



Annual Report

2018

CEL-SCI Corporation

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 (approximately 800 out of the 928 patients) 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.

Multikine is given to previously untreated, newly diagnosed head and neck cancer patients right after diagnosis for three weeks before the current standard of care treatments (surgery followed by radiation or combined radio-chemotherapy).

There is no delay of surgery or follow on standard of care treatments. The intent of adding Multikine treatment to the current standard of care treatment regimen is to either cure the patient or increase the time to recurrence of the patient's cancer since there is a known correlation between increased time to recurrence and increased survival of patients. No severe toxicity was reported as being associated with Multikine when it was added to the current standard of care in Phase II clinical trials. Our experience in our Phase 3 study with respect to toxicity has paralleled what was seen during the Phase 2 studies.

The most common misconception with respect to the use of Multikine is that it is in competition with all of the FDA approved immunotherapies (e.g., Keytruda, Opdivo, CAR-T) that have been recently in the news. In contrast to Multikine, these other immunotherapies are indicated only for patients whose cancers have recurred following standard of care treatment (surgery etc.) or those patients with metastatic cancer where surgery is no longer an option. The use of these other cancer immunotherapies in the patient population being treated with Multikine would be inappropriate and unethical because they are administered over many months, which would cause a delay in the application of the currently used standard of care treatment which is potentially curative on its own. Further, the toxicities that may be associated with these new products would preclude their use in patients that are potentially curable by the current standard of care.

CEL-SCI is also investigating a different peptide-based immunotherapy as a vaccine for Rheumatoid Arthritis using its LEAPS technology platform. CEL-SCI was awarded a Phase 2 Small Business Innovation Research (SBIR) grant in the amount of \$1.5 million from the National Institutes of Health (NIH) in September 2017. 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.

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

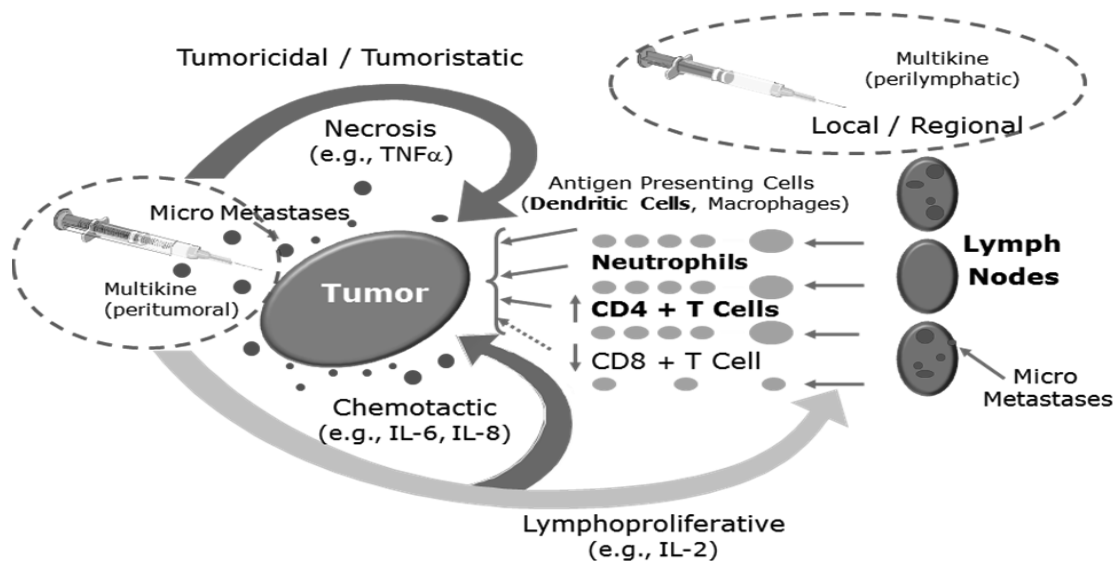
CEL-SCI's lead investigational therapy, Multikine, is currently being developed as a potential therapeutic agent directed at using the immune system to produce an anti-tumor immune response. Data from Phase 1 and Phase 2 clinical trials suggest that Multikine may help the immune system "see" the tumor 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 pro-inflammatory cytokine mixture includes interleukins, interferons, chemokines and colony-stimulating factors, which contain elements of the body's natural mix of defenses against cancer.

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The most common misconception with respect to the use of Multikine is that it is in competition with all of the FDA approved immunotherapies (e.g. Keytruda, Opdivo, CAR-T, and many more) that have been recently in the news. In contrast to Multikine these other immunotherapies are indicated only for patients whose cancers have recurred following standard of care (surgery, etc.) therapy or those patients with metastatic cancer where surgery is no longer an option. The use of these other cancer immunotherapies in the patient population being treated with Multikine would be inappropriate and unethical because they are administered over many months, which would cause a delay in the application the currently used standard of care treatment which is potentially curative on its own. Further, the toxicities that may be associated with these new products would preclude their use in patients that are potentially curable by the current standard of care.

Multikine 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 was injected locally at the site of the tumor and near the adjacent draining lymph nodes as a first line of treatment before surgery, radiation and/or chemotherapy because that is when the immune system is thought to be strongest. The goal is to help the intact immune system recognize and kill the tumor micro metastases that usually cause recurrence of the cancer. In short, CEL-SCI believes that the local administration and 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 (right after diagnosis, before the first treatment with surgery) 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 about 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.

The current Phase 3 study for Multikine 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 plus CIZ (CIZ = low dose (non-chemotherapeutic) of cyclophosphamide administered once, indomethacin and Zinc-multivitamins, all of which are thought to enhance Multikine activity), plus Standard of Care (Surgery + Radiotherapy or Chemoradiotherapy) over the Control comparator (Standard of Care alone) arm. As the study was designed, the final determination of whether this endpoint has been successfully reached can only be determined when 298 events (deaths) have occurred in the combined comparator arms of the study.

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.

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.

Since CEL-SCI launched its Phase 3 clinical trial for Multikine, CEL-SCI has incurred expenses of approximately \$50.6 million as of September 30, 2018 on direct costs for the Phase 3 clinical trial. CEL-SCI estimates it will incur additional expenses of approximately \$8.4 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 and speed 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.

Ultimately, the decision as to whether CEL-SCI's drug product candidate is safe and effective can only be made by the 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 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 set up clinical centers for the Phase 3 trial in Taiwan, Malaysia, the Philippines and Thailand 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 its territory as with its own products or other licensed products.

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

CEL-SCI has a licensing agreement with Byron Biopharma LLC, or Byron, under which CEL-SCI granted Byron an exclusive license to market and distribute Multikine in the Republic of South Africa, if approved. This license will terminate 20 years after marketing approval in South Africa or after bankruptcy of either party 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. CEL-SCI will be paid fifty (50%) percent of the net sales of Multikine in South Africa.

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 had been awarded a Phase 2 Small Business Innovation Research (SBIR) grant in the amount of \$1.5 million from the National Institute of Arthritis Musculoskeletal 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 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 Musculoskeletal 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., Katalin Mikecz, MD, Ph.D., 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- α . The data for CEL-4000 indicates it could be effective against rheumatoid arthritis cases where a Th1 signature cytokine (IFN- γ) 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 Review of Vaccines* 1 - 18 and can be found online 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- γ) and their action on reducing TNF- α 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.

In May 2011 NIAID scientists presented data at the Keystone Conference on “Pathogenesis of Influenza: Virus-Host Interactions” in Hong Kong, China, showing the positive results of efficacy studies in mice of LEAPS H1N1 activated dendritic cells (DCs) to treat the H1N1 virus. Scientists at the NIAID found that H1N1-infected mice treated with LEAPS-H1N1 DCs showed a survival advantage over mice treated with control DCs. The work was performed in collaboration with scientists led by Kanta Subbarao, M.D., Chief of the Emerging Respiratory Diseases Section in NIAID’s Division of Intramural Research, part of the National Institutes of Health, USA.

In July 2013, CEL-SCI announced the publication of the results of influenza studies by researchers from the NIAID in the *Journal of Clinical Investigation* (www.jci.org/articles/view/67550). 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 vaccine 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 U.S. 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 a 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.

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 19, 2018, there were no contested proceedings and/or third party claims with respect to CEL-SCI's patents or patent applications.

MANUFACTURING FACILITY

Before starting the Phase 3 clinical trial, 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. At that time CEL-SCI may buy the building or extend the lease by two ten year periods. 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 and to market Multikine for commercial sale, if Multikine is approved by the FDA. 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.

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

As of September 30, 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".

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

| <u>Quarter Ending</u> | <u>High</u> | <u>Low</u> |
|-----------------------|-------------|------------|
| 12/31/2016 | \$7.75 | \$1.50 |
| 3/31/2017 | \$4.50 | \$1.75 |
| 6/30/2017 | \$4.00 | \$1.46 |
| 9/30/2017 | \$3.69 | \$1.57 |
| 12/31/2017 | \$2.14 | \$1.60 |
| 3/31/2018 | \$2.50 | \$1.30 |
| 6/30/2018 | \$3.66 | \$0.83 |
| 9/30/2018 | \$4.44 | \$0.82 |

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

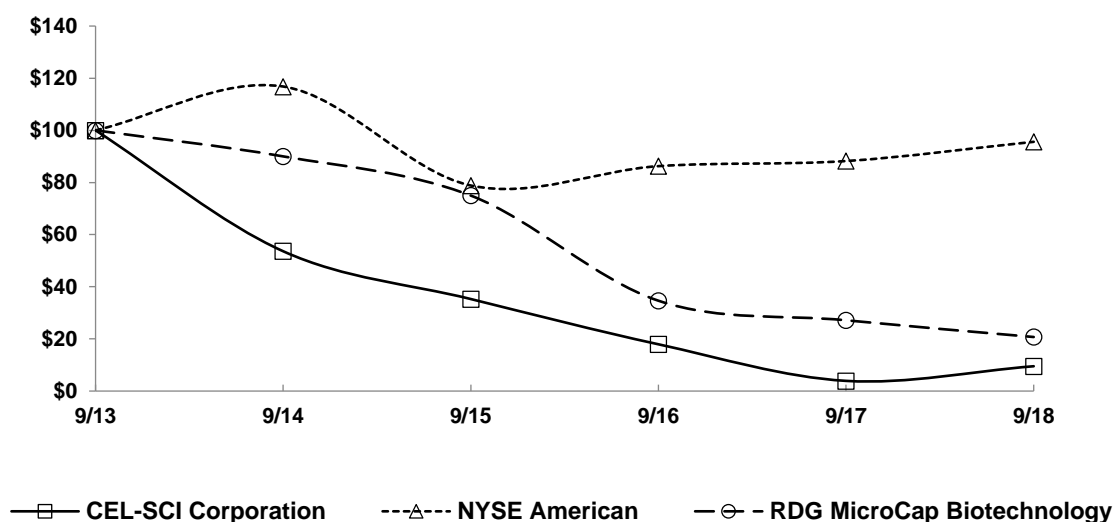
regulation, developments in patent or other proprietary rights, public concern as to the safety of products which may be developed by CEL-SCI or other biotechnology and pharmaceutical companies, and general market conditions may have a significant effect on the market price of CEL-SCI's common stock.

