEPTEMBER 30, 2016	<u>155,962,079</u>	<u>\$ 1,559,621</u>	<u>\$ 283,152,288</u>	<u>\$ (285,667,977)</u>	<u>\$ (956,068)</u>

See notes to financial statements.

CEL-SCI CORPORATION  
STATEMENTS OF CASH FLOWS  
YEARS ENDED SEPTEMBER 30, 2016, 2015 and 2014

	2016	2015	2014
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>			
Net loss	\$ (11,466,498)	\$ (34,674,646)	\$ (27,366,265)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	150,243	206,750	231,752
Issuance of common stock, warrants and options for services	751,651	565,915	694,955
Modification of warrants issued to consultants	-	-	76,991
Equity based compensation	2,113,433	5,105,827	3,958,637
Common stock contributed to 401(k) plan	161,571	165,646	155,434
Impairment loss on abandonment of patents	-	-	1,182
Loss on retired equipment	248	313	268
Gain on derivative instruments	(14,013,726)	(282,616)	(248,767)
Loss on debt extinguishment	-	620,457	-
(Increase)/decrease in assets:			
Receivables	(1,960)	(5,394)	(7,557)
Deferred rent	695,524	745,673	769,159
Prepaid expenses	15,999	(68,268)	(158,088)
Inventory used for R&D and manufacturing	393,197	50,181	(435,392)
Deposits	145,005	150,000	(200,000)
Increase/(decrease) in liabilities:			
Accounts payable	(2,389,931)	3,981,886	(751,971)
Accrued expenses	290,097	(458,633)	433,712
Deferred revenue	(1,639)	48	46
Due to employees	72,397	57,170	(78,376)
Deferred rent liability	1,896	6,358	(3,739)
Net cash used in operating activities	<u>(23,082,493)</u>	<u>(23,833,333)</u>	<u>(22,928,019)</u>
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>			
Purchases of equipment	(31,405)	(73,399)	(103,977)
Expenditures for patent costs	(2,819)	(20,132)	(34,887)
Net cash used in investing activities	<u>(34,224)</u>	<u>(93,531)</u>	<u>(138,864)</u>
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>			
Proceeds from issuance of common stock and warrants	21,420,301	21,148,378	28,428,641
Payment on related party loan	(1,104,057)	-	-
Proceeds from exercise of warrants	-	-	3,118,387
Payments on obligations under capital lease	(8,213)	(8,452)	(8,137)
Net cash provided by financing activities	<u>20,308,031</u>	<u>21,139,926</u>	<u>31,538,891</u>
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(2,808,686)	(2,786,938)	8,472,008
CASH AND CASH EQUIVALENTS, BEGINNING OF YEAR	<u>5,726,682</u>	<u>8,513,620</u>	<u>41,612</u>
CASH AND CASH EQUIVALENTS, END OF YEAR	<u>\$ 2,917,996</u>	<u>\$ 5,726,682</u>	<u>\$ 8,513,620</u>

See notes to financial statements.

CEL-SCI CORPORATION  
STATEMENTS OF CASH FLOWS  
YEARS ENDED SEPTEMBER 30, 2016, 2015 and 2014

SUPPLEMENTAL SCHEDULE OF NON-CASH INVESTING AND FINANCING ACTIVITIES:

	2016	2015	2014
Receivable due under the litigation funding arrangement offset by the same amount payable to the legal firm providing the services	\$ 305,341	\$ -	\$ -
Research and office equipment included in accounts payable at year end	\$ -	\$ (2,345)	\$ (1,074)
Capitalizable patent costs included in accounts payable at year end.	\$ -	\$ (11,685)	\$ 4,474
Patent costs purchased with common stock	\$ -	\$ -	\$ 9,999
Lease payments included in accounts payable at year end	\$ 815	\$ 43	\$ 3,477
Fair value of warrant liabilities on the date of issuance reclassified to liabilities	\$ (8,722,073)	\$ (8,463,957)	\$ (5,320,989)
Financing costs included in accounts payable at year end	\$ 46,605	\$ -	\$ -
Forfeiture of unvested restricted stock	\$ -	\$ 1,000	\$ -
Stock issued under an anti-dilution provision and cashless exercise of warrants	\$ -	\$ -	\$ (16,375)
Prepaid amount under consulting services paid with issuance of common stock	\$ 18,021	\$ 3,861	\$ 31,085
Cash paid for interest expense	\$ 43,673	\$ 147,166	\$ 180,654

See notes to financial statements.

# **CEL-SCI CORPORATION**

## **NOTES TO FINANCIAL STATEMENTS**

### **1. ORGANIZATION**

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 is focused on finding the best way to activate the immune system to fight cancer and infectious diseases. The Company's lead investigational therapy, Multikine (Leukocyte Interleukin, Injection), is currently 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. Further research is required, and early-phase clinical trial results must be confirmed in the Phase 3 clinical trial of this investigational therapy that is in progress and that is currently subject to a clinical hold on enrollment of additional new patients.

Multikine has been cleared by the regulators in twenty four countries around the world, including the U.S. FDA, for a global Phase 3 clinical trial in advanced primary (not yet treated) head and neck cancer patients. On September 26, 2016, the Company received verbal notice from the FDA that the Phase 3 clinical trial has been placed on clinical hold. The FDA's partial clinical hold letter identified the following specific deficiencies: there is an unreasonable and significant risk of illness or injury to human subjects; the investigator brochure is misleading, erroneous, and materially incomplete; and that the plan or protocol is deficient in design to meet its stated objectives. Pursuant to this communication from FDA, patients currently receiving study treatments could continue to receive treatment, and patients already enrolled in the study would continue to be followed, but no additional patients could be enrolled. On October 21, 2016, the Company announced it had received the Partial Clinical Hold letter from the FDA. On November 21, 2016, the Company announced it has submitted what it believes to be a complete response to the FDA. On December 8, 2016, the FDA advised CEL-SCI that the agency was denying CEL-SCI's request for a meeting at this time because FDA's review of CEL-SCI's November 17, 2016 response was ongoing. CEL-SCI was also advised that it will be receiving a letter addressing CEL-SCI's response by December 18, 2016.

