

# **Annual Report**

2017

# **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, for which CEL-SCI has received Orphan Drug Status from the U.S. FDA. The study was fully enrolled with 928 patients in September 2016. Currently CEL-SCI is waiting for the occurrence of 298 events (deaths) in the two main groups to determine final results. 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.

CEL-SCI's immune therapy, Multikine, is being used in a different way than immune therapy is usually used. It is given before any other therapy has been administered because that is when the immune system is thought to be strongest. It is also administered locally to treat tumors or infections. For example, in the Phase 3 clinical trial, Multikine is given locally at the site of the tumor as a first line treatment before surgery, radiation and/or chemotherapy. 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 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. CEL-SCI was recently awarded a Phase 2 Small Business Innovation Research (SBIR) grant in the amount of \$1.5 million from the National Institutes of Health (NIH). This grant will provide funding to allow CEL-SCI to advance its first LEAPS product candidate, CEL-4000, towards an Investigational New Drug (IND) application, by funding GMP manufacturing, IND enabling studies, and additional mechanism of action studies.

CEL-SCI was formed as a Colorado corporation in 1983. CEL-SCI's principal office is located at 8229 Boone Boulevard, Suite 802, Vienna, VA 22182. CEL-SCI's telephone number is 703-506-9460 and its website is 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, 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:

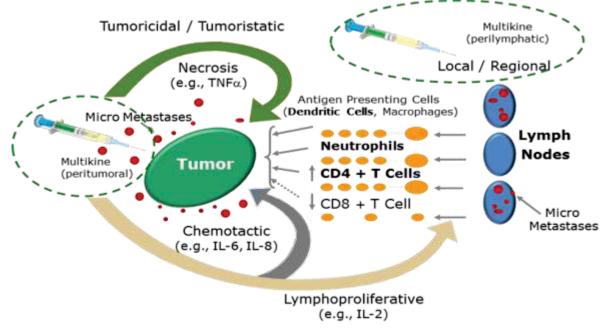
- 1) Multikine, an investigational immunotherapy under development for the potential treatment of certain head and neck cancers;
- 2) L.E.A.P.S. (Ligand Epitope Antigen Presentation System) technology, or LEAPS, with two investigational therapies, LEAPS-H1N1-DC, a product candidate under development 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.

# **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 may help the immune system "see" the tumor and then attack it, enabling the body's own anti-tumor immune response to fight the tumor. 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 proinflammatory 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 generally being used. Generally immunotherapy is given to patients who have already failed other treatments of such as surgery, radiation and/or chemotherapy and most of the time it is administered systemically. Multikine on the other hand is administered locally to treat tumors and their microenvironment before any other therapy has been administered because it is believed that is the time when the immune system is thought to be most amenable to activation against the tumor. 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 goal is to help the intact immune system recognize and kill the tumor micro metastases that usually cause recurrence of the cancer. In short, CEL-SCI believes that the local administration administration of Multikine and its 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 lesser 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).

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.

This trial is currently primarily under the management of two clinical research organizations, or CROs: ICON Inc., or ICON, and Ergomed Clinical Research Limited, or Ergomed.

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 CEL-SCI plans 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 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 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.

Nine hundred twenty-eight (928) newly diagnosed head and neck cancer patients have been enrolled in this Phase 3 cancer study and all the patients who have completed treatment continue to be followed for protocol-specific outcomes in accordance with the Study Protocol. The last patient was enrolled in the study in September 2016. Approximately 135 patients were enrolled in the study from 2011 to 2013, about 195 were enrolled in 2014, about 340 in 2015, and about 260 in 2016. The study protocol assumed an overall survival rate of about 55% at 3 years for the SOC treatment group alone. At this point in the study the 928 patients enrolled in the study are being followed-up as required by the study protocol.

Since CEL-SCI launched its Phase 3 clinical trial for Multikine, CEL-SCI has incurred expenses of approximately \$48.7 million as of March 31, 2018 on direct costs for the Phase 3 clinical trial. CEL-SCI estimates it will incur additional expenses of approximately \$10.5 million for the remainder of the Phase 3 clinical trial. It should be noted that this estimate is based only on the information currently available in CEL-SCI's contracts with the Clinical Research Organizations responsible for managing the Phase 3 clinical trial and does not include other related costs, e.g., the manufacturing of the drug. This number may be affected by the 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.

On August 10, 2017, we received a letter from the U.S. Food and Drug Administration (FDA) stating that the clinical hold that had been imposed on our Phase 3 cancer study with Multikine has been removed and that all clinical trial activities under this Investigational New Drug application (IND) may resume.

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 report 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.

# **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 for scots towards the clinical trials of Multikine. If Orient Europharma fails to make certain

minimum purchases of Multikine during the term of the agreement, Orient Europhorma'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.

# **MANUFACTURING FACILITY**

Before starting the Phase 3 clinical trial, for reasons related to regulatory considerations, 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.

# **ARBITRATION**

On October 31, 2013, we commenced arbitration proceedings against inVentiv Health Clinical, LLC, or inVentiv, our former clinical research organization (CRO), and now part of Syneos Health. 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. On June 25, 2018, the arbitrator ruled that inVentiv materially breached its contract with CEL-SCI and denied inVentiv all but one of its counterclaims (\$429,649 for certain unpaid invoices) against CEL-SCI. He awarded CEL-SCI \$2,917,834 in damages. This is a final and binding decision and to CEL-SCI's knowledge, marks the first ever decision in favor of a pharmaceutical/biomedical company against a CRO for breach of contract. However, pursuant to the terms of an agreement with an affiliate of Lake Whillans Litigation Finance, LLC, a firm that produced partial funding for the legal expenses incurred by us in the arbitration proceedings, all amounts received from inVentiv by virtue of the arbitration award will be paid to Lake Whillans Litigation Finance.

The arbitration and its findings are subject to certain confidentiality requirements and CEL-SCI is able to disclose only certain information at this time. Most importantly, the arbitrator concluded as follows:

- The arbitrator found that inVentiv materially breached its contract with CEL-SCI;
- The arbitrator found that inVentiv knowingly misled CEL-SCI with respect to "enrollment projections," which, in the arbitrator's opinion, was "fraudulent," but the arbitrator denied CEL-SCI's fraud claim as a result of certain legal "roadblocks";
- The arbitrator assessed inVentiv for the entirety of the arbitrator's fees for the arbitration as a result of inVentiv's "scorched earth litigation tactics"; and
- The arbitrator denied all but one of inVentiv's counterclaims against CEL-SCI.

# **LEAPS**

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

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

On September 19, 2017, CEL-SCI announced that it has been awarded a Phase 2 Small Business Innovation Research (SBIR) grant in the amount of \$1.5 million from the National Institute of Arthritis Muscoskeletal and Skin Diseases, which is part of the National Institutes of Health (NIH). This grant will provide funding to allow CEL-SCI to advance its first LEAPS product candidate, CEL-4000, towards an Investigational New Drug (IND) application, by funding GMP manufacturing, IND enabling studies, and additional mechanism of action studies. The work is being conducted at CEL-SCI's research laboratory and Rush University Medical Center in Chicago, Illinois in the laboratories of Tibor Glant, MD, Ph.D., The Jorge O. Galante Professor of Orthopedic Surgery and Katalin Mikecz, MD, Ph.D. Professor of Orthopedic Surgery & Biochemistry. The grant was awarded based on published data described below by Dr. Glant's team in collaboration with CEL-SCI showing that the administration of a proprietary peptide using CEL-SCI's LEAPS technology prevented the development, and lessened the severity, including inflammation, of experimental proteoglycan induced arthritis (PGIA or GIA) when it was administered after the disease was induced in the animals.

In July 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 Muscoskeletal and Skin Diseases, which is part of the National Institutes of Health. The grant funded the development of CEL-SCI's LEAPS technology as a potential treatment for rheumatoid arthritis, an autoimmune disease of the joints. The work was 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 as 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.

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.

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 (<u>www.jci.org/articles/view/67550</u>). 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.

# **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'S intellectual property portfolio covers its proprietary technologies, including Multikine and LEAPS, by multiple issued patents and pending patent applications in the United States and in key foreign markets.

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 2023. 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 three in Europe (issued in September 2015, May 2016 and October 4, 2017, currently set to expire in 2025 and 2026). In September 2017 CEL-SCI announced that the European Patent Office has issued a new patent to CEL-SCI for Multikine. Patent # EP 1 879 618 B1, titled "A Method for Modulating HLA Class II Tumor Cell Surface Expression with a Cytokine Mixture," addresses Multikine's mechanism of action to make tumors more visible to the immune system. This new patent is important because, along with the other Multikine issued patents, it addresses how Multikine enables the immune system to recognize and attack the tumor. One way tumor cells evade the immune system is by expressing human leukocyte antigens (HLA) on the tumor cell surface, thus appearing as 'self' to the immune cells and therefore the tumor cells are not attacked. It is important to note that the tumors of the Multikine-treated responders in CEL-SCI's prior Phase 2 studies had no HLA Class II expressed on the cell surface following Multikine treatment as compared to controls. This points to Multikine's ability to modulate HLA expression on the tumor cell surface, thereby allowing the immune system to recognize and attack the tumor.

In addition to the patents 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. In October 2017, a patent was issued in Europe for LEAPS, which expires in 2029. 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 21, 2017, there were no contested proceedings and/or third party claims with respect to CEL-SCI's patents or patent applications.

#### MARKET FOR CEL-SCI'S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

As of July 27, 2018, there were approximately 750 record holders of CEL-SCI's common stock. CEL-SCI's common stock is traded on the NYSE American under the symbol "CVM".

On June 12, 2017, CEL-SCI's shareholders approved a reverse split of CEL-SCI's common stock. The reverse split became effective on the NYSE American on June 15, 2017. On that date, every twenty-five issued and outstanding shares of CEL-SCI's common stock automatically converted into one outstanding share.

As a result of the reverse stock split, the number of CEL-SCI's outstanding shares of common stock decreased from 230,127,331 (pre-split) shares to 9,214,645 (post-split) shares.

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

|   | HIGH    | LOW     |
|---|---------|---------|
| FY 2018                                     |         |         |
| Fourth Quarter (through July 26, 2018)      | \$ 1.29 | \$ 0.83 |
| Third Quarter (through June 30, 2018)       | \$ 3.66 | \$ 0.83 |
| Second Quarter (through March 31, 2018)     | \$ 2.50 | \$ 1.30 |
| First Quarter (through December 31, 2017)   | \$ 2.14 | \$ 1.60 |
| FY 2017                                     |         |         |
| Fourth Quarter (through September 30, 2017) | \$ 3.69 | \$ 1.57 |
| Third Quarter (through June 30, 2017)       | \$ 4.00 | \$ 1.50 |
| Second Quarter (through March 31, 2017)     | \$ 4.50 | \$ 1.75 |
| First Quarter (through December 31, 2016)   | \$ 7.75 | \$ 1.50 |
| FY 2016                                     |         |         |
| Fourth Quarter (through September 30, 2016) | \$13.50 | \$ 6.00 |
| Third Quarter (through June 30, 2016)       | \$15.00 | \$11.00 |
| Second Quarter (through March 31, 2016)     | \$16.50 | \$ 9.00 |
| First Quarter (through December 31, 2015)   | \$18.75 | \$ 9.00 |

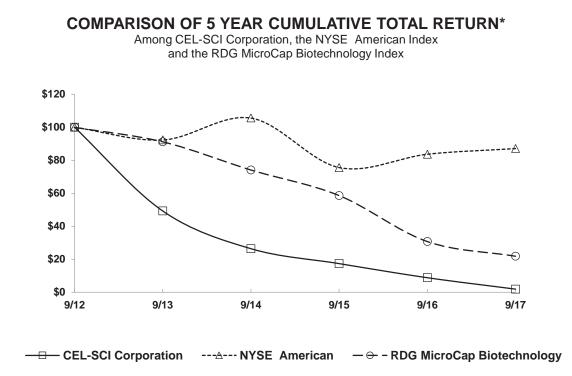
Holders of common stock are entitled to receive dividends as may be declared by CEL-SCI's Board of Directors out of legally available funds and, in the event of liquidation, to share pro rata in any distribution of CEL-SCI's assets after payment of liabilities. CEL-SCI's Board of Directors is not obligated 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 American 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, 2012 and tracks it through September 30, 2017.

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



\*\$100 invested on 9/30/12 in stock or index, including reinvestment of dividends. Fiscal year ending September 30.

|                            | 9/12   | 9/13  | 9/14   | 9/15  | 9/16  | 9/17  |
|----------------------------|--------|-------|--------|-------|-------|-------|
| CEL-SCI Corporation        | 100.00 | 49.28 | 26.43  | 17.39 | 8.84  | 1.92  |
| NYSE American              | 100.00 | 92.32 | 105.61 | 75.60 | 83.69 | 87.12 |
| RDG MicroCap Biotechnology | 100.00 | 91.20 | 74.12  | 58.64 | 30.77 | 21.86 |

#### 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 could continue to receive treatment, and patients already enrolled in the study continued to be followed.