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, 2013 and tracks it through September 30, 2018.

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

COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN*

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



*\$100 invested on 9/30/13 in stock or index, including reinvestment of dividends.
Fiscal year ending September 30.

| | 9/13 | 9/14 | 9/15 | 9/16 | 9/17 | 9/18 |
|----------------------------|--------|--------|-------|-------|-------|-------|
| CEL-SCI Corporation | 100.00 | 53.63 | 35.30 | 17.94 | 3.91 | 9.53 |
| NYSE American | 100.00 | 116.81 | 78.84 | 86.28 | 88.23 | 95.60 |
| RDG MicroCap Biotechnology | 100.00 | 90.01 | 74.98 | 34.65 | 27.14 | 20.73 |

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, has fully enrolled 928 patients in a Phase 3 clinical trial in advanced primary head and neck cancer. This study was cleared by the U.S. FDA as well as twenty-three other countries.

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

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

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

Results of Operations

Fiscal 2018

During the year ended September 30, 2018, grant and other income increased by approximately \$478,000 compared to the year ended September 30, 2017. The increase is due to work performed on a grant awarded in September 2017. CEL-SCI was awarded a Phase 2 Small Business Innovation Research (SBIR) grant in the amount of \$1.5 million from the National Institute of Arthritis Musculoskeletal 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.

During the year ended September 30, 2018, research and development expenses decreased by approximately \$6.2 million compared to the year ended September 30, 2017. CEL-SCI is continuing the Phase 3 clinical trial and research and development fluctuates based on the activity level of the clinical trial. The majority of CEL-SCI's research and development expense relates to its on-going Phase 3 clinical trial. Clinical trial costs tend to be higher during the enrollment phase of the study and because the study is fully enrolled, the expenses incurred over the last twelve months have decreased. However, as CEL-SCI investigates new study opportunities, research and development costs may increase.

During the year ended September 30, 2018, general and administrative expenses increased by approximately \$2.0 million compared to the year ended September 30, 2017. A major component of the increase is an approximate \$1.4 million increase in employee compensation costs, of which approximately \$0.9 million relates to expense associated with achievement of the second of four milestones under CEL-SCI's Incentive Stock Bonus Plan, and \$0.5 million relates to an increase in costs associated with employee stock options. Another major component of the increase is an approximate \$0.8 million increase in public relations costs, of which approximately \$0.3 million related to an increase in the value of non-employee stock compensation costs for consultants. Other components of the increase include a net decrease in other general and administrative expenses of approximately \$0.2 million.

During the years ended September 30, 2018, CEL-SCI recorded a derivative loss of approximately \$8.6 million as compared to a derivative gain of approximately \$11.0 million recorded during the year ended September 30, 2017. 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 \$2.5 million during the year ended September 30, 2018 compared to the year ended September 30, 2017. The increase is primarily due to: 1) an increase of

approximately \$1.1 million in amortization of discounts on notes payable issued in June and July 2017, restructured in October 2017 and fully converted in June 2018, and accrued interest on those notes; 2) the \$0.3 million inducement loss recorded in June 2018 on the conversion of the notes payable; and 3) the current period impact of the financing arrangement with Ergomed (as explained in Note 13 to the financial statements which are part of this report) which resulted in approximately \$1.1 million more in net interest expense in 2018 over 2017.

Research and Development Expenses

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 the reporting periods.

| | Year ended September 30, | |
|--------------------------------|---------------------------------|----------------------|
| | 2018 | 2017 |
| Multikine | \$ 8,666,936 | \$ 15,253,190 |
| LEAPS | 733,370 | 353,795 |
| Total research and development | <u>\$ 9,400,306</u> | <u>\$ 15,606,985</u> |

In January 2007, CEL-SCI received a “no objection” letter from the FDA indicating that it could proceed with Phase 3 trials with Multikine in head and neck cancer patients. CEL-SCI had previously received a “no objection” letter from the Canadian Biologics and Genetic Therapies Directorate which enabled CEL-SCI to begin its Phase 3 clinical trial in Canada. Subsequently, CEL-SCI received similar authorizations from twenty-two other regulators.

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

As of March __, 2019, 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 2018 and 2017, CEL-SCI raised net proceeds of approximately \$21.4 million and \$13.3 million, respectively, through a combination of the sale of stock, the exercise of warrants 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, 2018.

On December 8, 2016, CEL-SCI 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 and have an exercise price of \$5.00 per share. The Series DD warrants were immediately exercisable, expire on December 10, 2018 and have an exercise price of \$4.50 per share. The Series EE warrants were immediately exercisable, expire on December 10, 2018 and have an exercise price of \$4.50 per share. In addition, CEL-SCI 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 were approximately \$3.7 million, excluding any future proceeds that may be received from the exercise of the warrants. As of September 30, 2018, 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, 2018, 200,000 Series GG 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, 2018, 383,500 Series II 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, 2018, 182,100 Series KK warrants had been exercised.

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, 2018, 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, 2018, 1,577,500 Series PP warrants and 84,000 Series QQ warrants had been exercised.

During the year ended September 30, 2017, the Company issued two series of convertible notes to individual investors, Series MM and Series NN convertible notes (the Notes). The Notes had an aggregate principal amount of \$2.7 million, bore interest at 4% and were originally due on December 22, 2017. At the option of the note holders, the Series MM Notes could be converted into shares of the Company's common stock at a fixed conversion rate of \$1.69 and the Series NN Notes could be converted into shares of the Company's common stock at a fixed conversion rate of \$2.29. The purchasers of the convertible notes also received Series MM and Series NN warrants which allow the purchasers to acquire up to 893,491 and 539,300 shares of the Company's common stock, respectively. The Series MM warrants are exercisable at a price of \$1.86 per share and expire on June 22, 2022. The Series NN warrants are exercisable at a price of \$2.52 per share and expire on July 24, 2022.

On October 30, 2017, the Company extended the due dates of the Notes from December 22, 2017 to September 21, 2018, and issued the note holders 583,057 of Series RR Warrants. The Series RR warrants expire on October 30, 2022 and are exercisable at a price of \$1.65 per share. As of September 30, 2018, 27,687 Series RR warrants had been exercised for total proceeds of approximately \$46,000.

On June 11, 2018, as an inducement to convert, the Company issued the then outstanding note holders 187,562 Series UU warrants. The Series UU warrants are exercisable at a fixed price of \$2.80 per share, are exercisable on December 11, 2018 and expire on June 11, 2020.

During the year ended September 30, 2018, note holders converted all outstanding Notes in the principal amount of \$2,294,300, into 1,166,105 shares of common stock. During the year ended September 30, 2017, note holders converted Notes in the principal amount of \$450,700 into 266,686 shares of common stock. The unamortized debt discount relating to the converted notes was charged to interest expense.

On December 19, 2017 the Company sold 1,289,478 shares of its common stock at a price of \$1.90 per share for total proceeds of approximately \$2.45 million. The purchasers of the common stock also received Series SS warrants which allow 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, and will expire on December 18, 2022. As of September 30, 2018, 328,948 Series SS warrants had been exercised for total proceeds of approximately \$0.7 million.

On February 5, 2018, the Company sold 2,501,145 shares of its common stock at a price of \$1.87 per share for total proceeds of approximately \$4.7 million. The purchasers of the common stock also received Series TT warrants which allow the purchasers to acquire up to 1,875,860 shares of the Company's common stock. The warrants are exercisable at a fixed price of \$2.24 per share, were exercisable on August 6, 2018 and expire on February 5, 2023. As of September 30, 2018, 578,983 Series TT Warrants had been exercised for total proceeds of approximately \$1.30 million.

On July 2, 2018 the Company issued 3,900,000 registered shares of common stock at a purchase price of \$1.30 per share in a registered direct offering. For each share of common stock purchased, the investors received an unregistered Series VV warrant to purchase one share of common stock. The Series VV warrants have an exercise price of \$1.75 per share, will be exercisable on January 2, 2019 and expire on January 2, 2024. As part of this transaction, the Company also issued 195,000 Series WW warrants to the placement agent. These Series WW warrants have an exercise price of \$1.63 per share, will be exercisable on January 2, 2019 and expire on July 2, 2023.