Multikine is also being used in a Phase 1 study at the University of California, San Francisco (UCSF) in HIV/HPV co-infected men and women with peri-anal warts.

### **2. 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 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 as it believes that it has ready access to new equity capital should the need arise. During fiscal year 2016, the Company raised



approximately \$21.4 million in net proceeds through the sale of common stock and warrants from public and private offerings. During fiscal year 2015, the Company raised \$21.1 million net proceeds from public offerings. 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. The financial statements have been prepared assuming that the Company will continue as a going concern, but due to the Company's future liquidity needs, history of net losses, and the expectation that the Company will incur losses for the foreseeable future, there is substantial doubt about the Company's ability to continue as a going concern. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Since the Company launched its Phase 3 clinical trial for Multikine, the Company has spent approximately \$34.5 million as of September 30, 2016 on direct costs for the Phase 3 clinical trial. The total remaining cash cost of the Phase 3 clinical trial, excluding any costs that will be paid by CEL-SCI's partners, would be approximately \$12.1 million after September 30, 2016. This is based on the executed contract costs with the CROs only and does not include other related costs, e.g. the manufacturing of the drug. 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. The Company has filed an amendment to the original Phase 3 protocol for its head and neck cancer study with the FDA to allow for this expansion in patient enrollment. Should the FDA allow the amended protocol filed with them to proceed, the remaining cost of the Phase 3 clinical trial will be higher. It is therefore possible that the cost of the Phase 3 clinical trial will be higher than currently estimated.

On September 26, 2016, the Company received verbal notice from the FDA that the Phase 3 clinical trial has been placed on clinical hold. Pursuant to this communication from FDA, patients currently receiving study treatments could continue to receive treatment, and patients already enrolled in the study would continue to be followed, but no additional patients could be enrolled. On October 21, 2016, the Company announced it had received the Partial Clinical Hold letter from the FDA. On November 21, 2016, the Company announced it has submitted a complete response to the FDA and will work diligently with the FDA to seek to have the partial clinical hold lifted.

### **3. 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*– 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, are 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, specifically, the settlement provisions in the warrant agreements preclude the warrants from being treated as equity. 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, 2016.

*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. A full valuation allowance was recorded against the deferred tax assets as of September 30, 2016 and 2015.

*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 related valuation allowance, 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, a Stock Compensation Plan, 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.

*Reclassification* – Certain prior year items have been reclassified to conform to the current year presentation.

*Recent Accounting Pronouncements* – In May 2014, the FASB issued Accounting Standards Update (ASU) 2014-09, *Revenue from Contracts with Customers (Topic 606)* that will supersede virtually all recognition guidance in US GAAP. For public entities, the guidance is effective for annual and interim periods beginning after December 15, 2017. Early adoption is permitted for all entities for annual and interim periods beginning after December 15, 2016. The FASB issued the following ASUs to amend the new guidance: ASU 2015-14, *Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date*, ASU 2016-08, *Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations (Reporting Revenue Gross versus Net)*, ASU 2016-10, *Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing*, and ASU 2016-12, *Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients*. Management does not expect the new standard or any of the related updates to have a material effect on its financial statements and related disclosures.

In January 2016, the FASB issued Accounting Standards Update (ASU) No. 2016-01, *Financial Instruments – Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities*. The new guidance is intended to improve the recognition and measurement of financial instruments. The new guidance is effective for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years. Early adoption is permitted for specific provisions within the guidance. Management does not expect the new standard to have a material effect on its financial statements and related disclosures.

In February 2016, the FASB issued ASU 2016-02, *Leases*, which will require most leases (with the exception of leases with terms of less than one year) to be recognized on the balance sheet as an asset and a lease liability. Leases will be classified as an operating lease or a financing lease. Operating leases are expensed using the straight-line method whereas financing leases will be treated similarly to a capital lease under the current standard. The new standard will be effective for annual and interim periods, within those fiscal years, beginning after December 15, 2018, but early adoption is permitted. The new standard must be presented using the modified retrospective method beginning with the

earliest comparative period presented. The Company is currently evaluating the effect of the new standard on its financial statements and related disclosures.

In March 2016, the FASB issued ASU No. 2016-09, *Compensation - Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting*. ASU 2016-09 simplifies several aspects of the accounting for share-based payment award transactions, including income tax consequences, classification of awards as either equity or liabilities and classification on the statement of cash flows. The new standard will be effective for annual and interim periods, within those fiscal years, beginning after December 15, 2016 but early adoption is permitted. The Company is currently evaluating the effect of the new amendment on its financial statements and related disclosures.

In August 2016, the FASB issued ASU 2016-15, *Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments*. ASU 2016-15 amends eight specific cash flow issues: 1.) Debt Prepayment or Debt Extinguishment Costs, 2.) Settlement of Zero-Coupon Debt Instruments or Other Debt Instruments with Coupon Interest Rates That Are Insignificant in Relation to the Effective Interest Rate of the Borrowing, 3.) Contingent Consideration Payments Made after a Business Combination, 4.) Proceeds from the Settlement of Insurance Claims, 5.) Proceeds from the Settlement of Corporate-Owned Life Insurance Policies, including Bank-Owned Life Insurance Policies, 6.) Distributions Received from Equity Method Investees, 7.) Beneficial Interests in Securitization Transactions, 8.) Separately Identifiable Cash Flows and Application of the Predominance Principle. Management does not expect the adoption of the amendments in this Update to have a material effect on its financial statements and related disclosures.