On August 10, 2017, CEL-SCI received a letter from the FDA stating that the clinical hold that had been imposed on the Phase 3 cancer study with Multikine has been removed and that all clinical trial activities under this IND may resume.

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 2017

During the year ended September 30, 2017, grant and other income decreased by approximately \$216,000 compared to the year ended September 30, 2016. The decrease is primarily due to the timing of drug shipments to supply the Company's partner in Taiwan during fiscal year 2017 compared to fiscal year 2016.

During the year ended September 30, 2017, research and development expenses decreased by approximately \$1.8 million compared to the year ended September 30, 2016. The Company is continuing the Phase 3 clinical trial and research and development fluctuates based on the activity level of the clinical trial.

During the year ended September 30, 2017, general and administrative expenses decreased by approximately \$686,000, compared to the year ended September 30, 2016. Major components of the decrease are an approximate \$839,000 decrease in compensation costs, of which approximately \$733,000 relates to stock compensation, and an approximate decrease of \$915,000 related to non-employee compensation costs for consultants, of which approximately \$519,000 relates to stock compensation, and a net decrease of approximately \$32,000. These decreases are offset by an approximate \$1.1 million gain on derecognition of legal fees recorded during the year ended September 30, 2016 due to the transfer of the liability that existed prior to the execution of the Lake Whillans financing agreement from the Company to Lake Whillans. The gain on de-recognition of legal fees is recorded as a reduction of general and administrative expenses for the year ended September 30, 2016.

During the years ended September 30, 2017 and 2016, the Company recorded a derivative gain of approximately \$11.0 million and \$14.0 million, 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 expense increased approximately \$2.2 million during the year ended September 30, 2017 compared to the year ended September 30, 2016, primarily due to an approximate \$1.34 million in interest expense recorded on a stock financing transaction with Ergomed and \$0.9 million interest expense relating to the amortization of debt discounts and accrued interest on convertible notes payable issued during fiscal 2017.

#### **Research and Development Expenses**

During the five years ended September 30, 2017, 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>2017</u>      | <u>2016</u>      | <u>2015</u>      | <u>2014</u>      | <u>2013</u>      |
|-----------|------------------|------------------|------------------|------------------|------------------|
| MULTIKINE | \$<br>15,253,190 | \$<br>17,054,474 | \$<br>18,697,940 | \$<br>14,891,411 | \$<br>10,650,239 |
| LEAPS     | <br>353,795      | <br>390,908      | <br>493,810      | <br>374,778      | <br>377,485      |
| TOTAL     | \$<br>15,606,985 | \$<br>17,445,382 | \$<br>19,191,750 | \$<br>15,266,189 | \$<br>11,027,724 |

In January 2007, CEL-SCI received a "no objection" letter from the FDA indicating that it could proceed with Phase 3 trials with Multikine in head and neck cancer patients. CEL-SCI had previously received a "no objection" letter

from the Canadian Biologics and Genetic Therapies Directorate which enabled CEL-SCI to begin its Phase 3 clinical trial in Canada. Subsequently, CEL-SCI received similar authorizations from twenty-three other regulators.

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

As explained in Item 1 of this report, as of November 30, 2017, 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.

# 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 2017 and 2016, CEL-SCI raised net proceeds of approximately \$13.3 million and \$21.4 million, respectively, through the sale of stock and the issuance of convertible notes.

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 \$1.7 million during the twelve months ended September 30, 2017. See Item 2 of this report for more information concerning the terms of this lease.

On October 28, 2015, CEL-SCI closed an underwritten public offering of 688,930 shares of common stock and 688,930 Series W warrants to purchase shares of common stock. The common stock and warrants were sold at a combined per unit price of \$16.75 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 \$16.75 and expire on October 28, 2020. As of September 30, 2017, none of the Series W warrants had been exercised.

In January 2016, CEL-SCI repaid the note payable to the de Clara Trust, the balance of which was approximately \$1.1 million, including principal and interest At the same time, the Company sold 120,000 shares of its common stock and 120,000 Series X warrants to the de Clara Trust for approximately \$1.1 million, as noted above. Geert Kersten, the Company's Chief Executive Officer and a director, is a beneficiary of the de Clara Trust. Each Series X warrant allows the de Clara Trust to purchase one share of the CEL-SCI's common stock at a price of \$9.25 per share at any time on or before January 13, 2021. As of September 30, 2017, none of the Series X warrants had been exercised.

In February 2016, CEL-SCI sold 52,000 shares of its common stock and 26,000 Series Y warrants to a private investor for \$624,000. Each Series Y warrant allows the holder to purchase one share of CEL-SCI's common stock at a price of \$12.00 per share at any time on or before February 15, 2021. As of September 30, 2017, none of the Series Y warrants had been exercised.

On May 23, 2016, CEL-SCI closed a registered direct offering of 400,000 shares of common stock and 264,000 Series Z warrants to purchase shares of common stock. The common stock and warrants were sold at a combined per unit price of \$12.50 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 before November 23, 2021 at a price of \$13.75 per share. CEL-SCI also issued 20,000 Series ZZ warrants to the placement agent as part of its compensation. The Series ZZ warrants may be exercised at any time on or before May 18, 2021 at a price of \$13.75 per share. As of September 30, 2017, none of the Series Z and ZZ warrants had been exercised.

On August 26, 2016, CEL-SCI closed a registered direct offering of 400,000 shares of common stock and Series AA warrants to purchase up to 200,000 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 \$12.50. Each warrant can be exercised at any time on or before February 22, 2022 at a price of \$13.75 per share. CEL-SCI also issued 16,000 Series BB warrants to the placement agent as part of its compensation. The Series BB warrants may be exercised at any time on or before August 22, 2021 at a price of \$13.75 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, 2017, none of the Series AA and BB warrants had been exercised.

On December 8, 2016, the Company sold 1,360,960 shares of common stock and warrants to purchase common stock at a price of \$3.13 in a public offering. The warrants consist of 680,480 Series CC warrants to purchase 680,480 shares of common stock, 1,360,960 Series DD warrants to purchase 1,360,960 shares of common stock and 1,360,960 Series EE warrants to purchase 1,360,960 shares of common stock. The Series CC warrants are immediately exercisable, expire in five-years and have an exercise price of \$5.00 per share. The Series DD warrants are immediately exercisable, expire on December 1, 2017 and have an exercise price of \$4.50 per share. The Series EE warrants are immediately exercisable, expire on December 1, 2017 and have an exercise price of \$4.50 per share. The Series EE warrants are immediately exercisable, expire on December 1, 2017 and have an exercise price of \$4.50 per share. The Series EE warrants are immediately exercisable, expire on December 1, 2017 and have an exercise price of \$4.50 per share. In addition, the Company issued 68,048 Series FF warrants to purchase 68,048 shares of common stock to the placement agent. The FF warrants are exercisable at any time on or before December 1, 2021 and have an exercise price \$3.91. The net proceeds to CEL-SCI from this offering was approximately \$3.7 million, excluding any future proceeds that may be received from the exercise of the warrants. As of September 30, 2017, none of the Series CC, DD and EE warrants had been exercised.

On February 23, 2017, CEL-SCI sold 400,000 registered shares of common stock and 400,000 Series GG warrants to purchase 400,000 unregistered shares of common stock at a combined price of \$2.50 per share. The Series GG warrants have an exercise price of \$3.00 per share are exercisable on or before August 23, 2022. In addition, CEL-SCI issued 20,000 Series HH warrants to purchase 20,000 shares of unregistered common stock to the placement agent. The Series HH warrants have an exercise price \$3.13 and are exercisable on or before February 16, 2022. The net proceeds from this offering were approximately \$0.8 million. As of September 30, 2017, none of the Series GG and HH warrants had been exercised.

On March 14, 2017, CEL-SCI sold 600,000 registered shares of common stock and 600,000 Series II warrants to purchase 600,000 unregistered shares of common stock at combined offering price of \$2.50 per share. The Series II warrants have an exercise price of \$3.00 per share and are exercisable on or before September 14, 2022. In addition, CEL-SCI issued 30,000 Series JJ warrants to purchase 30,000 shares of unregistered common stock to the placement agent. The Series JJ warrants have an exercise price \$3.13 and are exercisable on or before March 8, 2022. The net proceeds from this offering were approximately \$1.3 million. As of September 30, 2017, none of the Series II and JJ warrants had been exercised.

On April 30, 2017, CEL-SCI sold 527,960 registered shares of common stock and 395,970 Series KK warrants to purchase 395,970 unregistered shares of common stock at combined offering price of \$2.88 per share. The Series KK warrants have an exercise price of \$3.04 per share, are exercisable on November 3, 2017 and expire on November 3, 2022. In addition, CEL-SCI issued 26,398 Series LL warrants to purchase 26,398 shares of unregistered common stock to the placement agent. The Series LL warrants have an exercise price \$3.59, are exercisable on October 30, 2017 and expire on April 30, 2022. The net proceeds from this offering were approximately \$1.4 million. As of September 30, 2017, none of the Series KK and LL warrants had been exercised.

On June 22, 2017, CEL-SCI issued Series MM warrants in connection with the issuance of convertible notes in the aggregate principal amount of \$1.5 million to six individual investors. Geert Kersten, CEL-SCI's Chief Executive Officer, participated in the offering and purchased notes in the principal amount of \$250,000. The notes bear interest at 4% per year and are due and payable on December 22, 2017. At the option of the note holders, the notes can be

converted into shares of the Company's common stock at a fixed conversion rate of \$1.69. The Series MM warrants entitle the purchasers to acquire 893,491 shares of CEL-SCI's common stock. The Series MM warrants are exercisable at \$1.86 per share and expire on June 22, 2022. Shares issuable upon the exercise of the notes and warrants were registered subsequently. As of September 30, 2017, \$450,700 of the notes had been converted into 266,686 shares of CEL-SCI's common stock and none of the Series MM warrants had been exercised.

On July 17, 2017, CEL-SCI extended the expiration date of the Series N warrants to August 18, 2018, reduced the exercise price from \$13.18 to \$3.00 and reduced the number of warrants outstanding from 113,785 to 85,339. As of September 30, 2017, the remaining 85,339 Series N warrants entitle the holders to purchase one share of CEL-SCI's common stock at a price of \$3.00 per share at any time prior to August 18, 2018.

On July 24, 2017, CEL-SCI issued Series NN warrants in connection with the issuance of convertible notes in the aggregate principal amount of \$1.2 million to twelve individual investors. A trust in which Geert Kersten, CEL-SCI's Chief Executive Officer, holds a beneficial interest participated in the offering and purchased notes in the principal amount of \$250,000. Patricia B. Prichep, CEL-SCI's Senior Vice President of Operations, purchased a note in the principal amount of \$25,000. The notes bear interest at 4% per year and are due and payable on December 22, 2017. At the option of the note holders, the notes can be converted into shares of the Company's common stock at a fixed conversion rate of \$2.29. The Series NN warrants entitle the purchasers to acquire 539,300 shares of CEL-SCI's common stock. The Series NN warrants are exercisable at \$2.52 per share and expire on July 24, 2022. Shares issuable upon the exercise of the notes and warrants were registered subsequently. As of September 30, 2017, none of the notes had been converted and none of the Series NN warrants had been exercised.

On November 2, 2017 holders of convertible notes in the principal amount of \$1,059,300 sold in June 2017 and holders of convertible notes in the principal amount of \$1,235,000 sold in July 2017 agreed to extend the maturity date of these notes to September 21, 2018.

In consideration for the extension of the maturity date of the convertible notes, the Company issued a total of 716,400 Series RR warrants to the convertible note holders that agreed to the extension. Each Series RR warrant entitles the holder to purchase one share of the Company's common stock. The Series RR warrants may be exercised at any time on or before October 30, 2022 at an exercise price of \$1.65 per share.

On July 26, 2017, CEL-SCI sold 100,000 registered shares of common stock and 60,000 Series OO warrants to purchase 60,000 unregistered shares of common stock at a combined price of \$2.29 per share. The Series OO warrants have an exercise price of \$2.52 per share are exercisable on January 31, 2018 and expire on July 31, 2022. The net proceeds from this offering were approximately \$222,000. As of September 30, 2017, none of the Series OO warrants had been exercised.