The following chart lists the warrants that were exercised and the proceeds received during the year ended September 30, 2018. No warrants were exercised during the year ended September 30, 2017.

| <u>Warrants</u> | <u>Warrants Exercised</u> | <u>Exercise Price</u> | <u>Proceeds</u> |
|-----------------|-------------------------------|---------------------------|-----------------|
| Series S | 709,391 | \$1.75 | \$1,241,434 |
| Series GG | 200,000 | \$3.00 | \$ 600,000 |
| Series II | 383,500 | \$3.00 | \$1,150,500 |
| Series KK | 182,100 | \$3.04 | \$ 552,674 |
| Series PP | 1,577,500 | \$2.30 | \$3,628,250 |
| Series QQ | 84,000 | \$2.50 | \$210,000 |
| Series RR | 27,687 | \$1.65 | \$45,684 |
| Series SS | 328,948 | \$2.09 | \$687,500 |
| Series TT | 578,983 | \$2.24 | \$1,296,922 |
| | 4,072,109 | | \$9,412,964 |

During the years ended September 30, 2018 and 2017, CEL-SCI entered into Securities Purchase Agreements with Ergomed plc, one of CEL-SCI's Clinical Research Organizations responsible for managing CEL-SCI's Phase 3 clinical trial, to facilitate a partial payment of the accounts payable balances due Ergomed. Under the Agreements, CEL-SCI issued Ergomed shares of common stock 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. Upon issuance, CEL-SCI expenses the full value of the shares and subsequently offsets the expense as amounts are realized through the resale by Ergomed and reduces accounts payable to Ergomed. During the year ended September 30, 2018, CEL-SCI issued Ergomed 2,260,000 shares valued at approximately \$5.5 million. During the year ended September 30, 2017, CEL-SCI issued Ergomed 480,000 shares valued at approximately \$1.3 million. During the years ended September 30, 2018 and 2017, Ergomed credited CEL-SCI approximately \$3.2 million and \$0.1 million for the resale of shares. As a result, CEL-SCI has recorded a net interest expense of \$2.3 million and \$1.2 million for the years ended September 30, 2018 and 2017, respectively. As of September 30, 2018, Ergomed holds 918,900 shares and may resell the shares or return the shares to CEL-SCI for cancellation until December 31, 2018. As of September 30, 2017, Ergomed held 415,208 shares, all of which were resold during the year ended September 30, 2018.

During the year ended September 30, 2018, CEL-SCI's cash increased by approximately \$7.9 million. Significant components of this increase include: net cash used in operating activities of approximately \$13.4 million, which were offset by proceeds from the sale of common stock and warrants of approximately \$12.0 million and proceeds from the exercise of warrants of approximately \$9.4 million.

Primarily as a result of our losses incurred to date, our expected continued future losses, and limited cash balances, we have included an explanatory paragraph in our financial statements expressing substantial doubt about our ability to continue as a going concern. CEL-SCI has included such an explanatory paragraph in the notes to its financial statements on numerous occasions in the past.

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.

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 \$8.4 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., manufacturing the drug.

CEL-SCI may or may not need to raise additional funds to reach the final read-out of the Phase 3 trial, the timing of which depends on when 298 events are reached in the study. However, CEL-SCI will need to raise additional funds, either through the exercise of outstanding warrants/options, through debt or equity financings or partnering arrangements, to 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 2019 to continue operations into the second half of fiscal year 2019. 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, 2018 and 2017, and
Report of Independent Registered Public Accounting Firm**

CEL-SCI CORPORATION

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Report of Independent Registered Public Accounting Firm

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

Opinion on the Financial Statements

We have audited the accompanying balance sheets of CEL-SCI Corporation (the “Company”) as of September 30, 2018 and 2017 and the related statements of operations, stockholders’ equity (deficit), and cash flows for the years then ended, and the related notes (collectively referred to as the “financial statements”). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company at September 30, 2018 and 2017, 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.

Going Concern Uncertainty

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 suffered recurring losses from operations 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.

Basis for Opinion

These financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (“PCAOB”) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting 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.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ BDO USA, LLP

We have served as the Company's auditor since 2005

McLean, Virginia
December 19, 2018

CEL-SCI CORPORATION
BALANCE SHEETS
SEPTEMBER 30, 2018 and 2017

| ASSETS | <u>2018</u> | <u>2017</u> |
|---|----------------------|----------------------|
| Current Assets: | | |
| Cash and cash equivalents | \$ 10,310,044 | \$ 2,369,438 |
| Receivables | 118,657 | 218,481 |
| Prepaid expenses | 364,622 | 826,429 |
| Deposits - current portion | - | 150,000 |
| Inventory used for R&D and manufacturing | <u>645,238</u> | <u>672,522</u> |
| Total Current Assets | 11,438,561 | 4,236,870 |
| Plant, property and equipment | 16,218,851 | 16,793,220 |
| Patent costs, net | 258,093 | 223,167 |
| Deposits | <u>1,670,917</u> | <u>1,670,917</u> |
| Total Assets | <u>\$ 29,586,422</u> | <u>\$ 22,924,174</u> |
| | | |
| LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT) | | |
| Current Liabilities: | | |
| Accounts payable | \$ 5,743,913 | \$ 8,196,334 |
| Accrued expenses | 205,310 | 936,698 |
| Due to employees | 764,941 | 693,831 |
| Notes payable, net of discounts | - | 994,258 |
| Derivative instruments, current portion | 2,498,606 | 10,984 |
| Other current liabilities | <u>14,029</u> | <u>12,449</u> |
| Total Current Liabilities | 9,226,799 | 10,844,554 |
| Derivative instruments, net of current portion | 6,818,458 | 2,042,418 |
| Lease liability | 13,379,962 | 13,211,925 |
| Deferred revenue | 126,795 | 125,000 |
| Other liabilities | <u>33,492</u> | <u>37,254</u> |
| Total liabilities | <u>29,585,506</u> | <u>26,261,151</u> |
| Commitments and Contingencies | | |
| STOCKHOLDERS' EQUITY (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; 28,034,487 and 11,903,133 shares issued and outstanding at September 30, 2018 and 2017, respectively | 280,346 | 119,031 |
| Additional paid-in capital | 331,312,184 | 296,298,401 |
| Accumulated deficit | <u>(331,591,614)</u> | <u>(299,754,409)</u> |
| Total stockholders' equity (deficit) | <u>916</u> | <u>(3,336,977)</u> |
| TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT) | <u>\$ 29,586,422</u> | <u>\$ 22,924,174</u> |

See notes to financial statements.

CEL-SCI CORPORATION
STATEMENTS OF OPERATIONS
YEARS ENDED SEPTEMBER 30, 2018 and 2017

| | 2018 | 2017 |
|---|-----------------|-----------------|
| Grant income | \$ 476,556 | \$ - |
| Operating expenses: | | |
| Research and development | 9,400,306 | 15,606,985 |
| General & administrative | 7,848,496 | 5,800,348 |
| | 17,248,802 | 21,407,333 |
| Operating loss | (16,772,246) | (21,407,333) |
| Other income | 70,896 | 69,020 |
| (Loss) gain on derivative instruments | (8,643,561) | 11,007,215 |
| Interest expense, net | (6,492,294) | (4,032,189) |
| Net loss | (31,837,205) | (14,363,287) |
| Modification of warrants | (14,368) | (63,768) |
| Net loss available to common shareholders | \$ (31,851,573) | \$ (14,427,055) |
| NET LOSS PER COMMON SHARE | | |
| BASIC | \$ (1.87) | \$ (1.83) |
| DILUTED | \$ (1.87) | \$ (1.91) |
| WEIGHTED AVERAGE COMMON SHARES OUTSTANDING | | |
| BASIC | 17,004,722 | 7,891,843 |
| DILUTED | 17,004,722 | 7,902,647 |

See notes to financial statements.

CEL-SCI CORPORATION
STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)
YEARS ENDED SEPTEMBER 30, 2018 and 2017

| | Common Shares | Stock Amount | Additional Paid-In Capital | Accumulated Deficit | Total |
|---|-------------------|-------------------|----------------------------------|-------------------------|-----------------------|
| BALANCE, OCTOBER 1, 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 Beneficial conversion feature on warrants issued | - | - | 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 |
| Shares issued for settlement of clinical research costs | 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) |
| Sale of common stock | 7,690,623 | 76,906 | 11,508,752 | - | 11,585,658 |
| Warrant exercises | 4,072,109 | 40,721 | 10,752,142 | - | 10,792,863 |
| 401(k) contributions paid in common stock | 93,640 | 937 | 144,153 | - | 145,090 |
| Stock issued to nonemployees for service | 356,197 | 3,562 | 689,626 | - | 693,188 |
| Equity based compensation - employees | - | - | 2,743,267 | - | 2,743,267 |
| Employee stock purchases | 463,855 | 4,639 | 380,361 | - | 385,000 |
| Warrants issued with notes payable Conversion of notes payable and interest to common stock | - | - | 947,616 | - | 947,616 |
| Shares issued for settlement of clinical research costs | 1,194,930 | 11,950 | 2,363,066 | - | 2,375,016 |
| Net loss | 2,260,000 | 22,600 | 5,484,800 | - | 5,507,400 |
| Net loss | - | - | - | (31,837,205) | (31,837,205) |
| BALANCE, SEPTEMBER 30, 2018 | 28,034,487 | \$ 280,346 | \$ 331,312,184 | \$ (331,591,614) | \$ 916 |

See notes to financial statements.