In November 2016, the FASB issued ASU 2016-18, *Statement of Cash Flows (Topic 230): Restricted Cash*. ASU 2016-18 requires that a statement of cash flows explain the change during the period in the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. Therefore, amounts generally described as restricted cash and restricted cash equivalents should be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. The amendments in this Update are effective for public business entities for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. Management does not expect the adoption of the amendments in this Update to have a material effect on its financial statements and related disclosures.

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.

#### 4. WARRANTS AND NON-EMPLOYEE OPTIONS

The following chart represents the warrants and non-employee options outstanding at September 30, 2016:

<u>Warrant</u>	<u>Issue Date</u>	Shares Issuable upon <u>Exercise of</u> <u>Warrant</u>	<u>Exercise</u> <u>Price</u>	<u>Expiration</u> <u>Date</u>	<u>Refer</u> <u>-ence</u>
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 W	10/28/15	17,223,248	\$0.67	10/28/20	1
Series X	1/13/16	3,000,000	\$0.37	1/13/21	2
Series Y	2/15/16	650,000	\$0.48	2/15/21	2
Series Z	5/23/16	6,600,000	\$0.55	11/23/21	1

<u>Warrant</u>	<u>Issue Date</u>	Shares Issuable upon Exercise of <u>Warrant</u>	<u>Exercise Price</u>	<u>Expiration Date</u>	<u>Refer- -ence</u>
Series ZZ	5/23/16	500,000	\$0.55	5/18/21	1
Series AA	8/26/16	5,000,000	\$0.55	2/22/22	1
Series BB	8/26/16	400,000	\$0.55	8/22/21	1
Series N	8/18/08	2,844,627	\$0.53	8/18/17	2
Series P	2/10/12	590,001	\$4.50	3/6/17	2
Consultants	12/2/11- 7/1/16	640,000	\$0.37- \$3.50	10/27/16- 6/30/19	3

The following chart represents the warrants and non-employee options outstanding at September 30, 2015:

<u>Warrants</u>	<u>Issue Date</u>	Shares Issuable upon Exercise of <u>Warrants</u>	<u>Exercise Price</u>	<u>Expiration Date</u>	<u>Refer- -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. Warrant Liabilities

The table below presents the warrants accounted for as derivative liabilities at September 30.

	<u>2016</u>	<u>2015</u>
Series S warrants	\$ 3,111,361	\$ 7,363,555
Series U warrants	-	44,551
Series V warrants	1,620,253	6,278,481
Series W warrants	1,799,858	-
Series Z warrants	970,604	-
Series ZZ warrants	70,609	-
Series AA warrants	763,661	-
Series BB warrants	<u>58,588</u>	<u>-</u>
Total derivative liabilities	<u>\$ 8,394,934</u>	<u>\$ 13,686,587</u>

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

<u>Warrant Series</u>	<u>2016</u>	<u>2015</u>	<u>2014</u>
Series A - E	\$ -	\$ 6,105	\$ 1
Series F and G	-	-	12,667
Series H	-	12,000	24,000
Series N	-	-	(1,404,027)

Series Q	-	12,000	36,000
Series R	-	157,500	131,250
Series S	4,252,193	(1,705,466)	1,098,787
Series T	-	-	276,122
Series U	44,552	75,738	73,967
Series V	4,658,228	1,724,739	-
Series W	3,260,913	-	-
Series Z	997,226	-	-
Series ZZ	75,229	-	-
Series AA	672,246	-	-
Series BB	<u>53,139</u>	<u>-</u>	<u>-</u>
Net gain	<u>\$ 14,013,726</u>	<u>\$ 282,616</u>	<u>\$ 248,767</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.

#### *Expired warrants*

As of September 30, 2015, all Series A, B, C, E, F, G, H, and Q warrants had expired.

#### *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 fair value at issuance of the warrants of \$4.2 million was recorded as a warrant liability.

#### *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 approximately \$16.4 million, 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 fair value at issuance of the Series S warrants of \$6.1 million was recorded as a warrant liability.

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 approximately \$2.8 million, 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 fair value at issuance of the Series S warrants of approximately \$1.2 million was recorded as a warrant liability. On February 7, 2014, the Series S warrants began trading on the NYSE MKT under the symbol CVM WT.

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 fair value at issuance of the Series S warrants of approximately \$461,000 was added to the existing Series S warrant liability.

During the years ended September 30, 2016 and 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 approximately \$2.6 million.

#### *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 approximately \$9.2 million, 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 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 fair value at issuance of the Series T and U warrants of approximately \$470,000 was recorded as a warrant liability.

#### *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 fair value at issuance of the Series V warrants of approximately \$8.0 million was recorded as a warrant liability.

#### *Series W Warrants*

On October 28, 2015, the Company 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 per unit price of \$0.67 for net proceeds of approximately \$10.5 million, net of underwriting discounts and commissions and offering expenses. The Series W warrants are immediately exercisable at a price of \$0.67 and expire on October 28, 2020. The fair value at issuance of the Series W warrants of approximately \$5.1 million was recorded as warrant liability.