On August 22, 2017, CEL-SCI sold 1,750,000 registered shares of common stock and 1,750,000 Series PP warrants to purchase 1,750,000 unregistered shares of common stock at combined offering price of \$2.00 per share. The Series PP warrants have an exercise price of \$2.30 per share, are exercisable on February 28, 2018 and expire on February 28, 2023. In addition, CEL-SCI issued 87,500 Series QQ warrants to purchase 87,500 shares of unregistered common stock to the placement agent. The Series QQ warrants have an exercise price \$2.50, are exercisable on February 22, 2018 and expire on August 22, 2022. The net proceeds from this offering were approximately \$3.2 million. As of September 30, 2017, none of the Series PP and QQ warrants had been exercised.

Inventory decreased by approximately \$336,000 at September 30, 2017 as compared to September 30, 2016, due to the timing of supplies purchased and used in the manufacturing of Multikine for the Phase 3 clinical trial. In addition, receivables decreased by approximately \$176,000, primarily due to the timing of payments reimbursed under the litigation funding arrangement noted above and the timing of shipments of Multikine.

During the year ended September 30, 2017, the Company's cash decreased by approximately \$549,000. Significant components of this decrease include: net cash used in operating activities of approximately \$13.8 million and expenditures for equipment and patents, as well as payments on capital leases, of approximately \$21,000, offset by proceeds from the sale of common stock and warrants of approximately \$10.5 million and proceeds from the issuance of notes payable of approximately \$2.7 million.

# **Future Capital Requirements**

The Company's material capital commitments include funding operating losses, funding its research and development program, making required lease payments and repaying convertible notes. As of September 30, 2017, material contractual obligations are as follows:

|                                  | Years Ending September 30, |              |              |              |              |              |                      |  |
|----------------------------------|----------------------------|--------------|--------------|--------------|--------------|--------------|----------------------|--|
|                                  | Total                      | 2018         | 2019         | 2020         | 2021         | 2022         | 2023 &<br>thereafter |  |
| Operating Leases                 | \$ 979,000                 | \$ 251,000   | \$ 258,000   | \$ 238,000   | \$ 163,000   | \$ 69,000    | \$ -                 |  |
| Financing Lease <sup>(1)</sup>   | 23,126,000                 | 1,747,000    | 1,808,000    | 1,872,000    | 1,937,000    | 2,004,000    | 13,758,000           |  |
| Convertible Notes <sup>(2)</sup> | 2,407,019                  | 2,407,019    | -            | -            | -            | -            | -                    |  |
| Total Contractual Obligations    | \$ 26,512,019              | \$ 4,405,019 | \$ 2,066,000 | \$ 2,110,000 | \$ 2,100,000 | \$ 2,073,000 | \$ 13,758,000        |  |

(1) The amounts include future minimum lease payments under the Company's lease of its manufacturing facility (the San Tomas lease)

<sup>(2)</sup> The amounts include future interest payments at a fixed rate of 4% and payment of the notes in full upon maturity in 2018

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 it will incur additional expenses of approximately \$13.0 million for the remainder of the Phase 3 clinical trial. It should be noted that this estimate is based only on the information currently available in CEL-SCI's contracts with the Clinical Research Organizations responsible for managing the Phase 3 clinical trial 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 2018 to continue operations into March 2018. 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 3 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 critical 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 and intangibles 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.

# **CEL-SCI CORPORATION**

Financial Statements for the Years Ended September 30, 2017 and 2016, and Report of Independent Registered Public Accounting Firm

# **CEL-SCI CORPORATION**

# TABLE OF CONTENTS

|   | Page |
|---|------|
| REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM               | F- 2 |
| FINANCIAL STATEMENTS FOR THE YEARS ENDED SEPTEMBER 30, 2017 and 2016: |      |
| Balance Sheets  | F- 3 |
| Statements of Operations  | F- 4 |
| Statements of Stockholders' Deficit                                   | 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, 2017 and 2016 and the related statements of operations, stockholders' deficit, and cash flows for the years then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of the Company at September 30, 2017 and 2016, and the results of its operations and its cash flows for the years then ended, 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 negative working capital, stockholders' deficit, 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.

/s/ BDO USA, LLP

McLean, Virginia December 29, 2017

#### CEL-SCI CORPORATION BALANCE SHEETS SEPTEMBER 30, 2017 and 2016

| ASSETS   | 2017          | 2016          |
|--|---------------|---------------|
| Current Assets:  |               |               |
| Cash and cash equivalents                                      | \$ 2,369,438  | \$ 2,917,996  |
| Receivables  | 218,481       | 394,515       |
| Prepaid expenses   | 826,429       | 981,677       |
| Deposits - current portion                                     | 150,000       | 154,995       |
| Inventory used for R&D and manufacturing                       | 672,522       | 1,008,642     |
| Total Current Assets   | 4,236,870     | 5,457,825     |
| Plant, property and equipment                                  | 16,793,220    | 17,350,836    |
| Patent costs, net  | 223,167       | 256,547       |
| Deposits   | 1,670,917     | 1,820,917     |
| Total Assets   | \$ 22,924,174 | \$ 24,886,125 |
| LIABILITIES AND STOCKHOLDERS' DEFICIT                          |               |               |
| Current Liabilities:   |               |               |
| Accounts payable   | \$ 8,196,334  | \$ 3,091,512  |
| Accrued expenses   | 936,698       | 378,672       |
| Due to employees   | 693,831       | 538,278       |
| Notes payable, net of discounts                                | 994,258       | -             |
| Derivative instruments, current portion                        | 10,984        | -             |
| Other current liabilities                                      | 12,449        | 3,310         |
| Total Current Liabilities                                      | 10,844,554    | 4,011,772     |
| Derivative instruments, net of current portion                 | 2,042,418     | 8,394,934     |
| Lease liability  | 13,211,925    | 13,011,023    |
| Deferred revenue   | 125,000       | 125,000       |
| Other liabilities  | 37,254        | 22,609        |
| Total liabilities  | 26,261,151    | 25,565,338    |
| Commitments and Contingencies                                  |               |               |
| STOCKHOLDERS' DEFICIT  |               |               |
| Preferred stock, \$.01 par value- 200,000 shares authorized;   |               |               |
| -0- shares issued and outstanding                              | -             | -             |
| Common stock, \$.01 par value - 600,000,000 shares authorized; |               |               |
| 11,903,133 and 6,248,035 shares issued and outstanding         |               |               |
| at September 30, 2017 and 2016, respectively                   | 119,031       | 62,480        |
| Additional paid-in capital                                     | 296,298,401   | 284,649,429   |
| Accumulated deficit  | (299,754,409) | (285,391,122) |
| Total stockholders' deficit                                    | (3,336,977)   | (679,213)     |
| TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT                    | \$ 22,924,174 | \$ 24,886,125 |

#### CEL-SCI CORPORATION STATEMENTS OF OPERATIONS YEARS ENDED SEPTEMBER 30, 2017 and 2016

|   |                       | 2017         | 2016       |              |  |
|---|-----------------------|--------------|------------|--------------|--|
| Grant and other income                        | \$                    | 69,020       | \$         | 285,055      |  |
| Operating expenses:                           |                       |              |            |              |  |
| Research and development                      |                       | 15,606,985   | 17         | 7,445,382    |  |
| General & administrative                      |                       | 5,800,348    | (          | 6,486,501    |  |
| Total operating expenses                      |                       | 21,407,333   | 23         | 3,931,883    |  |
| Operating loss                                | (21,338,313) (2       |              |            | (23,646,828) |  |
| Gain on derivative instruments                |                       | 11,007,215   | 14,013,726 |              |  |
| Interest expense, net                         | (4,032,189) (1,879,39 |              |            | ,879,390)    |  |
| Net loss                                      |                       | (14,363,287) | (11        | ,512,492)    |  |
| Modification of warrants                      |                       | (63,768)     |            | -            |  |
| Net loss available to common shareholders     | \$                    | (14,427,055) | \$ (11     | ,512,492)    |  |
| NET LOSS PER COMMON SHARE                     |                       |              |            |              |  |
| BASIC   | \$                    | (1.83)       | \$         | (2.37)       |  |
| DILUTED                                       | \$                    | (1.91)       | \$         | (2.37)       |  |
| WEIGHTED AVERAGE COMMON SHARES<br>OUTSTANDING |                       |              |            |              |  |
| BASIC   |                       | 7,891,843    | 2          | 4,866,204    |  |
| DILUTED                                       |                       | 7,902,647    | 2          | 4,866,204    |  |
|   |                       |              |            |              |  |

#### CEL-SCI CORPORATION STATEMENTS OF STOCKHOLDERS' DEFICIT YEARS ENDED SEPTEMBER 30, 2017 and 2016

| -  | Common<br>Shares | Stock<br>Amount | Additional<br>Paid-In<br>Capital | Accumulated<br>Deficit | Total          |
|--|------------------|-----------------|----------------------------------|------------------------|----------------|
| BALANCE, OCTOBER 1, 2015                       | 4,503,975        | \$ 45,040       | \$ 269,071,320                   | \$ (273,878,630)       | \$ (4,762,270) |
| Sale of common stock                           | 1,660,930        | 16,609          | 21,357,087                       | -                      | 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      | 16,340           | 163             | 161,408                          | -                      | 161,571        |
| Stock issued to nonemployees for service       | 49,953           | 500             | 689,813                          | -                      | 690,313        |
| Equity based compensation - employees          | 16,837           | 168             | 2,012,515                        | -                      | 2,012,683      |
| Equity based compensation - non-employees      | -                | -               | 79,359                           | -                      | 79,359         |
| Net loss                                       |                  |                 |                                  | (11,512,492)           | (11,512,492)   |
| BALANCE, SEPTEMBER 30, 2016                    | 6,248,035        | 62,480          | 284,649,429                      | (285,391,122)          | (679,213)      |
| Sale of common stock                           | 4,738,920        | 47,389          | 10,482,917                       | -                      | 10,530,306     |
| Issuance of warrants in connection with        |                  |                 |                                  |                        | -              |
| sale of common stock                           | -                | -               | (4,665,683)                      | -                      | (4,665,683)    |
| Warrants issued with notes payable             | -                | -               | 1,108,867                        | -                      | 1,108,867      |
| Beneficial conversion feature on notes payable |                  |                 | 1,108,867                        |                        | 1,108,867      |
| 401(k) contributions paid in common stock      | 79,941           | 799             | 150,509                          | -                      | 151,308        |
| Conversion of notes payable to common stock    | 266,686          | 2,667           | 448,033                          | -                      | 450,700        |
| Stock issued to nonemployees for service       | 76,551           | 766             | 203,817                          | -                      | 204,583        |
| Ergomed stock issuance                         | 480,000          | 4,800           | 1,305,600                        | -                      | 1,310,400      |
| Equity based compensation - employees          | 13,000           | 130             | 1,481,120                        | -                      | 1,481,250      |
| Equity based compensation - non-employees      | -                | -               | 24,925                           | -                      | 24,925         |
| Net loss                                       | -                |                 |                                  | (14,363,287)           | (14,363,287)   |
| BALANCE, SEPTEMBER 30, 2017                    | 11,903,133       | \$ 119,031      | \$ 296,298,401                   | \$ (299,754,409)       | \$ (3,336,977) |

#### CEL-SCI CORPORATION STATEMENTS OF CASH FLOWS YEARS ENDED SEPTEMBER 30, 2017 and 2016

|   | 2017               | 2016            |
|---|--------------------|-----------------|
| CASH FLOWS FROM OPERATING ACTIVITIES:                       |                    |                 |
| Net loss  | \$ (14,363,287)    | \$ (11,512,492) |
| Adjustments to reconcile net loss to                        |                    |                 |
| net cash used in operating activities:                      |                    | <b>662</b> 000  |
| Depreciation and amortization                               | 632,915            | 663,988         |
| Share based payments for services                           | 232,847            | 751,651         |
| Equity based compensation                                   | 1,380,500          | 2,113,433       |
| Common stock contributed to 401(k) plan                     | 151,308            | 161,571         |
| Ergomed stock issuance                                      | 1,310,400          | - 248           |
| Loss on retired equipment<br>Gain on derivative instruments | 1,187              | =               |
| Amortization of debt discount                               | (11,007,215)       | (14,013,726)    |
| Capitalized lease interest                                  | 917,692<br>200,902 | 227,773         |
| (Increase)/decrease in assets:                              | 200,902            | 221,113         |
| Receivables   | (129,307)          | (1,960)         |
| Prepaid expenses  | 151,909            | 15,999          |
| Inventory used for R&D and manufacturing                    | 336,120            | 393,197         |
| Deposits  | 154,995            | 145,005         |
| Increase/(decrease) in liabilities:                         | 154,775            | 145,005         |
| Accounts payable  | 5,420,816          | (2,389,931)     |
| Accrued expenses  | 558,026            | 290,097         |
| Deferred revenue  | -                  | (1,639)         |
| Due to employees  | 256,303            | 72,397          |
| Deferred rent liability                                     | 1,995              | 1,896           |
|   |                    |                 |
| Net cash used in operating activities                       | (13,791,894)       | (23,082,493)    |
| CASH FLOWS FROM INVESTING ACTIVITIES:                       |                    |                 |
| Purchases of equipment                                      | (10,525)           | (31,405)        |
| Expenditures for patent costs                               | (6,477)            | (2,819)         |
|   | (0,177)            | (2,01))         |
| Net cash used in investing activities                       | (17,002)           | (34,224)        |
| CASH FLOWS FROM FINANCING ACTIVITIES:                       |                    |                 |
| Proceeds from issuance of common stock and warrants         | 10,519,306         | 21,420,301      |
| Payment on related party loan                               | -                  | (1,104,057)     |
| Proceeds from notes payable                                 | 2,745,000          | -               |
| Payments on obligations under capital lease                 | (3,968)            | (8,213)         |
|   | i                  |                 |
| Net cash provided by financing activities                   | 13,260,338         | 20,308,031      |
| NET DECREASE IN CASH AND CASH EQUIVALENTS                   | (548,558)          | (2,808,686)     |
| CASH AND CASH EQUIVALENTS, BEGINNING OF YEAR                | 2,917,996          | 5,726,682       |
| CASH AND CASH EQUIVALENTS, END OF YEAR                      | \$ 2,369,438       | \$ 2,917,996    |