CEL-SCI CORPORATION
STATEMENTS OF CASH FLOWS
YEARS ENDED SEPTEMBER 30, 2018 and 2017

| | 2018 | 2017 |
|---|-----------------|-----------------|
| CASH FLOWS FROM OPERATING ACTIVITIES: | | |
| Net loss | \$ (31,837,205) | \$ (14,363,287) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation and amortization | 650,131 | 632,915 |
| Share based payments for services | 530,736 | 232,847 |
| Share based payments for interest | 80,716 | - |
| Equity based compensation | 2,743,267 | 1,380,500 |
| Common stock contributed to 401(k) plan | 145,090 | 151,308 |
| Shares issued for settlement of clinical research costs | 5,507,400 | 1,310,400 |
| Write off of prepaid research and development | 471,157 | - |
| Loss on retired equipment | - | 1,187 |
| Loss (gain) on derivative instruments | 8,643,561 | (11,007,215) |
| Amortization of debt discount | 1,956,424 | 917,692 |
| Inducement expense | 291,234 | - |
| Capitalized lease interest | 168,037 | 200,902 |
| (Increase)/decrease in assets: | | |
| Receivables | 99,824 | (129,307) |
| Prepaid expenses | 153,102 | 151,909 |
| Inventory used for R&D and manufacturing | 27,284 | 336,120 |
| Deposits | 150,000 | 154,995 |
| Increase/(decrease) in liabilities: | | |
| Accounts payable | (2,514,488) | 5,420,816 |
| Accrued expenses | (731,388) | 558,026 |
| Due to employees | 71,110 | 256,303 |
| Other liabilities | 4,450 | 1,995 |
| | (13,389,558) | (13,791,894) |
| Net cash used in operating activities | | |
| CASH FLOWS FROM INVESTING ACTIVITIES: | | |
| Purchases of equipment | (1,015) | (10,525) |
| Expenditures for patent costs | (57,125) | (6,477) |
| | (58,140) | (17,002) |
| Net cash used in investing activities | | |
| CASH FLOWS FROM FINANCING ACTIVITIES: | | |
| Proceeds from issuance of common stock and warrants | 11,596,652 | 10,519,306 |
| Proceeds from employee stock purchases | 385,000 | - |
| Proceeds from issuance of notes payable | - | 2,745,000 |
| Proceeds from exercise of warrants | 9,412,964 | - |
| Payments on obligations under capital lease | (6,312) | (3,968) |
| | 21,388,304 | 13,260,338 |
| Net cash provided by financing activities | | |
| NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS | 7,940,606 | (548,558) |
| CASH AND CASH EQUIVALENTS, BEGINNING OF YEAR | 2,369,438 | 2,917,996 |
| CASH AND CASH EQUIVALENTS, END OF YEAR | \$ 10,310,044 | \$ 2,369,438 |

See notes to financial statements.

CEL-SCI CORPORATION
 STATEMENTS OF CASH FLOWS
 YEARS ENDED SEPTEMBER 30, 2018 and 2017

SUPPLEMENTAL SCHEDULE OF NON-CASH INVESTING AND FINANCING ACTIVITIES:

| | 2018 | 2017 |
|---|--------------|----------------|
| Prepaid consulting services paid with issuance of common stock | \$ 162,452 | \$ (3,339) |
| Conversion of accrued salaries and fees to notes payable | \$ - | \$ 275,000 |
| Conversion of notes payable to common stock | \$ 2,294,300 | \$ 450,700 |
| Exercise of derivative liabilities | \$ 1,379,899 | \$ - |
| Fair value of warrants issued in connection with public offering | \$ - | \$ (4,665,683) |
| Lease payments included in accounts payable at year end | \$ 415 | \$ 1,890 |
| Financing costs included in accounts payable at year end | \$ 46,599 | \$ 35,605 |
| Decrease in receivable due under the litigation funding arrangement offset by the same amount payable to the legal firm providing the services | \$ - | \$ (305,341) |
| | | |
| Cash paid for interest | \$ 1,750,897 | \$ 1,888,612 |

See notes to financial statements.

CEL-SCI CORPORATION

NOTES TO FINANCIAL STATEMENTS

1. ORGANIZATION

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

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). The study was fully enrolled with 928 patients in September 2016. Currently the Company 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.

The Company's immune therapy, Multikine, is being used in a different way than other immune therapies. 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.

The Company is also investigating a different peptide-based immunotherapy as a vaccine for Rheumatoid Arthritis. The Company 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 the Company to advance its first LEAPS product candidate for Rheumatoid Arthritis towards an Investigational New Drug (IND) application, by funding GMP manufacturing, IND enabling studies, and additional mechanism of action studies.

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 2018 and 2017, the Company raised net proceeds of approximately \$21.4 million and \$13.3 million, respectively, through the sale of stock, the exercise of warrants 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 in the final stages of its 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 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 \$50.6 million as of September 30, 2018 on direct costs for the Phase 3 clinical trial. The Company estimates it will incur additional expenses of approximately \$8.4 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 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.

Nine hundred twenty-eight (928) head and neck cancer patients have been enrolled and have completed treatment in the Phase 3 study. The study end point 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 October 31, 2013, the Company commenced arbitration proceedings against inVentiv Health Clinical, LLC, or inVentiv, its former clinical research organization (CRO), and now part of Syneos Health. The arbitration claim, initiated under the Commercial Rules of the American Arbitration Association, alleged (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 the Company and denied inVentiv all but one of its counterclaims (\$429,649 for certain unpaid invoices) against the Company. The arbitrator awarded the Company \$2,917,834 in damages. This is a final and binding decision and to the Company'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 the Company in the arbitration proceedings, all amounts received from inVentiv by virtue of the arbitration award will be paid to Lake Whillans Litigation Finance. As a result of the arbitrator's ruling, the Company wrote off a prepaid asset in the amount of approximately \$471,000, which will no longer be realized.

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 and hybrid instruments based on available market data using appropriate valuation models,

giving consideration to all of the rights and obligations of each instrument. The derivative liabilities are remeasured at fair value at the end of each reporting period as long as they are outstanding.

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

Research and Development Costs – Research and development expenditures are expensed as incurred. Management accrues CRO expenses and clinical trial study expenses as services are performed and relies on the CROs to provide estimates of those costs according to the completion stage of a study. Estimated accrued CRO costs are subject to revisions as the clinical trial studies progress toward completion. The Company adjusts the estimated expense in the period in which the facts that give rise to the change 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, 2018.

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, 2018 and 2017.

On December 22, 2017, the “Tax Cuts and Jobs Act” (the “Tax Act”), was signed into law by the President of the United States. The Tax Act includes significant changes to corporate taxation, including reduction of the U.S. corporate tax rate from 35% to 21%, effective January 1, 2018, limitation of the tax deduction for interest expense to 30% of earnings (except for certain small businesses), limitation of the deduction for net operating losses to 80% of current year taxable income and elimination of net operating loss carrybacks. The Company has accounted for certain income tax effects of the Act in applying FASB ASC 740 to the current reporting period. Because the Company records a valuation allowance for its entire deferred income tax asset, there was no impact to the amounts reported in the Company’s financial statements resulting from the Tax Act.

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 that options granted are expected to be outstanding and has been determined based on an analysis of historical exercise behavior. Forfeitures of awards are recognized as they occur. 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 June 2018, the Financial Accounting Standards Board ("FASB") issued ASU 2018-07, *Compensation—Stock Compensation (Topic 718)*, ("ASU 2018-7"), which expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. An entity should apply the requirements of Topic 718 to nonemployee awards except for specific guidance on inputs to an option pricing model and the attribution of cost. Under current GAAP, non-employee share-based payment awards are measured at the fair value of the consideration received or the fair value of the equity instruments issued, whichever can be more reliably measured. Under ASU 2018-07, non-employee share-based payments would be measured at the grant-date fair value of the equity instruments an entity is obligated to issue when the good has been delivered or the service has been rendered and any other conditions necessary to earn the right to benefit from the instruments have been satisfied. Under current GAAP, the measurement date for equity classified non-employee share-based payment awards is the earlier of the date at which a commitment for performance by the counterparty is reached and the date at which the counterparty's performance is complete. Under ASU 2018-07, equity-classified nonemployee share-based payment awards are measured at the grant date. The definition of the term *grant date* is amended to generally state the date at which a *grantor* and a *grantee* reach a mutual understanding of the key terms and conditions of a share-based payment award. The amendments in this Update are effective for public business entities for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year. Early adoption is permitted, but no earlier than an entity's adoption date of Topic 606. An entity should only remeasure liability-classified awards that have not been settled by the date of adoption and equity classified awards for which a measurement date has not been established through a cumulative-effect adjustment to retained earnings as of the beginning of the fiscal year of adoption. Upon transition, the entity is required to measure these non-employee awards at fair value as of the adoption date. The entity must not remeasure awards that are completed. The Company is currently evaluating the impact the adoption of the standard will have on the Company's financial position and results of operations.

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 adopted the provisions of ASU 2017-09 effective January 1, 2018. There was no impact on the Company's financial position or results operations for the year ended September 30, 2018.

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 Company adopted the provisions of ASU 2017-11 effective October 1, 2017. There was no impact on the financial position or results operations for the year ended September 30, 2018.

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.

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, 2018:

| <u>Warrant</u> | <u>Issue Date</u> | Shares Issuable upon Exercise of <u>Warrants</u> | <u>Exercise Price</u> | <u>Expiration Date</u> | <u>Refer- ence</u> |
|----------------|-----------------------|--|-----------------------|------------------------|------------------------|
| Series S | 10/11/13- 10/24/14 | 327,729 | \$31.25 | 10/11/2018 | 1 |
| Series DD | 12/8/2016 | 1,360,960 | \$4.50 | 12/10/2018 | 1 |
| Series EE | 12/8/2016 | 1,360,960 | \$4.50 | 12/10/2018 | 1 |
| Series N | 8/18/2008 | 85,339 | \$3.00 | 2/18/2020 | 2 |
| Series V | 5/28/2015 | 810,127 | \$19.75 | 5/28/2020 | * |
| Series UU | 6/11/2018 | 187,562 | \$2.80 | 6/11/2020 | 2 |
| Series W | 10/28/2015 | 688,930 | \$16.75 | 10/28/2020 | * |
| Series X | 1/13/2016 | 120,000 | \$9.25 | 1/13/2021 | * |
| Series Y | 2/15/2016 | 26,000 | \$12.00 | 2/15/2021 | * |
| Series ZZ | 5/23/2016 | 20,000 | \$13.75 | 5/18/2021 | * |
| Series BB | 8/26/2016 | 16,000 | \$13.75 | 8/22/2021 | * |
| Series Z | 5/23/2016 | 264,000 | \$13.75 | 11/23/2021 | * |
| 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 | * |
| 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 | 3,500 | \$2.50 | 8/22/2022 | 2 |
| Series GG | 2/23/2017 | 200,000 | \$3.00 | 8/23/2022 | 1 |

| | | | | | |
|-------------|---------------------|-----------|--------------------|----------------------|---|
| Series II | 3/14/2017 | 216,500 | \$3.00 | 9/14/2022 | 1 |
| Series RR | 10/30/2017 | 555,370 | \$1.65 | 10/30/2022 | 2 |
| Series KK | 5/3/2017 | 213,870 | \$3.04 | 11/3/2022 | 1 |
| Series SS | 12/19/2017 | 960,530 | \$2.09 | 12/18/2022 | 2 |
| Series TT | 2/5/2018 | 1,296,877 | \$2.24 | 2/5/2023 | 2 |
| Series PP | 8/28/2017 | 172,500 | \$2.30 | 2/28/2023 | 2 |
| Series WW | 7/2/2018 | 195,000 | \$1.63 | 6/28/2023 | 2 |
| Series VV | 7/2/2018 | 3,900,000 | \$1.75 | 1/2/2024 | 2 |
| Consultants | 1/1/16 - 7/28/17 | 30,400 | \$2.18- \$11.50 | 12/31/18- 7/27/27 | 3 |

*No current period changes to these warrants.