#### *Series Z and ZZ Warrants*

On May 23, 2016, the Company closed a registered direct offering of 10,000,000 shares of common stock and 6,600,000 Series Z warrants to purchase shares of common stock. The common stock and warrants were sold at a combined per unit price of \$0.50 for net proceeds of approximately \$4.6 million, net of placement agent's commissions and offering expenses. The Series Z warrants may be exercised at any time on or after November 23, 2016 and on or before November 23, 2021 at a price of \$0.55 per



share. The Company also issued 500,000 Series ZZ warrants to the placement agent as part of its compensation. The Series ZZ warrants may be exercised at any time on or after November 23, 2016 and on or before May 18, 2021 at a price of \$0.55 per share. The fair value of the Series Z and Series ZZ warrants of approximately \$2.1 million on the date of issuance was recorded as a warrant liability.

#### *Series AA and BB Warrants*

On August 26, 2016, the Company closed a registered direct offering of 10,000,000 shares of common stock and 5,000,000 Series AA warrants to purchase shares of common stock. The common stock and warrants were sold at a combined per unit price of \$0.50 for proceeds of approximately \$4.5 million, net of placement agent's commissions and offering expenses. The series AA warrants may be exercised at any time after February 22, 2017 and on or before February 22, 2022 at a price of \$0.55 per share. The Company also issued 400,000 Series BB warrants to the placement agent as part of its compensation. The Series BB warrants may be exercised at any time on or after February 22, 2017 and on or before August 22, 2021 at a price of \$0.55 per share. The fair value of the Series AA and Series BB warrants of approximately \$1.5 million on the date of issuance was recorded as a warrant liability.

## 2. Equity Warrants

#### *Series X Warrants*

In January 2016, the Company sold 3,000,000 shares of its common stock and 3,000,000 Series X warrants to the de Clara Trust for approximately \$1.1 million. The de Clara Trust is controlled by Geert Kersten, the Company's Chief Executive Officer and a director. Each Series X 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. The Series X warrants qualify for equity treatment in accordance with ASC 815. The relative fair value of the warrants was calculated to be approximately \$417,000.

#### *Series Y Warrants*

On February 15, 2016, the Company sold 1,300,000 shares of its common stock and 650,000 Series Y warrants to a private investor for \$624,000. Each Series Y warrant allows the holder to purchase one share of the Company's common stock at a price of \$0.48 per share at any time on or before February 15, 2021. The Series Y warrants qualify for equity treatment in accordance with ASC 815. The relative fair value on the date of issuance of the warrants was calculated to be approximately \$144,000.

#### *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 cancellation of the reset provision. The fair value of the warrants on that date totaled approximately \$1.3 million 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 approximately \$7,000 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.

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 approximately \$475,000. 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, 2016, the remaining 2,844,627 Series N warrants entitle the holder 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, 2016 and 2015, 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 2014, 25,000 Series L warrants, with an exercise price of \$7.50, expired. In April 2015, the remaining 70,000 of the Series L warrants, which had been repriced to \$2.50 in April 2013, expired.

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 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.

#### *Series P Warrants*

On February 10, 2012, the Company issued 590,001 Series P warrants to purchase up to 590,001 shares of the Company's common stock at a price of \$4.50 per share as an inducement for the exercise of previously issued warrants. The Series P warrants are exercisable at any time prior to March 6, 2017.

### 3. Options and Shares Issued to Consultants

The Company typically enters into consulting arrangements in exchange for common stock or stock options. During the years ended September 30, 2016 and 2015, the Company issued 1,248,831 and 739,968 shares of common stock, respectively, to consultants, of which 784,000 and 180,000, respectively, were restricted shares. Under these arrangements, the common stock was issued with stock prices ranging between \$0.37 and \$1.11 per share.

Additionally, during the years ended September 30, 2016 and 2015, the Company issued to consultants 410,000 and 90,000 options, respectively, to purchase common stock with exercise prices ranging from \$0.37 to \$1.02 per share and fair values ranging from \$0.12 to \$0.50 per share. The aggregate values of the issuances of restricted common stock and common stock options are recorded as prepaid expenses and are charged to general and administrative expenses over the periods of service.

During the years ended September 30, 2016 and 2015, the Company recorded total expense of approximately \$752,000 and \$566,000, respectively, relating to these consulting agreements. At September 30, 2016 and 2015, approximately \$48,000 and \$30,000, respectively, are included in prepaid expenses. As of September 30, 2016, 640,000 options issued to consultants as payment for services remained outstanding, 440,000 of which are fully vested, and all of which were issued from the Non-Qualified Stock Option plans.

### 5. **RESEARCH AND OFFICE EQUIPMENT**

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

	<u>2016</u>	<u>2015</u>
Research equipment	\$ 3,158,633	\$ 3,268,757
Furniture and equipment	133,499	141,347
Leaschold improvements	<u>131,910</u>	<u>131,910</u>
	3,424,042	3,542,014
Accumulated depreciation and amortization	<u>(3,197,826)</u>	<u>(3,234,548)</u>
Net research and office equipment	<u>\$ 226,216</u>	<u>\$ 307,466</u>

Depreciation expense for the years ended September 30, 2016, 2015 and 2014 totaled approximately \$112,000, \$166,000 and \$189,000, respectively. One asset is recorded under capital lease with a net book value of \$0 and approximately \$8,000 on September 30, 2016 and 2015, respectively. Amortization of the capital lease asset is included in general and administrative expenses on the Statements of Operations.