#### CEL-SCI CORPORATION STATEMENTS OF CASH FLOWS YEARS ENDED SEPTEMBER 30, 2017 and 2016

#### SUPPLEMENTAL SCHEDULE OF NON-CASH INVESTING AND FINANCING ACTIVITIES:

| 2017 |             | 2016   |   |
|------|-------------|--|---|
|      |             |  |   |
| \$   | (305,341)   | \$   | 305,341   |
|      | 450,700     |  | -   |
|      | 1,890       |  | 815   |
|      | (4,665,683) |  | (8,722,073)   |
|      | 35,605      |  | 46,605  |
|      | (3,339)     |  | 18,021  |
|      | 275,000     |  | -   |
|      |             |  |   |
|      |             |  |   |
|      | \$          | \$ (305,341)<br>450,700<br>1,890<br>(4,665,683)<br>35,605<br>(3,339) | \$ (305,341) \$<br>450,700<br>1,890<br>(4,665,683)<br>35,605<br>(3,339) |

Cash paid for interest expense

See notes to financial statements.

\$ 1,888,612

\$ 1,900,567

# 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.

The Company 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, for which the Company has received Orphan Drug Status from the United States Food and Drug Administration (FDA). 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.

The Company's immune therapy, Multikine, is being used in a different way than immune therapy is usually used. It is given before any other therapy has been administered because that is when the immune system is thought to be strongest. It is also administered locally to treat tumors or infections. For example, in the Phase 3 clinical trial, Multikine is given locally at the site of the tumor as a first line treatment before surgery, radiation and/or chemotherapy. 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.

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.

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. On August 10, 2017, the Company received a letter from the FDA stating that the clinical hold that had been imposed on the Phase 3 cancer study with Multikine has been removed and that all clinical trial activities for the Phase 3 study may resume. On December 7, 2017, the Company announced that the Independent Data Monitoring Committee (IDMC) has completed its review of the Phase 3 study data. The data from all 928 enrolled patients were provided to the IDMC by the Clinical Research Organization (CRO) responsible for data management of this Phase 3 study. The IDMC made the following observation and recommendation: a) the IDMC saw no evidence of any significant safety questions and b) the IDMC recommends continuing the study. On December 11, 2017, the Company announced that the Phase 3 study was fully enrolled. The activities in the Phase 3 study are now focused on the follow-up of the patients enrolled to determine if there is a survival benefit in favor of Multikine.

# 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 securities. The Company will be required to raise additional capital or find additional long-term financing in order to continue with its research efforts. To date, the Company has not generated any revenue from product sales. As a result, the Company 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 2017 and 2016, the Company raised net proceeds of approximately \$13.3 million and \$21.4 million, respectively, through the sale of stock and the issuance of convertible notes. The ability of the Company to complete the necessary clinical trials and obtain FDA approval for the sale of products to be developed on a commercial basis is uncertain. Ultimately, the Company must complete the development of its products, obtain the appropriate regulatory approvals and obtain sufficient revenues to support its cost structure.

The Company is currently running a large multi-national Phase 3 clinical trial for head and neck cancer with its partners TEVA Pharmaceuticals and Orient Europharma. To finance the study beyond the next twelve months, the Company plans to raise additional capital in the form of corporate partnerships, debt and/or equity financings. 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 on a timely basis or that the funds will be available to the Company on acceptable terms or at all. If the Company does not raise the necessary amounts of money, it may have to 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 negative working capital, stockholders' deficit, recurring losses from operations and future liquidity needs, 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 incurred expenses of approximately \$45.9 million as of September 30, 2017 on direct costs for the Phase 3 clinical trial. The Company estimates it will incur additional expenses of approximately \$13.0 million for the remainder of the Phase 3 clinical trial. 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 and does not include other related costs, e.g., the manufacturing of the drug. This number can be affected by the speed of enrollment, foreign currency exchange rates and many other factors, some of which cannot be foreseen.

Nine hundred twenty-eight (928) head and neck cancer patients have been enrolled and have completed treatment in the Phase 3 study. The study endpoint is a 10% increase in overall survival of patients between the two main comparator groups in favor of the group receiving the Multikine treatment regimen. The determination if the study end point is met will occur when there are a total of 298 deaths in those two groups.

On June 12, 2017, the Company's shareholders approved a reverse split of the Company's common stock which became effective on the NYSE American on June 15, 2017. On that date, every twenty five issued and outstanding shares of the Company's common stock automatically converted into one outstanding share. As a result of the reverse stock split, the number of the Company's outstanding shares of common stock decreased from 230,127,331 (pre-split) shares to 9,201,645 (post-split) shares. In addition, by reducing the number of the Company's outstanding shares, the Company's loss per share in all prior periods increased by a factor of twenty five. The reverse stock split affected all stockholders of the Company's common stock uniformly, and did not affect any stockholder's percentage of ownership interest. The par value of the Company's stock remained unchanged at \$0.01

per share and the number of authorized shares of common stock remained the same after the reverse stock split.

# 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.

*Plant, property and equipment*– The leased manufacturing facility is recorded at total project costs incurred and is depreciated over the 20-year useful life of the building. 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 plant, property and equipment 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.

*Leases* – Leases are categorized as either operating or capital leases at inception. Operating lease costs are recognized on a straight-line basis over the term of the lease. An asset and a corresponding liability for the capital lease obligation are established for the cost of capital leases. The capital lease obligation is amortized over the life of the lease. For build-to-suit leases, the Company establishes an asset and liability for the estimated construction costs incurred to the extent that it is involved in the construction of structural improvements or takes construction risk prior to the commencement of the lease. Upon occupancy of facilities under build-to-suit leases, the Company assesses whether these arrangements qualify for sales recognition under the sale-leaseback accounting guidance. If a lease does not meet the criteria to qualify for a sale-leaseback transaction, the established asset and liability remain on the Company's balance sheet. See Note 11.

*Deferred Rent* – 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 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. Management accrues CRO expenses and clinical trial study expenses based on services performed and relies on the CROs to provide estimates of those costs applicable to the completion stage of a study. Estimated accrued CRO costs are subject to revisions as such studies progress to completion. The Company charges revisions to estimated expense in the period in which the facts that give rise to the revision become known.

*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, 2017.

*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, 2017 and 2016.

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 14 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.

#### Recent Accounting Pronouncements -

In May 2017, the FASB issued ASU 2017-09, *Compensation – Stock Compensation (Topic 718)*, which affects any entity that changes the terms or conditions of a share-based payment award. This Update amends the definition of modification by qualifying that modification accounting does not apply to changes to outstanding share-based payment awards that do not affect the total fair value, vesting requirements, or equity/liability classification of the awards. The amendments in this Update are effective for all entities for annual periods, and interim periods within those annual periods, beginning after December 15, 2017. Early adoption is permitted, including adoption in any interim period, for (1) public business entities for reporting periods for which financial statements have not yet been issued and (2) all other entities for reporting periods for which financial statements have not yet been made available for issuance. The amendments in this Update should be applied prospectively to an award modified on or after the adoption date. The Company is currently evaluating the impact the adoption of the standard will have on the Company's financial position or results of operations.

In July 2017, the FASB issued ASU 2017-11, Earnings Per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480), and Derivative and Hedging (Topic 815). The amendments in Part I of this Update change the classification analysis of certain equity-linked financial instruments (or embedded features) with down-round features. When determining whether certain financial instruments should be classified as liabilities or equity instruments, a down-round feature no longer precludes equity classification when assessing whether the instrument is indexed to an entity's own stock. The amendments also clarify existing disclosure requirements for equity-classified instruments. As a result, a freestanding equity-linked financial instrument (or embedded conversion option) no longer would be accounted for as a derivative liability at fair value as a result of the existence of a down-round feature. For freestanding equity classified financial instruments, the amendments require entities that present earnings per share ("EPS") in accordance with Topic 260 to recognize the effect of the down-round feature when it is triggered. That effect is treated as a dividend and as a reduction of income available to common shareholders in basic EPS. Convertible instruments with embedded conversion options that have down- round features are now subject to the specialized guidance for contingent beneficial conversion features (in Subtopic 470-20, Debt-Debt with Conversion and Other Options), including related EPS guidance (in Topic 260). The amendments in Part II of this Update recharacterize the indefinite deferral of certain provisions of Topic 480 that now are presented as pending content in the Accounting Standards Codification, to a scope exception. Those amendments do not have an accounting effect. For public business entities, the amendments in Part I of this Update are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018. For all other entities, the amendments in Part I of this Update are effective for fiscal years beginning after December 15, 2019, and interim periods within fiscal years beginning after December 15, 2020. Early adoption is permitted for all entities, including adoption in an interim period. If an entity early adopts the amendments in an interim period, any adjustments should be reflected as of the beginning of the fiscal year that includes that interim period. The amendments in Part I of this Update should be applied either retrospectively to outstanding financial instruments with a down-round feature by means of a cumulative-effect adjustment to the statement of financial position as of the beginning of the first fiscal year and interim period(s) in which the pending content that links to this paragraph is effective or retrospectively to outstanding financial instruments with a down-round feature for each prior reporting period presented in accordance with the guidance on accounting changes in paragraphs 250-10-45-5 through 45-10. The amendments in Part II of this Update do not require any transition guidance because those amendments do not have an accounting effect. The Company is currently evaluating the impact the adoption of the standard will have on the Company's financial position or results of operations.

In August 2017, the FASB issued ASU 2017-12, *Derivatives and Hedging (Topic 850)*, the objective of which is to improve the financial reporting of hedging relationships to better portray the economic results of an entity's risk management activities in its financial statements. In addition, the amendments in this Update make certain targeted improvements to simplify the application and disclosure of the hedge accounting guidance in current general accepted accounting principles. For public business

entities, the amendments in this Update are effective for fiscal years beginning after December 15, 2018, and interim periods within those fiscal years. For all other entities, the amendments are effective for fiscal years beginning after December 15, 2019, and interim periods beginning after December 15, 2020. Early adoption is permitted in any period after issuance. For cash flow and net investment hedges existing at the date of adoption, an entity should apply a cumulative-effect adjustment related to eliminating the separate measurement of ineffectiveness to accumulated other comprehensive income with a corresponding adjustment to the opening balance of retained earnings as of the beginning of the fiscal year that an entity adopts the amendments in this Update. The amended presentation and disclosure guidance is required only prospectively. The Company is currently evaluating the impact the adoption of the standard will have on the Company's financial position or results of operations.

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. Although the Company has not completed its evaluation of the impact of the adoption of ASU 2016-02, because the Company's most significant operating lease is currently on its balance sheet (see Note 11), the adoption of ASU 2016-02 is not expected to have a material impact to the financial statements.

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 does not expect the adoption of this new amendment to have a material impact on its financial statements and related disclosures. The estimated forfeiture rate is based on historical information, however, the Company will no longer estimate the forfeiture rate on share based payments, but rather recognize forfeitures as they occur.