The following chart represents the warrants and non-employee options outstanding at September 30, 2017:

| <u>Warrant</u> | <u>Issue Date</u> | Shares Issuable upon <u>Exercise of</u> <u>Warrants</u> | <u>Exercise</u> <u>Price</u> | <u>Expiration</u> <u>Date</u> | <u>Refer-</u> <u>ence</u> |
|----------------|-----------------------|---|---------------------------------|----------------------------------|------------------------------|
| Series 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- 10/24/14 | 1,037,120 | \$31.25 | 10/11/2018 | 1 |
| Series V | 5/28/2015 | 810,127 | \$19.75 | 5/28/2020 | * |
| Series W | 10/28/2015 | 688,930 | \$16.75 | 10/28/2020 | * |
| Series X | 1/13/2016 | 120,000 | \$9.25 | 1/13/2021 | * |
| Series Y | 2/15/2016 | 26,000 | \$12.00 | 2/15/2021 | * |
| Series ZZ | 5/23/2016 | 20,000 | \$13.75 | 5/18/2021 | * |
| Series BB | 8/26/2016 | 16,000 | \$13.75 | 8/22/2021 | * |
| Series Z | 5/23/2016 | 264,000 | \$13.75 | 11/23/2021 | * |
| 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 | * |
| 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- 7/28/17 | 42,000 | \$2.18- \$70.00 | 12/27/17- 7/27/27 | 3 |
|-------------|----------------------|--------|--------------------|----------------------|---|

*No current period changes to these warrants.

1. Warrant Liabilities

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

| | <u>2018</u> | <u>2017</u> |
|---------------------------|---------------------|---------------------|
| Series S warrants | \$ 33 | \$ 32,773 |
| Series V warrants | 770,436 | 72,912 |
| Series W warrants | 999,081 | 83,754 |
| Series Z warrants | 487,767 | 77,216 |
| Series ZZ warrants | 34,215 | 4,753 |
| Series AA warrants | 380,474 | 65,087 |
| Series BB warrants | 28,456 | 4,322 |
| Series CC warrants | 1,779,724 | 394,220 |
| Series DD warrants | 1,249,287 | 5,492 |
| Series EE warrants | 1,249,287 | 5,492 |
| Series FF warrants | 188,921 | 47,154 |
| Series GG warrants | 607,228 | 342,173 |
| Series HH warrants | 58,816 | 16,014 |
| Series II warrants | 660,135 | 511,636 |
| Series JJ warrants | 88,642 | 24,203 |
| Series KK warrants | 656,930 | 345,720 |
| Series LL warrants | <u>77,632</u> | <u>20,481</u> |
| Total warrant liabilities | <u>\$ 9,317,064</u> | <u>\$ 2,053,402</u> |

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

| | <u>2018</u> | <u>2017</u> |
|--|-----------------------|----------------------|
| Series S Warrants | \$ (751,378) | \$ 3,078,588 |
| Series V warrants | (697,526) | 1,547,341 |
| Series W warrants | (915,327) | 1,716,104 |
| Series Z warrants | (410,551) | 893,388 |
| Series ZZ warrants | (29,461) | 65,856 |
| Series AA warrants | (315,387) | 698,574 |
| Series BB warrants | (24,134) | 54,266 |
| Series CC warrants | (1,385,504) | 666,203 |
| Series DD warrants | (1,243,795) | 437,780 |
| Series EE warrants | (1,243,795) | 685,915 |
| Series FF warrants | (141,767) | 73,828 |
| Series GG warrants | (408,555) | 272,464 |
| Series HH warrants | (42,802) | 13,616 |
| Series II warrants | (462,519) | 404,823 |
| Series JJ warrants | (64,439) | 20,410 |
| Series KK warrants | (449,470) | 25,564 |
| Series LL warrants | <u>(57,151)</u> | <u>352,495</u> |
| Net (loss) gain on warrant liabilities | <u>\$ (8,643,561)</u> | <u>\$ 11,007,215</u> |

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

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

Issuance of Warrant Liabilities

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 DD 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.

On July 10, 2018, the Company extended the expiration date of its Series DD and Series EE warrants to December 10, 2018. The Series DD and Series EE warrants were issued on December 8, 2016. These warrants had been previously extended to July 12, 2018. The modifications are reflected in the fair value measurement of the 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. 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.

Exercise of Warrant Liabilities

The following chart lists the warrant liabilities that were exercised during the year ended September 30, 2018. No warrants were exercised during the year ended September 30, 2017.

| <u>Warrants</u> | <u>Warrants Exercised</u> | <u>Exercise Price</u> | <u>Proceeds</u> |
|-----------------|-------------------------------|---------------------------|--------------------|
| Series S | 709,391 | \$1.75 | \$1,241,434 |
| Series GG | 200,000 | \$3.00 | 600,000 |
| Series II | 383,500 | \$3.00 | 1,150,500 |
| Series KK | 182,100 | \$3.04 | 552,674 |
| | <u>1,474,991</u> | | <u>\$3,544,608</u> |

Expiration of Warrants

On October 17, 2017, 17,821 Series U warrants, with an exercise price of \$43.75, expired. The fair value of the Series U warrants was \$0 on the date of expiration.

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.

2. Equity Warrants

Series VV and Series WW Warrants

On July 2, 2018 the Company issued 3,900,000 registered shares of common stock at a purchase price of \$1.30 per share in a registered direct offering. For each share of common stock purchased, the investors received an unregistered Series VV warrant to purchase one share of common stock. The Series VV warrants have an exercise price of \$1.75 per share, will be exercisable on January 2, 2019 and expire on January 2, 2024. As part of this transaction, the Company also issued 195,000 Series WW warrants to the placement agent. These Series WW warrants have an exercise price of \$1.63 per share, will be exercisable on January 2, 2018 and expire on June 28, 2023. The Company allocated the proceeds received to the shares and the warrants on a relative fair value basis. As a result of such allocation, the Company determined the relative fair value of the Series VV warrants to be approximately \$1.88 million and the relative fair value of the Series WW warrants to be approximately \$0.1 million. The Series VV and WW warrants qualify for equity treatment in accordance with ASC 815.

Series UU Warrants

On June 11, 2018, the Company issued 187,562 Series UU Warrants to holders of the outstanding Series MM and NN notes payable as an inducement to convert their notes into common stock (See Note F). The Series UU warrants are exercisable at a fixed price of \$2.80 per share, will not be exercisable on December 11, 2018 and expire on June 11, 2020. Shares issuable upon the exercise of the warrants are restricted securities unless registered. The Company recognized an expense equal to the fair value of the consideration transferred in the transaction in excess of the fair value of consideration issuable under the original conversion terms. This expense represents the fair value of the Series UU warrants, which was calculated to be approximately \$291,000 and is included as interest expense on the statement of operations. The Series UU warrants qualify for equity treatment in accordance with ASC 815.

Series TT Warrants

On February 5, 2018, the Company sold 2,501,145 shares of its common stock at a price of \$1.87 per share for total proceeds of approximately \$4.7 million. The purchasers of the common stock also received Series TT warrants which allow the purchasers to acquire up to 1,875,860 shares of the Company's common stock. The warrants are exercisable at a fixed price of \$2.24 per share, were exercisable on August 6, 2018 and expire on February 5, 2023. The shares issued and those issuable upon the exercise of the warrants were restricted until they were registered on February 28, 2018. The Company allocated the proceeds received to the shares and the Series TT warrants on a relative fair value basis. As a result of such allocation, the Company determined the relative fair value of the Series TT warrants to be approximately \$1.56 million. The Series TT warrants qualify for equity treatment in accordance with ASC 815.

During the period from issuance through September 30, 2018, 578,983 Series TT Warrants were exercised for total proceeds of approximately \$1.3 million.

Series SS Warrants

On December 19, 2017 the Company sold 1,289,478 shares of its common stock at a price of \$1.90 per share for total proceeds of approximately \$2.45 million. The purchasers of the common stock also received Series SS warrants which allow 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, and will expire on December 18, 2022. Shares issuable upon the exercise of the warrants were restricted securities until they were registered on January 23, 2018. The Company allocated the proceeds received to the shares and the Series SS warrants on a relative fair value basis. As a result of such allocation, the Company determined the relative fair value of the Series SS warrants to be approximately \$1.0 million. The Series SS warrants qualify for equity treatment in accordance with ASC 815.

During the period from issuance through September 30, 2018, 328,948 Series SS warrants were exercised for total proceeds of approximately \$0.7 million.

Series RR Warrants

On October 30, 2017, in consideration for an extension of the maturity date of the Series MM and Series NN convertible notes, the Company issued a total of 583,057 Series RR warrants to the note holders who agreed to the extension. Each Series RR warrant allows the holder to purchase one share of the Company's common stock at an exercise price of \$1.65 per share through the expiration date of October 30, 2022. The Series RR warrants were classified as equity warrants and are recorded at approximately \$0.7 million, the relative fair value on the date of issuance, as described in Note 7.

During the period from issuance through September 30, 2018, 27,687 Series RR warrants were exercised for total proceeds of approximately \$46,000.

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 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 can be exercised 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.