## 6. PATENTS

Patents consisted of the following at September 30:

	<u>2016</u>	<u>2015</u>
Patents	\$ 1,528,610	\$ 1,525,791
Accumulated amortization	<u>(1,272,063)</u>	<u>(1,234,227)</u>
Net Patents	<u>\$ 256,547</u>	<u>\$ 291,564</u>

During the years ended September 30, 2016, 2015 there was no impairment of patent costs and a nominal impairment charge in 2014. Amortization expense for the years ended September 30, 2016, 2015 and 2014 totaled approximately \$38,000, \$40,000 and \$43,000, respectively. The total estimated future amortization is as follows:

<u>Years ending September 30,</u>	
2017	\$ 37,000
2018	36,000
2019	35,000
2020	31,000
2021	28,000
Thereafter	<u>90,000</u>
	<u>\$ 257,000</u>

## 7. INCOME TAXES

At September 30, 2016 and 2015, the Company had federal net operating loss carryforwards of approximately \$169.7 million and \$157.0 million, respectively. The NOLs begin to expire during the fiscal year ending September 30, 2019 and become fully expired by the end of the fiscal year ended 2036. 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, 2016 and 2015. The R&D credit begins to expire during the fiscal year ending September 30, 2020 and is fully expired during the fiscal year ended 2029. Deferred taxes consisted of the following at September 30:

	<u>2016</u>	<u>2015</u>
Net operating loss carryforwards	\$ 64,366,000	\$ 61,363,000
R&D credit	1,221,000	1,221,000
Stock-based compensation	6,379,000	5,855,000
Fixed assets and intangibles	57,000	41,000
Capitalized R&D	18,508,000	15,082,000
Vacation and other	179,000	114,000
Loan modification	<u>-</u>	<u>57,000</u>
Total deferred tax assets	90,710,000	83,733,000
Valuation allowance	<u>(90,710,000)</u>	<u>(83,733,000)</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 is as follows at September 30:

	<u>2016</u>	<u>2015</u>	<u>2014</u>
Federal Rate	34.00%	34.00%	34.00%
State tax rate, net of federal benefit	3.92	5.12	5.15
State tax rate change	(22.13)	(0.15)	(0.93)
Other adjustments	(0.03)	(0.21)	0.00
Adjustment to deferreds	0.00	0.00	19.13
Permanent differences (1)	45.08	(0.71)	(0.43)
Change in valuation allowance	<u>(60.84)</u>	<u>(38.05)</u>	<u>(58.78)</u>
Effective tax rate	<u>0.00%</u>	<u>0.00%</u>	<u>0.00%</u>

(1) The 2016 amount is mainly due to the gain on derivative instruments approximating \$14 million from the change in fair value of the Company's warrant liabilities during the year.

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 2015. These years remain open to examination by the major domestic taxing jurisdictions to which the Company is subject.

## 8. STOCK COMPENSATION

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

	<b>Year Ended September 30,</b>		
	<b>2016</b>	<b>2015</b>	<b>2014</b>
Employees	\$2,113,433	\$5,105,827	\$3,958,637
Non-employees	\$ 751,651	\$ 565,915	\$ 771,946

These expenses were recorded as general and administrative expense. During the years ended September 30, 2016, 2015 and 2014, non-employee stock compensation excluded approximately \$48,000, \$30,000 and \$26,000, respectively, for future services to be performed (Note 12).

During the years ended September 30, 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.

	<b>2016</b>	<b>2015</b>	<b>2014</b>
Expected stock price volatility	75.58 – 80.9%	73.38 – 86.19%	72.81 – 86.87%
Risk-free interest rate	0.71 – 1.56%	0.93 – 2.35%	0.59 – 2.65%
Expected life of options	3.0 – 9.69 Years	3.0 – 9.76 Years	3.0 – 9.76 Years
Expected dividend yield	-	-	-

**Non-Qualified Stock Option Plans**--At September 30, 2016, the Company has collectively authorized the issuance of 9,680,000 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, 2016, the Company had collectively authorized the issuance of 3,460,000 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, 2016 is summarized as follows:

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

	<b>Outstanding</b>				<b>Exercisable</b>			
	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, 2014	6,831,149	\$2.98	6.55	\$3,600	3,443,884	\$3.40	5.49	\$3,600
Vested Granted (a) Exercised	893,700	\$0.66			1,153,357	\$2.48		

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
Vested					1,401,716	\$1.27		
Granted (b)	1,213,600	\$0.48						
Exercised								
Forfeited	55,998	\$0.86						
Expired	106,000	\$5.80			106,000	\$5.80		
Cancelled								
Outstanding at September 30, 2016	8,589,287	\$2.37	5.35	\$0	5,822,458	\$2.65	4.76	\$0

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

(b) Includes 410,000 stock options granted to consultants

A summary of the status of the Company's non-vested options for the two years ended September 30, 2016 is presented below:

	<u>Number of Options</u>	<u>Weighted Average Grant Date Fair Value</u>
Unvested at October 1, 2014	3,387,265	\$2.15
Vested	(1,153,357)	
Granted	893,700	
Forfeited	<u>(116,665)</u>	
Unvested at September 30, 2015	3,010,943	\$1.72
Vested	(1,401,716)	
Granted	1,213,600	
Forfeited	<u>(55,998)</u>	
Unvested at September 30, 2016	<u>2,766,829</u>	\$1.48

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. 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, 2016 is approximately \$8.6 million. 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, 2016 and 2015, the Company recorded expense relating to the issuance of restricted stock pursuant to the plan of approximately \$634,000 and \$3.4 million, respectively. At September 30, 2016, the Company has unrecognized compensation expense of approximately \$3.1 million which is expected to be recognized over a weighted average period of 5.03 years.