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, 2017:

| <u>Warrant</u> | Issue Date            | Shares<br>Issuable<br>upon<br>Exercise of<br><u>Warrants</u> | Exercise<br><u>Price</u> | Expiration<br>Date | <u>Refer-</u><br>ence |
|----------------|-----------------------|--|--------------------------|--------------------|-----------------------|
| Series U       | 4/17/2014             | 17,821   | \$43.75                  | 10/17/2017         | 1                     |
| Series DD      | 12/8/2016             | 1,360,960  | \$4.50                   | 12/1/2017          | 1                     |
| Series EE      | 12/8/2016             | 1,360,960  | \$4.50                   | 12/1/2017          | 1                     |
| Series N       | 8/18/2008             | 85,339   | \$3.00                   | 8/18/2018          | 2                     |
| Series S       | 10/11/13-<br>10/24/14 | 1,037,120  | \$31.25                  | 10/11/2018         | 1                     |

| Series V    | 5/28/2015            | 810,127   | \$19.75            | 5/28/2020            | 1 |
|-------------|----------------------|-----------|--------------------|----------------------|---|
| Series W    | 10/28/2015           | 688,930   | \$16.75            | 10/28/2020           | 1 |
| Series X    | 1/13/2016            | 120,000   | \$9.25             | 1/13/2021            | 2 |
| Series Y    | 2/15/2016            | 26,000    | \$12.00            | 2/15/2021            | 2 |
| Series ZZ   | 5/23/2016            | 20,000    | \$13.75            | 5/18/2021            | 1 |
| Series BB   | 8/26/2016            | 16,000    | \$13.75            | 8/22/2021            | 1 |
| Series Z    | 5/23/2016            | 264,000   | \$13.75            | 11/23/2021           | 1 |
| Series FF   | 12/8/2016            | 68,048    | \$3.91             | 12/1/2021            | 1 |
| Series CC   | 12/8/2016            | 680,480   | \$5.00             | 12/8/2021            | 1 |
| Series HH   | 2/23/2017            | 20,000    | \$3.13             | 2/16/2022            | 1 |
| Series AA   | 8/26/2016            | 200,000   | \$13.75            | 2/22/2022            | 1 |
| Series JJ   | 3/14/2017            | 30,000    | \$3.13             | 3/8/2022             | 1 |
| Series LL   | 4/30/2017            | 26,398    | \$3.59             | 4/30/2022            | 1 |
| Series MM   | 6/22/2017            | 893,491   | \$1.86             | 6/22/2022            | 2 |
| Series NN   | 7/24/2017            | 539,300   | \$2.52             | 7/24/2022            | 2 |
| Series OO   | 7/31/2017            | 60,000    | \$2.52             | 7/31/2022            | 2 |
| Series QQ   | 8/22/2017            | 87,500    | \$2.50             | 8/22/2022            | 2 |
| Series GG   | 2/23/2017            | 400,000   | \$3.00             | 8/23/2022            | 1 |
| Series II   | 3/14/2017            | 600,000   | \$3.00             | 9/14/2022            | 1 |
| Series KK   | 5/3/2017             | 395,970   | \$3.04             | 11/3/2022            | 1 |
| Series PP   | 8/28/2017            | 1,750,000 | \$2.30             | 2/28/2023            | 2 |
| Consultants | 12/28/12-<br>7/28/17 | 42,000    | \$2.18-<br>\$70.00 | 12/27/17-<br>7/27/27 | 3 |
|             |                      |           |                    |                      |   |

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

|                |                   | Shares          |          |            |              |
|----------------|-------------------|-----------------|----------|------------|--------------|
|                |                   | Issuable upon   | <b>F</b> |            | Defen        |
| ***            |                   | Exercise of     | Exercise | Expiration | <u>Refer</u> |
| <u>Warrant</u> | Issue <u>Date</u> | <u>Warrants</u> | Price    | Date       | -ence        |
| Series N       | 8/18/08           | 113,785         | \$13.18  | 8/18/17    | 2            |
| Series R       | 12/6/12           | 105,000         | \$100.00 | 12/6/16    | 1            |
| Series U       | 4/17/14           | 17,821          | \$43.75  | 10/17/17   | 1            |
| Series S       | 10/11/13 -        |                 |          |            |              |
|                | 10/24/14          | 1,037,120       | \$31.25  | 10/11/18   | 1            |
| Series V       | 5/28/15           | 810,127         | \$19.75  | 5/28/20    | 1            |
| Series W       | 10/28/15          | 688,930         | \$16.75  | 10/28/20   | 1            |
| Series X       | 1/13/16           | 120,000         | \$9.25   | 1/13/21    | 2            |
| Series Y       | 2/15/16           | 26,000          | \$12.00  | 2/15/21    | 2            |
| Series ZZ      | 5/23/16           | 20,000          | \$13.75  | 5/18/21    | 1            |
| Series Z       | 5/23/16           | 264,000         | \$13.75  | 11/23/21   | 1            |
| Series AA      | 8/26/16           | 200,000         | \$13.75  | 2/22/22    | 1            |
| Series BB      | 8/26/16           | 16,000          | \$13.75  | 8/22/21    | 1            |
|                |                   |                 |          |            | _            |
| Series P       | 2/10/12           | 23,600          | \$112.50 | 3/6/17     | 2            |
| Consultants    | 12/2/11-          |                 | \$9.25-  | 10/27/16-  |              |
|                | 7/1/16            | 25,600          | \$87.50  | 6/30/19    | 3            |
|                |                   |                 |          |            |              |

#### 1. Warrant Liabilities

|                           | 2017      |           | 2016      |           |
|---------------------------|-----------|-----------|-----------|-----------|
| Series S warrants         | \$        | 32,773    | \$        | 3,111,361 |
| Series U warrants         |           | -         |           | -         |
| Series V warrants         |           | 72,912    |           | 1,620,253 |
| Series W warrants         |           | 83,754    |           | 1,799,858 |
| Series Z warrants         |           | 77,216    |           | 970,604   |
| Series ZZ warrants        |           | 4,753     |           | 70,609    |
| Series AA warrants        |           | 65,087    |           | 763,661   |
| Series BB warrants        |           | 4,322     |           | 58,588    |
| Series CC warrants        |           | 394,220   |           | -         |
| Series DD warrants        |           | 5,492     |           | -         |
| Series EE warrants        |           | 5,492     |           | -         |
| Series FF warrants        |           | 47,154    |           | -         |
| Series GG warrants        |           | 342,173   |           | -         |
| Series HH warrants        |           | 16,014    |           | -         |
| Series II warrants        |           | 511,636   |           | -         |
| Series JJ warrants        |           | 24,203    |           | -         |
| Series KK warrants        |           | 345,720   |           | -         |
| Series LL warrants        |           | 20,481    |           | _         |
| Total warrant liabilities | <u>\$</u> | 2,053,402 | <u>\$</u> | 8,394,934 |

The table below presents the warrant liabilities and their respective balances at September 30:

The table below presents the gains on the warrant liabilities for the years ended September 30:

|                                 | 2017                | 2016                 |  |
|---------------------------------|---------------------|----------------------|--|
| Series S Warrants               | \$ 3,078,588        | \$ 4,252,193         |  |
| Series U warrants               | -                   | 44,552               |  |
| Series V warrants               | 1,547,341           | 4,658,228            |  |
| Series W warrants               | 1,716,104           | 3,260,913            |  |
| Series Z warrants               | 893,388             | 997,226              |  |
| Series ZZ warrants              | 65,856              | 75,229               |  |
| Series AA warrants              | 698,574             | 672,246              |  |
| Series BB warrants              | 54,266              | 53,139               |  |
| Series CC warrants              | 666,203             | -                    |  |
| Series DD warrants              | 437,780             | -                    |  |
| Series EE warrants              | 685,915             | -                    |  |
| Series FF warrants              | 73,828              | -                    |  |
| Series GG warrants              | 272,464             | -                    |  |
| Series HH warrants              | 13,616              | -                    |  |
| Series II warrants              | 404,823             | -                    |  |
| Series JJ warrants              | 20,410              | -                    |  |
| Series KK warrants              | 25,564              | -                    |  |
| Series LL warrants              | 352,495             |                      |  |
| Net gain on warrant liabilities | <u>\$11,007,215</u> | <u>\$ 14,013,726</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 revalued 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.

# Issuance of Fiscal 2017 Warrant Liabilities

On April 30, 2017, the Company entered into a securities purchase agreement with an institutional investor whereby it sold 527,960 shares of its common stock for net proceeds of approximately \$1.4 million, or \$2.875 per share, in a registered direct offering. In a concurrent private placement, the Company also issued to the purchaser of the Company's common stock Series KK warrants to purchase 395,970 shares of common stock. The warrants can be exercised at a price of \$3.04 per share at any time on or after November 3, 2017 and expire on November 3, 2022. In addition, the Company issued 26,398 Series LL warrants to the placement agent as part of its compensation. The Series LL warrants are exercisable on October 30, 2017 at a price of \$3.59 per share and expire on April 30, 2022. The fair value of the Series KK and LL warrants of approximately \$0.7 million on the date of issuance was recorded as a warrant liability.

On March 14, 2017, the Company sold 600,000 registered shares of common stock and 600,000 Series II warrants to purchase 600,000 unregistered shares of common stock at combined offering price of \$2.50 per share. The Series II warrants have an exercise price of \$3.00 per share and expire September 14, 2022. In addition, the Company issued 30,000 Series JJ warrants to purchase 30,000 shares of unregistered common stock to the placement agent. The Series JJ warrants have an exercise price \$3.13 and expire on March 8, 2022. The net proceeds from this offering were approximately \$1.3 million. The fair value of the Series II and JJ warrants of approximately \$1.0 million on the date of issuance was recorded as a warrant liability.

On February 23, 2017, the Company sold 400,000 registered shares of common stock and 400,000 Series GG warrants to purchase 400,000 unregistered shares of common stock at a combined price of \$2.50 per share. The Series GG warrants have an exercise price of \$3.00 per share and expire August 23, 2022. In addition, the Company issued to the placement agent 20,000 Series HH warrants to purchase 20,000 shares of unregistered common stock. The Series HH warrants have an exercise price \$3.13 and expire on February 16, 2022. The net proceeds from this offering were approximately \$0.8 million. The fair value of the Series GG and HH warrants of approximately \$0.6 million on the date of issuance was recorded as a warrant liability.

On December 8, 2016, the Company sold 1,360,960 shares of common stock and warrants to purchase common stock at a price of \$3.13 in a public offering. The warrants consist of 680,480 Series CC warrants to purchase 680,480 shares of common stock, 1,360,960 Series DD warrants to purchase 1,360,960 shares of common stock and 1,360,960 Series EE warrants to purchase 1,360,960 shares of common stock. The Series CC warrants were immediately exercisable, expire in five-years from the offering date and have an exercise price of \$5.00 per share. The Series DD warrants were immediately exercisable and have an exercise price of \$4.50 per share. On June 5, 2017 and June 29, 2017, the expiration date of the Series DD warrants was extended from June 8, 2017 to July 10, 2017 and then to August 10, 2017. On August 29, 2017, the expiration date of the Series EE warrants are immediately exercisable and have an exercise price of \$4.50 per share. The Series EE warrants was extended to December 1, 2017. The Series EE warrants are immediately exercisable and have an exercise price of \$4.50 per share. On August 29, 2017, the initial expiration date of the Series EE warrants was extended from September 8, 2017 to December 1, 2017. In addition, the Company issued 68,048 Series FF warrants to purchase 68,048 shares of common stock to the placement agent. The FF warrants expire on December 1, 2021 and have an exercise price \$3.91. Net proceeds from this

offering were approximately \$3.7 million. The fair value of the Series CC, DD, EE and FF warrants of approximately \$2.3 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 400,000 shares of common stock and 200,000 Series AA warrants to purchase 200,000 shares of common stock. The common stock and warrants were sold at a combined per unit price of \$12.50 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 \$13.75 per share. The Company also issued 16,000 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 \$13.75 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.

# Series Z and ZZ Warrants

On May 23, 2016, the Company closed a registered direct offering of 400,000 shares of common stock and 264,000 Series Z warrants to purchase shares of common stock. The common stock and warrants were sold at a combined per unit price of \$12.50 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 \$13.75 per share. The Company also issued 20,000 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 \$13.75 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 W Warrants

On October 28, 2015, the Company closed an underwritten public offering of 688,930 shares of common stock and 688,930 Series W warrants to purchase shares of common stock. The common stock and warrants were sold at a combined per unit price of \$16.75 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 \$16.75 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.

# Expiration of Warrants

On March 16, 2017, 23,600 Series P warrants, with an exercise price of \$112.50, expired. The fair value of the Series P warrants was \$0 on the date of expiration.

On December 6, 2016, 105,000 Series R warrants, with an exercise price of \$100.00, expired. The fair value of the Series R warrants was \$0 on the date of expiration.

On December 22, 2015, 48,000 Series Q warrants, with an exercise price of \$125.00, expired. The fair value of the Series Q warrants was \$0 on the date of expiration.