During the period from issuance through September 30, 2018, 1,577,500 and 84,000 Series PP and Series QQ warrants were exercised for total proceeds of approximately \$3.6 and \$0.2 million, respectively.

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, and expire on July 31, 2022. 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. 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. 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 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 August 4, 2018, the Series N warrants were modified. The modification extended the expiration date to February 18, 2020. The incremental cost of this modification was approximately \$14,000, which was recorded as a deemed dividend. The warrants had previously been modified on July 17, 2017, when the expiration date was extended by one year to 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.

On August 4, 2018 the expiration date of the Series N warrants was extended by eighteen months to expire on February 18, 2020. The incremental cost of this extension was approximately \$14,000, which was recorded as a deemed dividend.

Exercise of Equity Warrants

The following chart lists the equity warrants that were exercised during the year ended September 30, 2018.

| <u>Warrants</u> | <u>Warrants Exercised</u> | <u>Exercise Price</u> | <u>Proceeds</u> |
|-----------------|-------------------------------|---------------------------|--------------------|
| Series PP | 1,577,500 | \$2.30 | \$3,628,250 |
| Series QQ | 84,000 | \$2.50 | 210,000 |
| Series RR | 27,687 | \$1.65 | 45,684 |
| Series SS | 328,948 | \$2.09 | 687,500 |
| Series TT | 578,983 | \$2.24 | 1,296,922 |
| | <u>2,597,118</u> | | <u>\$5,868,356</u> |

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, 2018 and 2017 the Company issued 356,197 and 76,551 shares, respectively, of common stock to consultants of which 353,197 and 68,352 shares, respectively, were restricted shares. Under these arrangements, the common stock was issued with stock prices ranging between \$0.85 and \$7.25 per share. The weighted average grant price was \$1.95 and \$2.67 for stock issued during the years and September 30, 2018 and 2017, respectively.

Additionally, during the year ended September 30, 2017 the Company issued to consultants 20,000 options 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, 2018 and 2017, the Company recorded total expense of approximately \$531,000 and \$233,000, respectively, relating to these consulting agreements. At September 30, 2018 and 2017, approximately \$207,000 and \$45,000, respectively, are included in prepaid expenses. As of September 30, 2018, 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:

| | 2018 | 2017 |
|---|----------------------|----------------------|
| Leased manufacturing facility | \$ 21,183,756 | \$ 21,183,756 |
| Research equipment | 3,162,150 | 3,169,158 |
| Furniture and equipment | 124,369 | 124,369 |
| Leasehold improvements | 131,910 | 131,910 |
| | <u>24,602,186</u> | <u>24,609,193</u> |
| Accumulated depreciation and amortization | <u>(8,383,335)</u> | <u>(7,815,973)</u> |
| Net plant, property and equipment | <u>\$ 16,218,851</u> | <u>\$ 16,793,220</u> |

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, 2018 and 2017, accumulated depreciation on the manufacturing building is approximately \$5.1 million and \$4.6 million, respectively. Depreciation expense for the years ended September 30, 2018 and 2017 totaled approximately \$575,000 and, \$593,000, 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 \$16,000 and \$21,000 on September 30, 2018 and 2017, respectively. Amortization of the capital lease asset is included in general and administrative expenses on the Statements of Operations.

6. PATENTS

Patents consisted of the following at September 30:

| | 2018 | 2017 |
|--------------------------|--------------------|--------------------|
| Patents | \$ 1,644,759 | \$ 1,535,087 |
| Accumulated amortization | <u>(1,386,666)</u> | <u>(1,311,920)</u> |
| Patents, net | <u>\$ 258,093</u> | <u>\$ 223,167</u> |

During the years ended September 30, 2018 and 2017, there was no impairment of patent costs. Amortization expense for the years ended September 30, 2018 and 2017 totaled approximately \$75,000 and \$40,000, respectively. The total estimated future amortization is as follows:

| <u>Years ending September 30,</u> | |
|-----------------------------------|-------------------|
| 2019 | \$ 42,000 |
| 2020 | 38,000 |
| 2021 | 35,000 |
| 2022 | 31,000 |
| 2023 | 21,000 |
| Thereafter | 91,000 |
| | <u>\$ 258,000</u> |

7. NOTES PAYABLE

During the year ended September 30, 2017, the Company issued two series of convertible notes to individual investors, Series MM and Series NN (the Notes). The Notes had an aggregate principal amount of \$1.5 million and \$1.2 million, respectively, bore interest at 4% and were originally due on December 22, 2017. At the option of the note holders, the Series MM Notes could be converted into shares of the Company's common stock at a fixed conversion rate of \$1.69 and the Series NN Notes could be converted into shares of the Company's common stock at a fixed conversion rate of \$2.29. The purchasers of the convertible notes also received Series MM and Series NN warrants which allow the purchasers to acquire up to 893,491 and 539,300 shares of the Company's common stock, respectively. The Series MM warrants are exercisable at a price of \$1.86 per share and expire on June 22, 2022. The Series NN warrants are exercisable at a price of \$2.52 per share and expire on July 24, 2022. 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. Upon issuance, 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 Notes to be approximately \$1.6 million, the Series MM warrants to be approximately \$0.6 million, the Series NN warrants to be approximately \$0.5 million, and recorded a debt discount in the amount of approximately \$1.1 million.

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 non-bifurcation, 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.

On October 30, 2017, the Company extended the due dates of the Notes from December 22, 2017 to September 21, 2018, and issued the note holders 583,057 of Series RR Warrants. The Series RR warrants expire on October 30, 2022 and are exercisable at a price of \$1.65 per share. These Series RR warrants are classified as equity warrants and are recorded at approximately \$0.7 million, the fair value on the date of issuance.

Because the Company was experiencing financial difficulties at the time of the modification and the creditors granted the Company a concession they would not have otherwise considered in the form of a lower effective interest rate, this modification was accounted for under ASC 470-60, “*Troubled Debt Restructuring*.” The Company calculated the future cash flows of the restructured debt to be greater than the carrying value of the debt and accounted for the change in debt prospectively, using the effective interest rate that equated the carrying amount to the future cash flows. The carrying value of the debt on the date of restructuring was approximately \$0.7 million, which was net of a discount of approximately \$1.6 million. The discount is being amortized to interest expense over the life of the Notes using the effective interest method.

On June 11, 2018, all remaining outstanding Series MM and Series NN notes were converted into common stock in accordance with the original agreements resulting in notes in the principal amount of \$1,860,000 being converted into 937,804 shares of common stock. As an inducement to convert, the Company issued the note holders 187,562 Series UU warrants. The Series UU warrants are exercisable at a fixed price of \$2.80 per share, are exercisable on December 11, 2018 and expire on June 11, 2020. Shares issuable upon the exercise of the warrants are restricted securities unless registered. The Company recognized an expense equal to the fair value of the consideration transferred in the transaction in excess of the fair value of consideration issuable under the original conversion terms. This expense represents the fair value of the Series UU warrants, which was calculated to be approximately \$291,000 and is included as interest expense on the statement of operations.

During the year ended September 30, 2018 and including the inducement, note holders converted all outstanding Notes in the principal amount of \$2,294,300, into 1,166,105 shares of common stock. During the year ended September 30, 2017, note holders converted Notes in the principal amount of \$450,700 into 266,686 shares of common stock. The unamortized debt discount relating to the converted notes was charged to interest expense.

The total debt discount was amortized to interest expense using the effective interest method over the expected term of the Notes. During the years ended September 30, 2018 and 2017, the Company recorded approximately \$2.0 million and \$0.9 million in interest expense, respectively, relating to the amortization of the debt discount. At September 30, 2017, the remaining debt discount is approximately \$1.3 million.

On June 11, 2018, all note holders were given the option to receive the interest accrued on the Notes in cash or in shares converted at \$2.80, the fair value of the shares on that date. Accrued interest in the amount of approximately \$0.1 million was converted into 28,825 shares of common stock.

8. INCOME TAXES

At September 30, 2018 and 2017, the Company had net deferred tax assets of \$24.8 million and \$99.0 million, respectively. Due to uncertainties surrounding the Company’s ability to generate future taxable income to realize these assets, a full valuation allowance has been established to offset the net deferred tax assets. 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.

Pursuant to Section 382 of the Internal Revenue Code, or IRC, annual use of the Company’s net operating loss (NOL) carryforwards may be limited in the event a cumulative change in ownership of more than 50% occurs within a three-year period. The Company determined that because of various stock issuances used to finance its operations, an ownership change as defined in the provisions of Section 382 of the IRC occurred on February 5, 2018. Such ownership change resulted in annual

limitations on the utilization of tax attributes, including NOL carryforwards and tax credits. The Company estimates that \$188.9 million of its NOL carryforwards were effectively eliminated under Section 382 for federal income tax purposes. A portion of the remaining NOL carryforwards limited by Section 382 will become available each year. As a result of the Section 382 estimated analysis completed during 2018, the Company has included \$18.6 million in the deferred tax asset schedule, which is the deferred tax asset relating to the unlimited portion of the NOL carryforwards. The Company's Section 382 estimated analysis was completed through September 30, 2018. If additional changes in ownership occur subsequent to year end, additional NOL and tax credit carryforwards could be eliminated or restricted. If eliminated, the related asset would be removed from the deferred tax asset schedule with a corresponding reduction in the valuation allowance.

The Company had federal NOL carryforwards of approximately \$18.6 million and \$187.8 million at September 30, 2018 and 2017, respectively. The NOL carryforwards begin to expire during the year ended September 30, 2020 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, 2018 and 2017. The R&D credit begins to expire during the year ended September 30, 2020 and becomes fully expired during the fiscal year ended 2029.