A summary of the status of the Company's restricted stock units issued from the Incentive Stock Bonus Plan for the two years in the period ended September 30, 2016 is presented below:

	<u>Number of Shares</u>	<u>Weighted Average Grant Date Fair Value</u>
Unvested at October 1, 2014	15,700,000	\$0.55
Vested	(500,000)	
Granted	-	
Forfeited	(100,000)	
Unvested at September 30, 2015	15,100,000	\$0.55
Vested	-	
Unvested at September 30, 2016	15,100,000	\$0.55

Stock Bonus Plans -- At September 30, 2016, the Company was authorized to issue up to 5,594,000 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, 2016, 408,497 shares were issued to the Company's 401(k) plan for a cost of approximately \$162,000. During the year ended September 30, 2015, 243,178 shares were issued to the Company's 401(k) plan for a cost of approximately \$166,000. During the year ended September 30, 2014, 164,787 shares were issued to the Company's 401(k) plan for a cost of approximately \$155,000. As of September 30, 2016, the Company has issued a total of 3,161,211 shares of common stock from the Stock Bonus Plans.

Stock Compensation Plans-- At September 30, 2016, 3,350,000 shares were authorized for use in the Company's stock compensation plans. During the years ended September 30, 2016, 2015 and 2014, 464,831, 218,328 and 409,968 shares, respectively, were issued from the Stock Compensation Plans to consultants for payment of services at a cost of approximately \$234,000, \$147,000 and \$439,000, respectively. During the year ended September 30, 2016 and 2015, 95,935 and 107,050 shares, respectively, were issued to employees from the Stock Compensation Plans as part of their compensation at a cost of approximately \$45,000 and \$58,000, respectively. No shares were issued to employees from the Stock Compensation Plans during the year ended September 30, 2014. As of September 30, 2016, the Company has issued 1,984,765 shares of common stock from the Stock Compensation Plans.

## 9. 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, 2016, 2015 and 2014, in connection with this Plan was approximately \$168,000, \$170,000 and \$160,000, respectively.

## 10. 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. The agreement required the Company to make \$600,000 in advance payments which are being credited against future invoices in \$150,000 annual increments through December 2017. As of September 30, 2016, the total balance advanced is \$300,000, of which \$150,000 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 study in the form of offering discounted clinical services in exchange for a single digit percentage of milestone and royalty payments, up to a specific maximum amount. In October 2015, the Company entered into a second co-development and revenue sharing agreement with Ergomed for an additional \$2 million, for a total of \$12 million. 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 \$19.2 million related to Ergomed’s services. This amount is net of Ergomed’s discount of approximately \$6.3 million. During the years ended September 30, 2016, 2015 and 2014, the Company recorded, approximately \$7.2 million, \$6.7 million and \$4.4 million, respectively, as research and development expense related to Ergomed’s services. These amounts were net of Ergomed’s discount of approximately \$2.1 million, \$2.4 million and \$1.5 million, 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 Phase 1 study being conducted at UCSF for 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.

The Company is currently involved in a pending arbitration proceeding, CEL-SCI Corporation v. inVentiv Health Clinical, LLC (f/k/a PharmaNet LLC) and PharmaNet GmbH (f/k/a PharmaNet AG). On October 31, 2013, the Company initiated the proceedings against inVentiv Health Clinical, LLC, or inVentiv, the former third-party CRO, and are 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. The Company is seeking at least \$50 million in damages in its amended statement of claim. Based upon further analysis, however, the Company believes that its damages (direct and consequential) presently total over \$150 million.

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” which, under New Jersey law, is 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. However, if inVentiv successfully asserts any of its counterclaims, such an adverse determination could have a material adverse effect on the Company’s business, results, financial condition and liquidity.



In October 2015 the Company signed an arbitration 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 provides the Company with funding for litigation expenses to support its arbitration claims against inVentiv. The funding is available to the Company to fund the expenses of the ongoing arbitration and will only be repaid when the Company receives proceeds from the arbitration. During the year ended September 30, 2016, the Company recognized a gain of approximately \$1.1 million on the derecognition of legal fees to record the transfer of the liability that existed prior to the execution of the financing agreement from the Company to Lake Whillans. The gain on derecognition of legal fees is recorded as a reduction of general and administration expenses on the Statement of Operations. All related legal fees are directly billed to and paid by Lake Whillans. As part of the agreement with Lake Whillans, the law firm agreed to cap its fees and expenses for the arbitration at \$5 million.

The arbitration hearing on the merits (the “trial”) began on September 26, 2016.

#### *Lease Agreements*

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

#### Years Ending September 30,

2017	\$	1,930,000
2018		1,997,000
2019		2,066,000
2020		2,110,000
2021		2,100,000
Thereafter		<u>15,831,000</u>
Total minimum lease payments:	\$	<u>26,034,000</u>

Rent expense, including amortization of deferred rent, for the years ended September 30, 2016, 2015 and 2014, was approximately \$2.7 million. The Company’s three leases expire between June 2020 and October 2028.

The Company leases 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 3 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, 2016, the Company recorded a total deferred rent asset of approximately \$3.8 million, of which approximately \$3.4 million is long term and the balance of approximately \$430,000 is included in current assets. At September 30, 2015, the Company recorded a total deferred rent asset of approximately \$4.5 million, of which approximately \$4 million is long term and the balance of approximately \$488,000 is included in current assets. On September 30, 2016 and 2015, the Company has included in deferred rent the following: 1) deposit on the manufacturing facility (\$3.1 million); 2) the fair value of the warrants issued to lessor (\$1.4 million); 3) additional investment (\$3.0); 4) deposit on the cost of the leasehold improvements for the manufacturing facility (\$1.8 million). At September 30, 2016, the Company has accumulated amortization of approximately \$5.5 million. At September 30, 2015, the Company has also included accrued interest on deposit of approximately \$128,000, and accumulated amortization of approximately \$4.9 million.

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 approximate \$1.7 million deposit is included in non-current assets on September 30, 2016 and 2015.