# 2. Equity Warrants

#### Series PP and Series QQ Warrants

On August 22, 2017, the Company entered into a securities purchase agreement with institutional investors whereby it sold 1,750,000 shares of its common stock for net proceeds of approximately \$3.2 million, or \$2.00 per share, in a registered direct offering. In a concurrent private placement, the

Company also issued to the purchasers of the Company's common stock Series PP warrants to purchase 1,750,000 shares of common stock. The warrants can be exercised at a price of \$2.30 per share at any time on or after February 28, 2018 and expire on February 28, 2023. In addition, the Company issued 87,500 Series QQ warrants to the placement agent as part of its compensation. The Series QQ warrants are exercisable on February 22, 2018 at a price of \$2.50 per share and expire on August 22, 2022. The Series PP and Series QQ warrants qualify for equity treatment in accordance with ASC 815. The relative fair value of the warrants was approximately \$1.4 million.

## Series OO Warrants

On July 26, 2017, the Company entered into a securities purchase agreement with an investor whereby it sold 100,000 shares of its common stock for gross proceeds of \$229,000, or \$2.29 per share, in a registered offering. In a concurrent private placement, the Company also issued to the purchaser of the common stock Series OO warrants to purchase 60,000 shares of the Company's common stock. The warrants can be exercised at a price of \$2.52 per share, commencing six months after the date of issuance and ending five years after the date of issuance. The Series OO warrants qualify for equity treatment in accordance with ASC 815. The relative fair value of the warrants was approximately \$62,000.

## Series NN Warrants

On July 24, 2017, in connection with the issuances of convertible notes (See Note 7), the Company issued the note holders Series NN warrants which entitle the purchasers to acquire up to an aggregate of 539,300 shares of the Company's common stock. The warrants are exercisable at a fixed price of \$2.52 per share and expire on July 24, 2022. Shares issuable upon the exercise of the notes and warrants were restricted securities unless registered. The shares were registered effective September 1, 2017. Proceeds from the sale of notes payable and the issuance of the warrants were approximately \$1.2 million. The Company allocated the proceeds received to the notes and the Series NN warrants on a relative fair value basis. As a result of such allocation, the Company determined the initial carrying value of the Series NN warrants to be approximately \$0.5 million. The Series NN warrants qualify for equity treatment in accordance with ASC 815.

## Series MM Warrants

On June 22, 2017, in connection with the issuance of convertible notes (see Note 7), the Company issued the note holders Series MM warrants, which entitle the purchasers to acquire up to an aggregate of 893,491 shares of the Company's common stock. The Series MM warrants are exercisable at a price of \$1.86 per share and expire on June 22, 2022. Shares issuable upon the exercise of the notes and warrants were restricted securities unless registered. The shares were registered effective August 8, 2017. Proceeds from the sale of notes payable and the issuance of the warrants were \$1.5 million. The Company allocated proceeds received to the Notes and the Series MM warrants on a relative fair value basis. As a result of such allocation, the Company determined the initial carrying value of the Series MM warrants to be approximately \$0.6 million. The Series MM warrants qualify for equity treatment in accordance with ASC 815.

## Series X Warrants

In January 2016, the Company sold 120,000 shares of its common stock and 120,000 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 \$9.25 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 approximately \$417,000.

### Series Y Warrants

On February 15, 2016, the Company sold 52,000 shares of its common stock and 26,000 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 \$12.00 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 approximately \$144,000.

### Series N Warrants

Series N warrants were previously issued in connection with a financing and were subsequently transferred to the de Clara Trust, of which the Company's CEO, Geert Kersten, is a beneficiary.

On July 17, 2017, the Series N warrants held in the de Clara Trust were modified. The modification extended the expiration date by one year to expire on August 18, 2018; the 113,785 warrants outstanding were reduced by 25% to 85,339 warrants outstanding; and the exercise price was reduced to \$3.00 per share. The incremental cost of this modification was approximately \$64,000, which was recorded as a deemed dividend.

## 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, 2017 and 2016 the Company issued 76,551 and 49,954 shares, respectively, of common stock to consultants of which 68,352 and 31,360 shares, respectively, were restricted shares. Under these arrangements, the common stock was issued with stock prices ranging between \$1.73 and \$7.25 per share.

Additionally, during the years ended September 30, 2017 and 2016 the Company issued to consultants 20,000 and 16,400 options, respectively, to purchase common stock with an exercise price of \$2.18 per share and a fair value of \$1.87 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, 2017 and 2016, the Company recorded total expense of approximately \$233,000 and \$752,000, respectively, relating to these consulting agreements. At September 30, 2017 and 2016, approximately \$45,000 and \$48,000, respectively, are included in prepaid expenses. As of September 30, 2017, 42,000 options issued to consultants as payment for services remained outstanding, all of which were issued from the Non-Qualified Stock Option plans and are fully vested.

## 5. PLANT, PROPERTY AND EQUIPMENT

Plant, property and equipment consisted of the following at September 30:

|   | 2017          | 2016          |
|---|---------------|---------------|
| Leased manufacturing facility             | \$ 21,183,756 | \$ 21,183,756 |
| Research equipment                        | 3,169,158     | 3,158,633     |
| Furniture and equipment                   | 124,369       | 133,499       |
| Leasehold improvements                    | 131,910       | 131,910       |
|   | 24,609,193    | 24,607,798    |
| Accumulated depreciation and amortization | (7,815,973)   | (7,256,962)   |

| Net plant, property and equipment | \$<br>16,793,220 | \$<br>17,350,836 |
|-----------------------------------|------------------|------------------|
|                                   |                  |                  |

The Company is not the legal owner of the manufacturing building, but is deemed to be the owner for accounting purposes, based on the accounting guidance for build-to-suit leases. See Note 11, Commitments and Contingencies–Lease Obligations, for additional information. As of September 30, 2017 and 2016, accumulated depreciation on the manufacturing building is approximately \$4.6 million and \$4.1 million, respectively. Depreciation expense for the years ended September 30, 2017 and 2016 totaled approximately \$593,000 and, \$626,000, respectively. Depreciation expense includes depreciation on the leased manufacturing building of approximately \$514,000, which is included in research and development costs on the Statements of Operations. During the year ended September 30, 2017, the Company purchased an asset under a lease classified as a capital lease. That asset has a net book value of approximately \$21,000 on September 30, 2017. 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:

|                          | 2017         | 2016        |           |
|--------------------------|--------------|-------------|-----------|
| Patents                  | \$ 1,535,087 | \$ 1        | ,5268,610 |
| Accumulated amortization | (1,311,920)  | 920) (1,272 |           |
| Patents, net             | \$ 223,167   | \$          | 256,547   |

During the years ended September 30, 2017 and 2016, there was no impairment of patent costs. Amortization expense for the years ended September 30, 2017 and 2016 totaled approximately \$40,000 and \$38,000, respectively. The total estimated future amortization is as follows:

| Years ending September 30, |    |         |  |  |
|----------------------------|----|---------|--|--|
| 2018                       | \$ | 37,000  |  |  |
| 2019                       |    | 35,000  |  |  |
| 2020                       |    | 32,000  |  |  |
| 2021                       |    | 28,000  |  |  |
| 2022                       |    | 25,000  |  |  |
| Thereafter                 |    | 66,000  |  |  |
|                            | \$ | 223,000 |  |  |
|                            |    |         |  |  |

## 7. NOTES PAYABLE

On July 24, 2017, the Company issued Series NN convertible notes in the aggregate principal amount of \$1.2 million to 12 individual investors. A trust in which Geert Kersten, the Company's Chief Executive Officer, holds a beneficial interest participated in the offering and purchased a note in the principal amount of \$250,000. Patricia B. Prichep, the Company's Senior Vice President of Operations, participated in the offering and purchased a note in the principal amount of \$25,000. The Series NN Notes bear interest at 4% per year and are due on December 22, 2017. At the option of the note holders, the Series NN Notes can be converted into shares of the Company's common stock at a fixed conversion rate of \$2.29, the closing price on July 21, 2017. The purchasers of the convertible notes also received Series NN warrants which entitle the purchasers to acquire up to 539,300 shares of the Company's common stock. The warrants are exercisable at a price of \$2.52 per share and expire on July 24, 2022.

Shares issuable upon the exercise of the warrants were restricted securities unless registered. The shares were registered effective September 1, 2017.

The Series NN Notes were issued together with Series NN warrants, as discussed in the preceding section. Upon issuance of the Series NN Notes and Series NN warrants, the Company allocated proceeds received to the notes and warrants on a relative fair value basis. As a result of such allocation, the Company determined the initial carrying value of the Series NN Notes to be approximately \$0.7 million, the initial carrying value of the Series NN warrants to be approximately \$0.5 million, and recorded a debt discount in the amount of approximately \$0.5 million.

On June 22, 2017, CEL-SCI issued Series MM convertible notes in the aggregate principal amount of \$1.5 million to six individual investors. The Series MM Notes bear interest at 4% per year and are due on December 22, 2017. At the option of the note holders, the Series MM Notes can be converted into shares of the Company's common stock at a fixed conversion rate of \$1.69. The number of shares of the Company's common stock issued upon conversion will be determined by dividing the principal amount to be converted by \$1.69, which could result in the issuance of 893,491 shares of the Company's common stock. The purchasers of the convertible notes also received Series MM warrants which entitle the purchasers to acquire up to 893,491 shares of the Company's common stock. The warrants are exercisable at a price of \$1.86 per share and expire on June 22, 2022. Shares issuable upon the exercise of the warrants were restricted securities unless registered. The shares were registered effective August 8, 2017.

The Series MM Notes were issued together with Series MM warrants, as discussed in the preceding section. Upon issuance of the Series MM Notes and Series MM warrants, the Company allocated proceeds received to the notes and warrants on a relative fair value basis. As a result of such allocation, the Company determined the initial carrying value of the Series MM Notes to be approximately \$0.9 million, the initial carrying value of the Series MM warrants to be approximately \$0.6 million, and recorded a debt discount in the amount of approximately \$0.6 million.

During the quarter ended September 30, 2017, two note holders converted their Series MM notes into shares of common stock. The face value of the converted notes was \$450,700. The unamortized debt discount relating to the converted notes was charged to interest expense.

Pursuant to the guidance in ASC 815-40, Contracts in Entity's Own Equity, the Company evaluated whether the conversion feature of the note needed to be bifurcated from the host instrument as a freestanding financial instrument. Under ASC 815-40, to qualify for equity classification (or nonbifurcation, if embedded) the instrument (or embedded feature) must be both (1) indexed to the issuer's own stock and (2) meet the requirements of the equity classification guidance. Based upon the Company's analysis, it was determined the conversion option is indexed to its own stock and also met all the criteria for equity classification. Accordingly, the conversion option is not required to be bifurcated from the host instrument as a freestanding financial instrument. Since the conversion feature meets the equity scope exception from derivative accounting, the Company then evaluated whether the conversion feature needed to be separately accounted for as an equity component under ASC 470-20, Debt with Conversion and Other Options. Based upon the Company's analysis, it was determined that a beneficial conversion feature existed as a result of the reduction in the face value of the Series MM and NN Notes, due to a portion of proceeds being allocated to the related warrants, and thus the conversion features needed to be separately accounted for as an equity component. The Company recorded beneficial conversion features relating to the Series MM and NN notes of approximately \$603,000 and \$506,000, respectively, which were also recorded as debt discounts.

The total debt discount on both Series MM and NN notes is being amortized to interest expense using the effective interest method over the expected term of the notes. At September 30, 2017, the remaining debt discount is approximately \$1.3 million.

During the year ended September 30, 2017, the Company recorded approximately \$941,000 in interest expense related to the Series MM and NN notes, of which approximately \$23,000 was recorded as accrued interest, and approximately \$918,000 was recorded as amortization of the debt discount.

The Series MM and Series NN notes are secured by a first lien on all of the Company's assets.