Significant components of the Company's deferred tax assets as of September 30, 2018 and 2017 are listed below:

| | <u>2018</u> | <u>2017</u> |
|------------------------------|-------------------|-------------------|
| NOL carryforwards | \$ 5,052,000 | \$ 70,752,000 |
| R&D credit | 1,221,000 | 1,221,000 |
| Stock-based compensation | 3,097,000 | 6,292,000 |
| Capitalized R&D | 15,518,000 | 21,160,000 |
| Vacation and other | 544,000 | 121,000 |
| Total deferred tax assets | <u>25,432,000</u> | <u>99,546,000</u> |
| Fixed assets and intangibles | (634,000) | (523,000) |
| Total deferred tax liability | <u>(634,000)</u> | <u>(523,000)</u> |
| Net deferred tax asset | 24,798,000 | 99,023,000 |
| Valuation allowance | (24,798,000) | (99,023,000) |
| Ending Balance | <u>\$ -</u> | <u>\$ -</u> |

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 for the years ended September 30:

| | <u>2018</u> | <u>2017</u> |
|--|-------------|-------------|
| Federal Rate | 24.28% | 34.00% |
| Federal rate change | (88.94) | - |
| State tax rate, net of federal benefit | 4.47 | 6.44 |
| State tax rate change | - | (3.91) |
| Net operating loss – write-off | (161.21) | - |
| Other adjustments | (5.95) | (3.39) |

| | | |
|-------------------------------|---------------|----------------|
| Permanent differences | (5.79) | 25.49 |
| Change in valuation allowance | <u>233.14</u> | <u>(58.63)</u> |
| Effective tax rate | <u>0.00%</u> | <u>0.00%</u> |

The Company applies the provisions of ASC 740, "Accounting for Uncertainty in Income Taxes," which requires financial statement benefits to be recognized for positions taken for tax return purposes when it is more likely than not that the position will be sustained. The Company has elected to reflect any tax penalties or interest resulting from tax assessments on uncertain tax positions as a component of tax expense. The Company has generated federal net operating losses in tax years ending September 30, 1998 through 2017. These years remain open to examination by the major domestic taxing jurisdictions to which the Company is subject.

On December 22, 2017, the U.S. government enacted comprehensive tax legislation commonly referred to as the Tax Cuts and Jobs Act (the "Act" or "Tax Reform"). Among other changes, the Act reduces the current corporate federal income tax rate from 35% to 21% effective January 1, 2018. As deferred tax assets and deferred tax liabilities are measured using the tax rates expected to apply to taxable income in the years during which the temporary differences are anticipated to be recovered or settled, the Company determined that it was necessary to revalue its deferred tax assets and deferred tax liabilities as of December 31, 2017.

9. STOCK COMPENSATION

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

| | <u>Year Ended September 30,</u> | |
|---------------|---------------------------------|-------------|
| | <u>2018</u> | <u>2017</u> |
| Employees | \$2,743,267 | \$1,380,500 |
| Non-employees | \$ 530,736 | \$ 232,847 |

Stock compensation expenses were recorded as general and administrative expense. During the years ended September 30, 2018 and 2017, non-employee stock compensation excluded approximately \$207,000 and \$45,000, respectively, for future services to be performed (Note 12).

During the years ended September 30, 2018 and 2017 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>2018</u> | <u>2017</u> |
|---------------------------------|-------------------|-----------------|
| Expected stock price volatility | 89.90 – 94.32% | 88.54 – 90.67% |
| Risk-free interest rate | 2.30 – 3.04% | 2.18 – 2.29% |
| Expected life of options | 9.67 – 9.70 Years | 9.69 – 10 Years |
| Expected dividend yield | - | - |

Non-Qualified Stock Option Plans – At September 30, 2018, the Company has collectively authorized the issuance of 3,387,200 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.

Incentive Stock Option Plans – At September 30, 2018, 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, 2018 is summarized as follows:

Non-Qualified and Incentive Stock Option Plans

| | <u>Outstanding</u> | | | | <u>Exercisable</u> | | | |
|-----------------------------------|-------------------------|--|--|----------------------------------|-------------------------|--|--|----------------------------------|
| | <u>Number of Shares</u> | <u>Weighted Average Exercise Price</u> | <u>Weighted Ave Remaining Contractual Term (Years)</u> | <u>Aggregate Intrinsic Value</u> | <u>Number of Shares</u> | <u>Weighted Average Exercise Price</u> | <u>Weighted Ave Remaining Contractual Term (Years)</u> | <u>Aggregate Intrinsic Value</u> |
| Outstanding at September 30, 2016 | 343,575 | \$59.22 | 5.35 | \$0 | 232,931 | \$66.28 | 4.76 | \$0 |
| Vested | | | | | 63,812 | \$18.45 | | |
| Granted (a) | 932,825 | \$2.17 | | | | | | |
| Exercised | | | | | | | | |
| Forfeited | 15,795 | \$9.46 | | | | | | |
| Expired | 20,761 | \$88.80 | | | 20,761 | \$88.80 | | |
| Cancelled | | | | | | | | |
| Outstanding at September 30, 2017 | 1,239,844 | \$16.44 | 8.50 | \$1,400 | 275,982 | \$53.53 | 4.91 | \$0 |
| Vested | | | | | 334,111 | \$7.63 | | |
| Granted | 1,958,108 | \$2.50 | | | | | | |
| Exercised | | | | | | | | |
| Forfeited | 5,426 | \$3.79 | | | | | | |
| Expired | 32,399 | \$67.73 | | | 32,399 | \$67.73 | | |
| Cancelled | | | | | | | | |
| Outstanding at September 30, 2018 | 3,160,127 | \$7.30 | 8.88 | \$4,761,973 | 577,694 | \$26.18 | 6.74 | \$604,763 |

(a) 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, 2018 is presented below:

| | <u>Number of Options</u> | <u>Weighted Average Grant Date Fair Value</u> |
|--------------------------------|--------------------------|---|
| Unvested at October 1, 2016 | 110,644 | \$ 36.96 |
| Vested | (63,812) | |
| Granted | 932,825 | |
| Forfeited | (15,795) | |
| Unvested at September 30, 2017 | 963,862 | \$ 4.91 |
| Vested | (334,111) | |
| Granted | 1,958,108 | |
| Forfeited | (5,426) | |
| Unvested at September 30, 2018 | <u>2,582,433</u> | \$ 2.48 |

Incentive Stock Bonus Plan – 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, 2018 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, 2018 and 2017, the Company recorded expense relating to the issuance of restricted stock pursuant to the plan of approximately \$1.4 million and \$633,000, respectively. At September 30, 2018, the Company has unrecognized compensation expense of approximately \$1.0 million which is expected to be recognized over a weighted average period of 3.3 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, 2018 is presented below:

| | Number of Shares | Weighted Average Grant Date Fair Value |
|--------------------------------|---------------------|--|
| Unvested at September 30, 2016 | 604,000 | \$13.75 |
| Vested | (136,000) | |
| Unvested at September 30, 2017 | 468,000 | \$13.75 |
| Vested | (156,000) | |
| Unvested at September 30, 2018 | <u>312,000</u> | \$13.75 |

Stock Bonus Plans – At September 30, 2018, the Company was authorized to issue up to 783,760 shares of common stock under its Stock Bonus Plans. All employees, directors, officers, consultants, and advisors are eligible to be granted shares. As of September 30, 2018, the Company has issued a total of 297,230 shares of common stock from the Stock Bonus Plans.

Stock Compensation Plans – At September 30, 2018, 134,000 shares were authorized for use in the Company’s Stock Compensation Plans. During the years ended September 30, 2018, and 2017, zero and 23,202 shares, respectively, were issued from the Stock Compensation Plans to consultants for payment of services at a cost of approximately \$0 and \$60,000, respectively. During the year ended September 30, 2018 and 2017, 3,000 and 13,000 shares, respectively, were issued to employees and directors from the Stock Compensation Plans as part of their compensation at a cost of approximately \$4,000 and \$24,000, respectively. As of September 30, 2018, the Company has issued 118,590 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. During the year ended September 30, 2018, 93,640 shares were issued to the Company’s 401(k) plan for a cost of approximately \$145,000. 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.

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 were being credited against future invoices in \$150,000 annual increments through December 2017. As of September 30, 2018, all advance payments have been expensed.

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 Company’s Phase III clinical 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 \$28.1 million related to Ergomed’s services. This amount is net of Ergomed’s discount of approximately \$9.4 million. During the years ended September 30, 2018 and 2017, the Company recorded, approximately \$3.1 million and \$5.8 million, respectively, as research and development expense related to Ergomed’s services. These amounts were net of Ergomed’s discount of approximately \$1.0 and \$2.1 million during the years ended September 30, 2018 and 2017, respectively.

In October 2013, the Company entered into two co-development and profit sharing agreements with Ergomed. One agreement supported the Phase 1 study 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.

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 derecognized.

As of September 30, 2018 and 2017, the leased building asset has a net book value of approximately \$16.1 million and \$16.6 million, respectively, and the landlord liability has a balance of \$13.4 million and \$13.2 million, respectively. 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, 2018 and 2017.

Approximate future minimum lease payments under the San Tomas lease as of September 30, 2018 are as follows:

| Years ending September 30, | | |
|---|----|-------------|
| 2019 | \$ | 1,808,000 |
| 2020 | | 1,872,000 |
| 2021 | | 1,937,000 |
| 2022 | | 2,004,000 |
| 2023 | | 2,073,000 |
| Thereafter | | 11,685,000 |
| Total future minimum lease obligation | | 21,379,000 |
| Less: imputed interest on financing obligation | | (7,999,000) |
| Net present value of lease financing obligation | \$ | 13,380,000 |

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, 2018 and 2017 was approximately \$71,000 and \$69,000, respectively.

The Company leases its research and development laboratory under a 60 month lease which expires 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, 2018 and 2017, the Company has recorded a deferred rent liability of approximately \$12,000 and \$5,000, 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, 2018 and 2017, the Company has recorded a deferred rent liability of approximately \$14,000 and \$18,000, respectively.

The Company leases office equipment under a capital lease arrangement. The term of the capital lease is 60 months and it expires on October 31, 2021. The monthly lease payment is \$505. The lease bears annual interest at approximately 6.25%.