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, 2016, 2015 and 2014 was approximately \$67,000, \$65,000 and \$63,000, 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. In September 2016, the lease was extended through February 28, 2022. 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 approximately \$11,000 per month. As of September 30, 2016 and 2015, the Company has recorded a deferred rent liability of approximately \$2,000 and \$6,000, respectively.

The Company leases its 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 approximately \$8,000 per month. As of September 30, 2016 and 2015, the Company has recorded a deferred rent liability of approximately \$18,000 and \$13,000, respectively.

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

#### *Vendor Obligations*

Further, the Company has contingent obligations with other 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 total remaining cash cost of the Phase 3 clinical trial, excluding any costs that will be paid by CEL-SCI's partners, would be approximately \$12.1 million after September 30, 2016. This is based on the executed contract costs with the CROs only and does not include other related costs, e.g. the manufacturing of the drug. The Company has filed an amendment to the original Phase 3 protocol for it head and neck cancer study with the FDA to allow for this expansion in patient enrollment. Should the FDA allow the amended protocol filed with them to proceed, the remaining cost of the Phase 3 clinical trial will be higher.

## **11. RELATED PARTY TRANSACTIONS**

Effective August 31, 2016, Maximilian de Clara, the Company's President and a director, resigned for health reasons. In payment for past services, the Company agreed to issue Mr. de Clara 650,000 shares of restricted stock; 325,000 shares upon his resignation and 325,000 on August 31, 2017. The market value of the shares granted, including the accrued value of the shares to be issued in August 2017, totaled \$253,500.

On January 13, 2016, the de Clara Trust demanded payment on the note payable, of which the balance, including accrued and unpaid interest, was \$1,105,989. The de Clara Trust was established by Maximilian de Clara, the Company's former President and a director. The Company's Chief Executive Officer, Geert Kersten, is the trustee and a beneficiary. When the de Clara Trust demanded payment on the note, the Company sold 3,000,000 shares of its common stock and 3,000,000 Series X warrants to the de Clara Trust for approximately \$1.1 million. 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.

Prior to the repayment, on June 29, 2015, the Company had extended the maturity date of the note to July 6, 2017, lowered the interest rate from 15% to 9% and changed the conversion price from \$4.00 to \$0.59, the closing stock price on the previous trading day. The Company determined these modifications to be substantive and accounted for the modification 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 approximately \$166,000, which was credited to additional paid in capital. Concurrently, the Company extended the expiration date of the Series N warrants to August 18, 2017. The incremental cost of this modification was approximately \$475,000 and was included in debt extinguishment loss on the note, for a total loss of approximately \$620,000 during the year ended September 30, 2015.

During the years ended September 30, 2016, 2015 and 2014, the Company paid approximately \$43,000, \$146,000 and \$179,000, respectively, in interest expense to Mr. de Clara.

## **12. STOCKHOLDERS' EQUITY**

During the years ended September 30, 2016 and 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 approximately \$3.1 million from the exercise of these warrants since 92,715 Series N warrants were exercised in a cashless exercise.

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 \$16.4 million, 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 approximately \$24,000.

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 approximately \$2.8 million, 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 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 approximately \$1.1 million. This cost was recorded as a 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 offering expenses. The Series S warrants trade on the NYSE MKT under the symbol CVM WT.

On April 17, 2014, the Company closed a public offering of units consisting 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

\$9.1 million 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 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.

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.

On October 28, 2015, the Company 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 \$10.5 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.

On May 23, 2016, the Company closed a registered direct offering of 10,000,000 shares of common stock and 6,600,000 Series Z warrants to purchase shares of common stock. The common stock and warrants were sold at a combined per unit price of \$0.50 for net proceeds of approximately \$4.6 million, net of placement agent's commissions and offering expenses. The Series Z warrants may be exercised at any time on or after November 23, 2016 and on or before November 23, 2021 at a price of \$0.55 per share. The Company also issued 500,000 Series ZZ warrants to the placement agent as part of its compensation. The Series ZZ warrants may be exercised at any time on or after November 23, 2016 and on or before May 18, 2021 at a price of \$0.55 per share.

On August 26, 2016, the Company closed a registered direct offering of 10,000,000 shares of common stock and Series AA warrants to purchase up to 5,000,000 shares of common stock. Each share of common stock was sold together with a Series AA warrant to purchase one-half of a share of common stock for the combined purchase price of \$0.50. Each warrant can be exercised at any time after February 22, 2017 and on or before February 22, 2022 at a price of \$0.55 per share. The Company also issued 400,000 Series BB warrants to the placement agent as part of its compensation. The Series BB warrants may be exercised at any time on or after February 22, 2017 and on or before August 22, 2021 at a price of \$0.55 per share. The Company received proceeds from the sale of Series AA and Series BB shares and warrants of approximately \$4.5 million, net of placement agent's commissions and offering expenses.

### **13. 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 liabilities measured at fair value on a recurring basis, by input level, on the balance sheet at September 30, 2016:

	Quoted Prices in Active Markets for Identical <u>Liabilities (Level 1)</u>	Significant Other Observable <u>Inputs (Level 2)</u>	Significant Unobservable <u>Inputs (Level 3)</u>	<u>Total</u>
Derivative Instruments	\$ <u>3,111,361</u>	\$ <u>-</u>	\$ <u>5,283,573</u>	\$ <u>8,394,934</u>

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

	Quoted Prices in Active Markets for Identical Assets or <u>Liabilities (Level 1)</u>	Significant Other Observable <u>Inputs (Level 2)</u>	Significant Unobservable <u>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 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>2016</u>	<u>2015</u>
Beginning balance	\$ 6,323,032	\$ 307,894
Issuances	8,722,073	8,003,220
Net realized and unrealized derivative gain	<u>(9,761,532)</u>	<u>(1,988,082)</u>
Ending balance	<u>\$ 5,283,573</u>	<u>\$ 6,323,032</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. At September 30, 2016, the Company’s Level 3 derivative instruments have a weighted average fair value of \$0.10 per share and a weighted average exercise price of \$0.86 per share. Fair values were determined using a weighted average risk free interest rate of 1.04% and 75% volatility.