## 8. INCOME TAXES

At September 30, 2017 and 2016, the Company had federal net operating loss carryforwards of approximately \$187.8 million and \$169.7 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 2037. 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, 2017 and 2016. 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>2017</u> |           | 4  | 2016         |
|----------------------------------|-------------|-----------|----|--------------|
| Net operating loss carryforwards | \$ 70       | ),752,000 | \$ | 64,366,000   |
| R&D credit                       | 1           | 1,221,000 |    | 1,221,000    |
| Stock-based compensation         | 6           | 5,292,000 |    | 6,379,000    |
| Capitalized R&D                  | 21          | 1,160,000 |    | 18,508,000   |
| Vacation and other               |             | 121,000   |    | 179,000      |
| Total deferred tax assets        | 99          | 9,546,000 |    | 90,653,000   |
| Fixed assets and intangibles     | (           | (523,000) |    | (49,000)     |
| Total deferred tax liability     | (           | (523,000) |    | (49,000)     |
| Net deferred tax asset           | 99          | 9,023,000 |    | 90,604,000   |
| Valuation allowance              | (99)        | ,023,000) |    | (90,604,000) |
| Ending Balance                   | \$          | _         | \$ |              |

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:

|  | 2017    | <u>2016</u>    |
|--|---------|----------------|
| Federal Rate                           | 34.00%  | 34.00%         |
| State tax rate, net of federal benefit | 6.44    | 3.92           |
| State tax rate change                  | (3.91)  | (22.00)        |
| Other adjustments                      | (3.39)  | (0.03)         |
| Permanent differences <sup>(1)</sup>   | 25.49   | 44.90          |
| Change in valuation allowance          | (58.63) | <u>(60.79)</u> |
| Effective tax rate                     | 0.00%   | 0.00%          |

<sup>(1)</sup> Primarily due to the approximate \$11 million and \$14 million gain on derivative instruments from the change in fair value of the Company's warrant liabilities during the years ended September 30, 2017 and 2016, respectively.

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 2016. These years remain open to examination by the major domestic taxing jurisdictions to which the Company is subject.

# 9. STOCK COMPENSATION

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

|               | Year Ended September 30, |             |   |
|---------------|--------------------------|-------------|---|
| _             | <u>2017</u>              | <u>2016</u> | _ |
| Employees     | \$1,380,500              | \$2,113,433 |   |
| Non-employees | \$ 232,847               | \$ 751,651  |   |

Stock compensation expenses were recorded as general and administrative expense. During the years ended September 30, 2017 and 2016, non-employee stock compensation excluded approximately \$45,000 and \$48,000, respectively, for future services to be performed (Note 12).

During the years ended September 30, 2017 and 2016 the fair value of each option grant was estimated on the date of grant using the Black-Scholes option-pricing model with the following assumptions.

|                                 | <u>2017</u>     | <u>2016</u>      |
|---------------------------------|-----------------|------------------|
| Expected stock price volatility | 88.54 - 90.67%  | 75.58 - 80.9%    |
| Risk-free interest rate         | 2.18 - 2.29%    | 0.71 - 1.56%     |
| Expected life of options        | 9.69 – 10 Years | 3.0 – 9.69 Years |
| Expected dividend yield         | -               | -                |

<u>Non-Qualified Stock Option Plans</u> – At September 30, 2017, the Company has collectively authorized the issuance of 1,187,200 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 were 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.

<u>Incentive Stock Option Plans</u> – At September 30, 2017, the Company had collectively authorized the issuance of 138,400 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, 2017 is summarized as follows:

|                                      |                        | Out                                      | standing   |                                 | Exercisable            |  |  |                                 |
|--------------------------------------|------------------------|--|--|---------------------------------|------------------------|--|--|---------------------------------|
|                                      |                        |  | Weighted   |                                 |                        |  | Weighted   |                                 |
|                                      | Number<br>of<br>Shares | Weighted<br>Average<br>Exercise<br>Price | Ave<br>Remaining<br>Contractual<br>Term<br>(Years) | Aggregate<br>Intrinsic<br>Value | Number<br>of<br>Shares | Weighted<br>Average<br>Exercise<br>Price | Ave<br>Remaining<br>Contractual<br>Term<br>(Years) | Aggregate<br>Intrinsic<br>Value |
| Outstanding at<br>October 1, 2015    | 301,511                | \$67.75                                  | 5.98   | \$50                            | 181,102                | \$78.75                                  | 5.01   | \$0                             |
| Vested<br>Granted (a)<br>Exercised   | 48,544                 | \$12.00                                  |  |                                 | 56,069                 | \$31.75                                  |  |                                 |
| Forfeited<br>Expired<br>Cancelled    | 2,240<br>4,240         | \$21.50<br>\$145.00                      |  |                                 | 4,240                  | \$145.00                                 |  |                                 |
| Outstanding at<br>September 30, 2016 | 343,575                | \$59.22                                  | 5.35   | \$0                             | 232,931                | \$66.28                                  | 4.76   | \$0                             |
| Vested                               | 000.005                | <b>\$2.17</b>                            |  |                                 | 63,812                 | \$18.45                                  |  |                                 |
| Granted (b)<br>Exercised             | 932,825                | \$2.17                                   |  |                                 |                        |  |  |                                 |
| Forfeited<br>Expired<br>Cancelled    | 15,795<br>20,761       | \$9.46<br>\$88.80                        |  |                                 | 20,761                 | \$88.80                                  |  |                                 |
| Outstanding at<br>September 30, 2017 | 1,239,844              | \$16.44                                  | 8.50   | \$1,400                         | 275,982                | \$53.53                                  | 4.91   | \$0                             |

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

(a) Includes 16,400 stock options granted to consultants

(b) Includes 20,000 stock options granted to consultants

A summary of the status of the Company's non-vested options for the two years ended September 30, 2017 is presented below:

|                                | Number of Options | Grant I | d Average<br>Date Fair<br>due |
|--------------------------------|-------------------|---------|-------------------------------|
| Unvested at October 1, 2015    | 120,409           | \$      | 43.09                         |
| Vested                         | (56,069)          |         |                               |
| Granted                        | 48,544            |         |                               |
| Forfeited                      | (2,240)           |         |                               |
| Unvested at September 30, 2016 | 110,644           | \$      | 36.96                         |
| Vested                         | (63,812)          |         |                               |
| Granted                        | 932,825           |         |                               |
| Forfeited                      | (15,795)          |         |                               |
| Unvested at September 30, 2017 | 963,862           | \$      | 4.91                          |

<u>Incentive Stock Bonus Plan</u> – Up to 640,000 shares are authorized under the 2014 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, 2017 was 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, 2017 and 2016, the Company recorded expense relating to the issuance of restricted stock pursuant to the plan of approximately \$633,000 and \$634,000, respectively. At September 30, 2017, the Company has unrecognized compensation expense of approximately \$2.5 million which is expected to be recognized over a weighted average period of four years.

A summary of the status of the Company's restricted common stock issued from the Incentive Stock Bonus Plan for the two years ended September 30, 2017 is presented below:

|  | Number of<br>Shares | Weighted Average<br>Grant Date Fair<br>Value |
|--|---------------------|--|
| Unvested at September 30, 2015<br>Vested | 604,000             | \$13.75                                      |
| Unvested at September 30, 2016           | 604,000             | \$13.75                                      |
| Vested                                   | (136,000)           |  |
| Unvested at September 30, 2017           | 468,000             | \$13.75                                      |

<u>Stock Bonus Plans</u> – At September 30, 2017, the Company was authorized to issue up to 383,760 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, 2017, 79,941 shares were issued to the Company's 401(k) plan for a cost of approximately \$151,000. During the year ended September 30, 2016, 16,340 shares were issued to the Company's 401(k) plan for a cost of approximately \$162,000. As of September 30, 2017, the Company has issued a total of 206,390 shares of common stock from the Stock Bonus Plans.

<u>Stock Compensation Plans</u> – At September 30, 2017, 134,000 shares were authorized for use in the Company's Stock Compensation Plans. During the years ended September 30, 2017, and 2016, 23,202 and 18,593 shares, respectively, were issued from the Stock Compensation Plans to consultants for payment of services at a cost of approximately \$60,000 and \$234,000, respectively. During the year ended September 30, 2017 and 2016, 13,000 and 3,837 shares, respectively, were issued to employees from the Stock Compensation Plans as part of their compensation at a cost of approximately \$24,000 and \$45,000, respectively. As of September 30, 2017, the Company has issued 115,590 shares of common stock from the Stock Compensation Plans.

# **10. 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, 2017 and 2016, in connection with this Plan was approximately \$163,000 and \$168,000, respectively.

# **11. 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, 2017, the total balance advanced is \$150,000 and 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 \$25.0 million related to Ergomed's services. This amount is net of Ergomed's discount of approximately \$8.4 million. During the years ended September 30, 2017 and 2016, the Company recorded, approximately \$5.8 million and \$7.2 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 in each of the periods presented.

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). The Company initiated the proceedings against inVentiv Health Clinical, LLC, or inVentiv, the former third-party CRO, and is seeking payment for damages related to inVentiv's prior involvement in the ongoing Phase 3 clinical trial of Multikine. The arbitration claim, initiated under the Commercial Rules of the American Arbitration Association, alleges (i) breach of contract, (ii) fraud in the inducement, and (iii) common law fraud. Currently, the Company is seeking at least \$50 million in damages in its amended statement of claim.

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 has been going on longer than expected, but it is finally nearing its end. The hearing (the "trial") started on September 26, 2016. The last witness in the arbitration hearing testified on Wednesday, November 8, 2017, and no further witnesses or testimony are expected. With that final witness, the testimony phase of the arbitration concluded. All that remains at the trial level are closing statements and post-trial submissions.

## Lease Agreements

The Company leases a manufacturing facility near Baltimore, Maryland under an operating lease (the San Tomas lease). 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. The Company contributed approximately \$9.3 million towards the tenant-directed improvements, of which \$3.2 million is being refunded during years six through twenty through reduced rental payments. The landlord paid approximately \$11.9 million towards the purchase of the building, land and the tenant-directed improvements. The asset was placed in service in October 2008.

Because the terms of the original lease agreements required the Company to be responsible for cost overruns, if there had been any, but of which there were none, the Company was deemed to be the owner of the building for accounting purposes under the build-to-suit guidance in ASC 840-40-55. In addition to the tenant improvements the Company incurred and capitalized on its balance sheet, the Company recorded an asset for tenant-directed improvements and for the costs paid by the lessor to purchase the building and to perform improvements, as well as a corresponding liability for the landlord costs. Upon completion of the improvements, the Company did not meet the "sale-leaseback" criteria

under ASC 840-40-25, *Accounting for Leases, Sale-Leaseback Transactions*, and therefore, treated the lease as a financing obligation. Therefore, the asset and corresponding liability were not be derecognized.

As of September 30, 2017 and 2016, the leased building asset has a net book value of approximately \$16.6 million and \$17.1 million and the landlord liability as a balance of \$13.2 million and \$13.0 million. The leased asset is being depreciated using a straight line method of the 20 year lease term to a residual value. The landlord liability is being amortized over the 20 years using the effective interest method.

The Company was required to deposit the equivalent of one year of base rent in accordance with the San Tomas 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, 2017 and 2016.

Approximate future minimum lease payments under the San Tomas lease as of September 30, 2017 are as follows:

| Years ending September 30,                      |    |             |  |  |
|---|----|-------------|--|--|
| 2018  | \$ | 1,747,000   |  |  |
| 2019  |    | 1,808,000   |  |  |
| 2020  |    | 1,872,000   |  |  |
| 2021  |    | 1,937,000   |  |  |
| 2022  |    | 2,004,000   |  |  |
| Thereafter                                      |    | 13,758,000  |  |  |
| Total future minimum lease obligation           |    | 23,126,000  |  |  |
| Less: imputed interest on financing obligation  |    | (9,914,000) |  |  |
| Net present value of lease financing obligation | \$ | 13,212,000  |  |  |

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, 2017 and 2016 was approximately \$69,000 and \$67,000, 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 \$13,000 per month. As of September 30, 2017 and 2016, the Company has recorded a deferred rent liability of approximately \$5,000 and \$2,000, 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, 2017 and 2016, the Company has recorded a deferred rent liability of approximately \$18,000.

The Company leases office equipment under a capital lease arrangement. The terms of the capital lease is 60 months and expires on October 31, 2021. The monthly lease payment is \$505. The lease bears interest at approximately 6.25% per annum. The Company's previous equipment lease expired on September 30, 2016.

Approximate future minimum annual lease payments due under non-cancelable operating leases, excluding the San Tomas lease, for the years ending after September 30, 2017 are as follows:

| Years ending September 30, |               |
|----------------------------|---------------|
| 2018                       | \$<br>251,000 |
| 2019                       | 258,000       |
| 2020                       | 238,000       |
| 2021                       | 163,000       |
| 2022                       | 69,000        |
| Thereafter                 | -             |
| Total future minimum lease |               |
| obligation                 | \$<br>979,000 |

Rent expense, for the years ended September 30, 2017 and 2016, excluding the rent paid on the San Tomas lease, was approximately \$245,000 and \$234,000, respectively. The Company's three leases expire between June 2020 and October 2028.

### 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. CEL-SCI estimates it will incur additional expenses of approximately \$13.0 million for the remainder of the Phase 3 clinical trial. It should be noted that this estimate is based only on the information currently available in CEL-SCI's contracts with the Clinical Research Organizations responsible for managing the Phase 3 clinical trial and does not include other related costs, e.g. the manufacturing of the drug.