Approximate future minimum annual lease payments due under non-cancelable operating leases, excluding the San Tomas lease, for the years ending after September 30, 2018 are as follows:

| Years ending September 30, | | |
|---------------------------------------|----|----------------|
| 2019 | \$ | 258,000 |
| 2020 | | 238,000 |
| 2021 | | 163,000 |
| 2022 | | 69,000 |
| Thereafter | | - |
| Total future minimum lease obligation | \$ | <u>728,000</u> |

Rent expense, for the years ended September 30, 2018 and 2017, excluding the rent paid on the San Tomas lease, was approximately \$253,000 and \$245,000, respectively.

Vendor Obligations

Further, the Company 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 \$8.4 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 August 13, 2018, four officers of the Company (Geert Kersten, Patricia Prichep, Daniel Zimmerman and John Cipriano) purchased 463,855 restricted shares of the Company's common stock from the Company for \$385,000, or \$0.83 per share. The shares are subject to the conditions of Rule 144 under the Securities Act of 1933.

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 convertible notes, Mr. Kersten also received 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.

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 would 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 upon conversion. Along with the other purchasers of the convertible notes, the trust and 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 October 30, 2017, in consideration for an extension of the maturity date of the Series MM and Series NN convertible notes, the Company issued a total of 583,057 Series RR warrants to the note holders who agreed to the extension. Mr. Kersten, the trust and Ms. Prichep received 73,965, 54,585 and 5,459 Series RR warrants, respectively. The Series RR warrants were classified as equity warrants in accordance with ASC 815 and the fair value of the portion attributable to Mr. Kersten, the trust and Ms. Prichep was calculated to be approximately \$151,000 on the date of issuance.

On June 11, 2018, to induce conversion of the Series MM and NN Notes, all note holders, including Mr. Kersten and Ms. Prichep were issued Series UU warrants in an amount equal to 20% of the shares into which the Notes were convertible. This resulted in the issuance of 29,586, 21,834 and 2,183 Series UU warrants to Mr. Kersten, the trust and Ms. Prichep, respectively. The Series UU warrants have an exercise price of \$2.80 per share and expired on June 11, 2018. These terms are identical to the other recipients of the Series UU Warrants. At that time, all outstanding Notes were converted, including those held by the related parties. The Company recognized an expense equal to the fair value of the consideration transferred in the transaction in excess of the fair value of consideration issuable under the original conversion terms. The portion of the expense attributed to the fair value of the Series UU warrants issued to Mr. Kersten, the trust and Ms. Prichep was approximately \$83,000 and is included as interest expense on the Statement of Operations. The Series UU warrants qualify for equity treatment in accordance with ASC 815.

The Series MM and NN Notes accrued interest at 4%. Upon conversion, the officers elected to receive the accrued interest in shares of common stock instead of cash. On the conversion date, the officers converted approximately \$19,000 in accrued interest into 6,930 shares of common stock.

No other interest payments were made to officers during the years ended September 30, 2018 and 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 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.

13. STOCKHOLDERS' EQUITY

Sales of Securities

On July 2, 2018, the Company closed on a registered direct offering and concurrent private placement with institutional investors. The Company received net proceeds of approximately \$4.7 million. The Company issued approximately 3,900,000 registered shares of common stock at a purchase price of \$1.30 per share. Concurrently in a private placement, the Company issued to the investors warrants to purchase up to 3,900,000 shares of its common stock. For each share of common stock purchased in the registered direct offering, the investors in the private placement received an unregistered warrant to purchase one share of common stock. The warrants have an exercise price of \$1.75 per share, will be exercisable on January 2, 2019, and will expire on January 2, 2024. The Company also issued 195,000 Series WW warrants to the placement agent. These Series WW warrants have an exercise price of \$1.63 per share, will be exercisable on January 2, 2018 and expire on July 2, 2023. The Company allocated the proceeds received to the shares and the warrants on a relative fair value basis. As a result of such allocation, the Company determined the relative fair value of the Series VV warrants to be approximately \$1.88 million and the relative fair value of the Series WW warrants to be approximately \$0.1 million. The Series VV and WW warrants qualify for equity treatment in accordance with ASC 815.

On February 5, 2018, the Company sold 2,501,145 shares of its common stock at a price of \$1.87 per share for total proceeds of approximately \$4.7 million. The common stock was restricted until registered. The purchasers of the common stock also received Series TT warrants which allow the purchasers to acquire up to 1,875,860 shares of the Company's common stock. The warrants are exercisable at a fixed price of \$2.24 per share, were exercisable on August 6, 2018 and expire on February 5, 2023. The shares and warrants were registered on February 28, 2018. The Company allocated the proceeds received to the shares and the Series TT warrants on a relative fair value basis. As a result of such allocation, the Company determined the relative fair value of the Series TT warrants to be approximately \$1.56 million. The Series TT warrants qualify for equity treatment in accordance with ASC 815.

During the period from issuance through September 30, 2018, 578,983 Series TT Warrants were exercised for total proceeds of approximately \$1.3 million.

On December 19, 2017 the Company sold 1,289,478 shares of its common stock at a price of \$1.90 per share for total proceeds of approximately \$2.45 million. The common stock was restricted until registered. The purchasers of the common stock also received warrants which allow 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, were exercisable on December 20, 2017 and will expire on December 18, 2022. The shares and warrants were registered on January 23, 2018. The Company allocated the proceeds received to the shares and the Series SS warrants on a relative fair value basis. As a result of such allocation, the Company determined the relative fair value of the Series SS warrants to be approximately \$1.0 million. The Series SS warrants qualify for equity treatment in accordance with ASC 815.

During the period from issuance through September 30, 2018, 328,948 Series SS warrants were exercised for total proceeds of approximately \$0.7 million.

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 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.

Other Equity Transactions

Periodically, the Company has entered into Securities Purchase Agreements with Ergomed plc, one of the Company's Clinical Research Organizations responsible for managing the Company's Phase 3 clinical trial, to facilitate a partial payment of the accounts payable balances due Ergomed. Under the Agreements, the Company issued Ergomed shares of common stock 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. Upon issuance, the Company expenses the full value of the shares as interest expense and subsequently offsets the expense as amounts are realized through the resale by Ergomed and reduces accounts payable to Ergomed. During the year ended September 30, 2018, the Company issued Ergomed 2,260,000 shares valued at approximately \$5.5 million. During the year ended September 30, 2017, the Company issued Ergomed 480,000 shares valued at approximately \$1.3 million. During the years ended September 30, 2018 and 2017, Ergomed

credited the Company approximately \$3.2 million and \$0.1 million for the resale of shares. As a result, the Company has recorded a net interest expense of \$2.3 million and \$1.2 million for the years ended September 30, 2018 and 2017, respectively. As of September 30, 2018, Ergomed holds 918,900 shares and may resell the shares or return the shares to the Company for cancellation until December 31, 2018. As of September 30, 2017, Ergomed held 415,208 shares, all of which were resold during the year ended September 30, 2018.

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 with respect to the future amounts.

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

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

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

The table below sets forth the liabilities measured at fair value on a recurring basis, by input level, on the balance sheet at September 30, 2018:

| | Quoted Prices in Active Markets for Identical Liabilities (Level 1) | Significant Other Observable Inputs (Level 2) | Significant Unobservable Inputs (Level 3) | Total |
|------------------------|---|---|---|---------------------|
| Derivative Instruments | \$ <u>33</u> | \$ <u>-</u> | \$ <u>9,317,031</u> | \$ <u>9,317,064</u> |

The table below sets forth the liabilities measured at fair value on a recurring basis, by input level, on the balance sheet at September 30, 2017:

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

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

| | <u>2018</u> | <u>2017</u> |
|--|---------------------|---------------------|
| Beginning balance | \$ 2,020,629 | \$ 5,283,573 |
| Issuances | - | 4,665,683 |
| Exercises | (595,780) | - |
| Net realized and unrealized derivative loss (gain) | <u>7,892,182</u> | <u>(7,928,627)</u> |
| Ending balance | <u>\$ 9,317,031</u> | <u>\$ 2,020,629</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, 2018, the Company's Level 3 derivative instruments have a weighted average fair value of \$1.50 per share and a weighted average exercise price of \$8.50 per share. Fair values were determined using a weighted average risk free interest rate of 2.68% and 121% volatility. The instruments have a weighted average time to maturity of 2.3 years. 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.

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:

| | <u>Year ended September 30,</u> | |
|--|---------------------------------|------------------------|
| | <u>2018</u> | <u>2017</u> |
| Loss per share - basic | | |
| Net loss available to common shareholders - basic | \$ (31,851,573) | \$ (14,427,055) |
| Weighted average shares outstanding - basic | 17,004,722 | 7,891,843 |
| Basic loss per common share | <u>\$ (1.87)</u> | <u>\$ (1.83)</u> |
| Loss per share - diluted | | |
| Net loss available to common shareholders - basic | \$ (31,851,573) | \$ (14,427,055) |
| Gain on derivatives (1) | - | (677,287) |
| Net loss available to common shareholders - diluted | <u>\$ (31,851,573)</u> | <u>\$ (15,104,342)</u> |
| Weighted average shares outstanding - basic | 17,004,722 | 7,891,843 |
| Incremental shares underlying dilutive "in the money" warrants (1) | - | 10,804 |
| Weighted average shares outstanding - diluted | <u>17,004,722</u> | <u>7,902,647</u> |
| Diluted loss per common share | <u>\$ (1.87)</u> | <u>\$ (1.91)</u> |

(1) Includes series GG & II for the year ended September 30, 2017

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:

| | <u>2018</u> | <u>2017</u> |
|---------------------------|-------------------|------------------|
| Options and Warrants | 11,794,603 | 2,538,130 |
| Convertible Debt | - | 1,166,106 |
| Unvested Restricted Stock | 312,000 | 604,000 |
| Total | <u>12,106,603</u> | <u>4,308,236</u> |

16. SUBSEQUENT EVENTS

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

CORPORATE INFORMATION

Board of Directors

Geert R. Kersten
Chief Executive Officer
CEL-SCI Corporation

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

Bruno Baillavoine
Director
Pericles Group UK

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
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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.

There are approximately 720 stockholders of record as of March 26, 2019. 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 filed with 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
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