#### 14. 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>2016</u>	<u>2015</u>	<u>2014</u>
Net loss available to common shareholders	\$ (11,466,498)	\$ (34,674,646)	\$ (28,483,712)
Less: Gain on derivative Instruments	<u>-</u>	<u>-</u>	<u>(248,767)</u>
Net loss - diluted	\$ (11,466,498)	\$ (34,674,646)	\$ (28,732,479)
Weighted average number of shares - basic and diluted	121,655,108	82,519,027	58,804,622
Loss per share - basic	\$ <u>(0.09)</u>	\$ <u>(0.42)</u>	\$ <u>(0.48)</u>
Loss per share - diluted	\$ <u>(0.09)</u>	\$ <u>(0.42)</u>	\$ <u>(0.49)</u>

For the years ended September 30, 2016 and 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>2016</u>	<u>2015</u>	<u>2014</u>
Options and Warrants	91,882,022	58,421,058	39,994,707
Convertible Debt	-	1,871,283	276,014
Unvested Restricted Stock	<u>15,100,000</u>	<u>15,100,000</u>	<u>15,700,000</u>
Total	<u>106,982,022</u>	<u>75,392,341</u>	<u>55,970,721</u>

#### 15. 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.

## 16. QUARTERLY INFORMATION (UNAUDITED)

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

### Financial Data

#### Fiscal 2016

	Three months ended December 31 <u>2015</u>	Three months ended March 31, <u>2016</u>	Three months ended June 30, <u>2016</u>	Three months Ended September 30, <u>2016</u>	Year ended September 30, <u>2016</u>
Grant income and other	\$ 20,976	\$ 32,775	\$ 129,975	\$ 101,329	\$ 285,055
Operating expenses	5,804,108	6,306,378	6,512,722	7,215,072	25,838,280
Non-operating (expense) income, net	1,985	22,478	24,679	23,859	73,001
Gain (loss) on derivative instruments	8,122,960	(2,593,730)	2,508,744	5,975,752	14,013,726
Net income (loss) available to common shareholders	<u>\$ 2,341,813</u>	<u>\$ (8,844,855)</u>	<u>\$ (3,849,324)</u>	<u>\$ (1,114,132)</u>	<u>\$ (11,466,498)</u>
EPS (LPS) -basic and diluted	<u>\$ 0.02</u>	<u>\$ (0.07)</u>	<u>\$ (0.03)</u>	<u>\$ (0.01)</u>	<u>\$ (0.09)</u>
Weighted average shares:					
Basic	109,768,502	118,420,327	124,132,500	134,290,870	121,655,108
Diluted	111,639,785	118,420,327	124,132,500	134,290,870	121,655,108

#### 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)	(35,985)	22,369	(40,260)
Gain (loss) on derivative instruments	2,162,970	(4,782,796)	4,428,780	(1,526,338)	282,616
Loss on debt extinguishment	-	-	(620,457)	-	(620,457)
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

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

## 17. SUBSEQUENT EVENTS

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

On December 8, 2016, the Company sold 34,024,000 shares of common stock and warrants to purchase common stock at a price of \$0.125 in a public offering. The warrants consist of 17,012,000 Series CC warrants to purchase 17,012,000 shares of common stock, 34,024,000 Series DD warrants to purchase 34,024,000 shares of common stock and 34,024,000 Series EE warrants to purchase 34,024,000 shares of common stock. The Series CC warrants are immediately exercisable, expire in five-years and have an exercise price of \$0.20 per share. The Series DD warrants are immediately exercisable, expire in six-months and have an exercise price of \$0.18 per share. The Series EE warrants are immediately exercisable, expire in nine-months and have an exercise price of \$0.18 per share. In addition, the Company issued 1,701,000 Series FF warrants to purchase 1,701,000 shares of common stock to the placement agent. The FF warrants are exercisable at any time on or after June 8, 2017 and expire on December 1, 2021 and have an exercise price \$0.15625. The net proceeds to CEL-SCI from this offering was approximately \$3.8 million, excluding any future proceeds that may be received from the exercise of the warrants.

On December 9, 2016, the Company reported on a communication received from the staff of the NYSE MKT, its current listing exchange, that it considered the Company to be noncompliant with certain listing requirements based on its quarterly report for the period ended June 30, 2016. The Company has been given the opportunity to maintain its listing by submitting a plan of compliance by January 9, 2017. This plan must advise of actions the company has taken or will take to regain compliance with the continued listing standards by June 11, 2018. The Company intends to submit such a plan by January 9, 2017. The communication and compliance plan has no current effect on the listing of the Company's shares on the exchange. If the plan is not acceptable or the Company does not make sufficient progress under the plan or reestablish compliance by June 11, 2018, then staff of the exchange may initiate proceedings for delisting from the NYSE MKT. The Company may then appeal a staff determination to initiate such proceedings in accordance with the exchange's Company Guide.



## **CORPORATE INFORMATION**

### **Board of Directors**

**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**

**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  
8742 Lucent Boulevard, Suite 300  
Highlands Ranch, CO 80129  
(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 820 stockholders of record as of April 5, 2017. 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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