## **12. RELATED PARTY TRANSACTIONS**

On July 24, 2017, the Company issued convertible notes (Series NN Notes) in the aggregate principal amount of \$1.2 million to 12 individual investors. A trust in which Geert Kersten, the Company's Chief Executive Officer, holds a beneficial interest participated in the offering and purchased a note in the principal amount of \$250,000. Patricia B. Prichep, the Company's Senior Vice President of Operations, participated in the offering and purchased a note in the principal amount of \$25,000. The terms of the trust's Note and Ms. Prichep's Note were identical to the other participants. The number of shares of the Company's common stock issued upon conversion will be determined by dividing the principal amount to be converted by \$2.29, which would result in the issuance of 109,170 shares to the trust and 10,917 shares to Ms. Prichep also received Series NN warrants to purchase up to 109,170 and 10,917 shares, respectively, of the Company's common stock. The Series NN warrants are exercisable at a fixed price of \$2.52 per share and expire on July 24, 2022. Shares issuable upon the exercise of the notes and warrants were restricted securities unless registered. The shares were registered effective September 1, 2017.

On June 22, 2017, CEL-SCI issued convertible notes (Series MM Notes) in the aggregate principal amount of \$1.5 million to six individual investors. Geert Kersten, the Company's Chief Executive Officer, participated in the offering and purchased notes in the principal amount of \$250,000. The terms of Mr. Kersten's Note were identical to the other participants. The number of shares of the Company's common stock issued upon conversion will be determined by dividing the principal amount to be converted by \$1.69, which would result in the issuance of 147,929 shares to Mr. Kersten upon conversion. Along with the other purchasers of the Company's common stock. The Series MM warrants to purchase up to 147,929 shares of the Company's common stock. The Series MM warrants are exercisable at a fixed price of \$1.86 per share and expire on June 22, 2022. Shares issuable upon the exercise of the notes and warrants were restricted securities unless registered. The shares were registered effective August 8, 2017.

No interest payments were made to officers during the year ended September 30, 2017.

Effective August 31, 2016, the Company issued Maximilian de Clara, the Company's then President and a director, through the de Clara Trust, 26,000 shares of restricted stock in payment of past services. The de Clara Trust was established by Maximilian de Clara, the Company's former President and a director. The shares were issued as follows; 13,000 shares upon his resignation on August 31, 2016 and 13,000 on August 31, 2017. The total value of the shares issued was approximately \$176,000, of which approximately \$24,000 was expensed during the year ended September 30, 2017 and \$152,000 was expensed during the year ended September 30, 2016, the fair value accrued for unissued shares was approximately \$101,000.

On January 13, 2016, the de Clara Trust demanded payment on a note payable, of which the balance, including accrued and unpaid interest, was approximately \$1.1 million. The Company's Chief Executive Officer, Geert Kersten, is a beneficiary of the de Clara Trust. When the de Clara Trust demanded payment on the note, the Company sold 120,000 shares of its common stock and 120,000 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 \$9.25 per share at any time on or before January 13, 2021.

No interest payments were made to Mr. de Clara or the de Clara Trust during the year ended September 30, 2017. During the year ended September 30, 2016, the Company paid approximately \$43,000 interest expense to Mr. de Clara.

# **13. STOCKHOLDERS' EQUITY**

On August 22, 2017, the Company entered into a securities purchase agreement with institutional investors whereby it sold 1,750,000 shares of its common stock for net proceeds of approximately \$3.2 million, or \$2.00 per share, in a registered direct offering. In a concurrent private placement, the Company also issued to the purchasers of the Company's common stock Series PP warrants to purchase 1,750,000 shares of common stock. In addition, the Company issued 87,500 Series QQ warrants to the placement agent as part of its compensation. See Note 4 for more information with respect to the Series PP & QQ warrants.

On August 15, 2017, the Company entered into a Securities Purchase Agreement with Ergomed plc, the Company's Clinical Research Provider, to facilitate the payment of some of the accounts payable balances due Ergomed. Under the Agreement, the Company issued Ergomed 480,000 shares, with a fair market value of approximately \$1.3 million, as a forbearance fee in exchange for Ergomed's agreement to provisionally forbear collection of the payables. In an amount equal to the net proceeds from the resales of the shares issued to Ergomed. The Company recorded the full amount of the expense upon issuance and will credit any amounts realized through reduction of the payables. During the quarter ended September 30, 2017, 64,792 shares were resold and the Company reduced the expense by approximately \$107,000. The net expense of \$1.2 million recorded during the quarter is included in interest expense.

On July 26, 2017, the Company entered into a securities purchase agreement with an investor whereby it sold 100,000 shares of its common stock for gross proceeds of \$229,000, or \$2.29 per share, in a registered offering. In a concurrent private placement, the Company also issued to the purchaser of that common stock Series OO warrants to purchase 60,000 shares of the Company's common stock. See Note 4 for more information with respect to the Series OO warrants.

On April 30, 2017, the Company entered into a securities purchase agreement with an institutional investor whereby it sold 527,960 shares of its common stock for net proceeds of approximately \$1.4 million, or \$2.875 per share, in a registered direct offering. In a concurrent private placement, the Company also issued to the purchaser of the Company's common stock, Series KK warrants to purchase 395,970 shares of common stock. In addition, the Company issued 26,398 Series LL warrants to the

Placement Agent as part of its compensation. See Note 4 for more information with respect to the Series KK and LL warrants.

On March 14, 2017, the Company sold 600,000 registered shares of common stock and 600,000 Series II warrants to purchase 600,000 unregistered shares of common stock at combined offering price of \$2.50 per share. In addition, the Company issued 30,000 Series JJ warrants to purchase 30,000 shares of unregistered common stock to the placement agent. The net proceeds from this offering were approximately \$1.3 million. See Note 4 for more information with respect to the Series II and JJ warrants.

On February 23, 2017, the Company sold 400,000 registered shares of common stock and 400,000 Series GG warrants to purchase 400,000 unregistered shares of common stock at a combined price of \$2.50 per share. In addition, the Company issued to the placement agent, 20,000 Series HH warrants to purchase 20,000 shares of unregistered common stock. The net proceeds from this offering were approximately \$0.8 million. See Note 4 for more information with respect to the Series GG and HH warrants.

On December 8, 2016, the Company sold 1,360,960 shares of common stock and warrants to purchase common stock at a price of \$3.13 in a public offering. The warrants consist of 680,480 Series CC warrants to purchase 680,480 shares of common stock, 1,360,960 Series DD warrants to purchase 1,360,960 shares of common stock and 1,360,960 Series EE warrants to purchase 1,360,960 shares of common stock. In addition, the Company issued 68,048 Series FF warrants to purchase 68,048 shares of common stock to the placement agent. Net proceeds from this offering were approximately \$3.7 million. See Note 4 for more information with respect to the Series CC, DD, EE and FF warrants.

On August 26, 2016, the Company closed a registered direct offering of 400,000 shares of common stock and Series AA warrants to purchase up to 200,000 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 \$13.75. The Company also issued 16,000 Series BB warrants to the placement agent as part of its compensation. 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. See Note 4 for more information with respect to the Series AA and BB warrants.

On May 23, 2016, the Company closed a registered direct offering of 400,000 shares of common stock and 264,000 Series Z warrants to purchase shares of common stock. The common stock and warrants were sold at a combined per unit price of \$13.75 for net proceeds of approximately \$4.6 million, net of placement agent's commissions and offering expenses. The Company also issued 20,000 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 \$13.75 per share. See Note 4 for more information with respect to the Series Z and ZZ warrants.

On October 28, 2015, the Company closed an underwritten public offering of 688,930 shares of common stock and 688,930 Series W warrants to purchase shares of common stock. The common stock and warrants were sold at a combined price of \$16.75 for net proceeds of approximately \$10.5 million, net of underwriting commissions and offering expenses. See Note 4 for more information with respect to the Series W warrants.

## **14. 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:

- o 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
- o 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, 2017:

|                        | Quoted Prices in      |                          |                  |              |
|------------------------|-----------------------|--------------------------|------------------|--------------|
|                        | Active Markets for    | Significant Other        | Significant      |              |
|                        | Identical Liabilities | <b>Observable Inputs</b> | Unobservable     |              |
|                        | (Level 1)             | (Level 2)                | Inputs (Level 3) | Total        |
| Derivative Instruments | \$ 32,773             | \$                       | \$ 2,020,629     | \$ 2,053,402 |

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    | Significant Other | Significant      |                     |
|                        | Identical Liabilities | Observable Inputs | Unobservable     |                     |
|                        | (Level 1)             | (Level 2)         | Inputs (Level 3) | Total               |
| Derivative Instruments | \$ 3,111,361          | \$                | \$ 5,283,573     | <u>\$ 8,394,934</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:

|   | 2017               | 2016                         |
|---|--------------------|------------------------------|
| Beginning balance                           | \$ 5,283,57        | 3 \$ 6,323,032               |
| Issuances                                   | 4,665,68           | 3 8,722,073                  |
| Net realized and unrealized derivative gain | (7,928,627         | (9,761,532)                  |
| Ending balance                              | <u>\$ 2,029,62</u> | <u>9</u> <u>\$ 5,283,573</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, 2017, the Company's Level 3 derivative instruments have a weighted average fair value of \$0.29 per share and a weighted average exercise price of \$5.41 per share. Fair values were determined using a weighted average risk free interest rate of 1.85% and 80% volatility. The instruments have a weighted average time to maturity of 4.55 years. At September 30, 2016, the Company's Level 3 derivative instruments have a weighted average fair value of \$2.50 per share and a weighted average exercise price of \$21.50 per share. Fair values were determined using a weighted average risk free interest rate of 1.04% and 75% volatility.

# **15. 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:

|  | Year Ended September 30, 2017 |              |                            |              |
|--|-------------------------------|--------------|----------------------------|--------------|
|  |                               | Net Loss     | Weighted Average<br>Shares | LPS          |
| Basic loss per share                     | \$                            | (14,427,055) | 7,891,843                  | \$<br>(1.83) |
| Less: gain on derivatives <sup>(1)</sup> |                               | (677,287)    | 10,804                     |              |
| Dilutive loss per share                  | \$                            | (15,104,342) | 7,902,647                  | \$<br>(1.91) |

(1) Includes series GG and II warrants

|                                   | Year Ended September 30, 2016           |              |           |           |
|-----------------------------------|---|--------------|-----------|-----------|
|                                   | Weighted Average<br>Net Loss Shares LPS |              | LPS       |           |
| Basic and dilutive loss per share | \$                                      | (11,512,492) | 4,866,204 | \$ (2.37) |

The gain on derivative instruments that contain exercise prices lower than the average market share price during the period is excluded from the numerator and the related shares are excluded from the denominator in calculating diluted loss per share.

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:

|                           | 2017      | <u>2016</u> |
|---------------------------|-----------|-------------|
| Options and Warrants      | 2,538,130 | 3,675,281   |
| Convertible Debt          | 1,166,106 | -           |
| Unvested Restricted Stock | 604,000   | 604,000     |
| Total                     | 4,308,236 | 4,279,281   |
|                           |           |             |

## **16. SUBSEQUENT EVENTS**

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

On December 19, 2017 the Company received subscription agreements for the purchase of 1,289,478 shares of CEL-SCI common stock at a price of \$1.90 in the principal amount of \$2,450,000 from 19 investors. The common stock will be restricted unless registered. The purchasers of the common stock also received warrants which entitle the purchasers to acquire up to 1,289,478 shares of the Company's common stock. The warrants are exercisable at a fixed price of \$2.09 per share, will not be exercisable for 6 months and one day and will expire on December 18, 2022. Shares issuable upon the exercise of the warrants will be restricted securities unless registered.

On December 18, 2017 CEL-SCI Corporation appointed Robert Watson to its Board of Directors.

On November 2, 2017, holders of convertible notes in the principal amount of \$1.1 million sold in June 2017 and holders of convertible notes in the principal amount of \$1.2 million sold in July 2017 agreed to extend the maturity date of these notes to September 21, 2018. In consideration for the extension of the maturity date of the convertible notes, the Company issued a total of 716,400 Series RR warrants to the convertible note holders that agreed to the extension. Each Series RR warrant entitles the holder to purchase one share of the Company's common stock. The Series RR warrants may be exercised at any time on or before October 30, 2022 at an exercise price of \$1.65 per share.

#### CORPORATE INFORMATION

#### **Board of Directors**

Geert R. Kersten Chief Executive Officer CEL-SCI Corporation

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

**Bruno Baillavoine** Partner Globomass Holdings Limited

**Robert Watson** President, Preparedness Tech. Division Intermedix, Inc.

## **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

#### **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 American 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 American exchange under the symbol CVM WS

There are approximately 750 stockholders of record as of July 31, 2018. 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