



Annual Report

2019

CEL-SCI Corporation

CEL-SCI Corporation (CEL-SCI) is a clinical-stage biotechnology company 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 for patients who are newly diagnosed with advanced primary squamous cell carcinoma of the head and neck, for which CEL-SCI has received Orphan Drug Status from the U.S. Food and Drug Administration, or FDA. The study was fully enrolled with 928 patients in September 2016. The study's primary 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's primary end-point is met will occur when there are a total of 298 deaths in those two groups. If the primary end-point of this global study is achieved, CEL-SCI expects to use the results to support a Biologics License Application, or BLA, to the FDA for Multikine for neoadjuvant therapy in patients with squamous cell carcinoma of the head and neck, or SCCHN (hereafter also referred to as advanced primary head and neck cancer).

CEL-SCI's investigational immunotherapy, Multikine, is being used in a different way than cancer immunotherapy 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 (i.e., as a neoadjuvant). It is also administered locally around the tumors and near the draining lymph node. For example, in the Phase 3 clinical trial, Multikine was given locally for three weeks, five days per week 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 of this neoadjuvant therapy and administration before weakening of the immune system by surgery, chemotherapy and radiation will result in improved outcomes and better overall survival rates for patients suffering from head and neck cancer.

CEL-SCI is also investigating a 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 a clinical-stage biotechnology company 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:

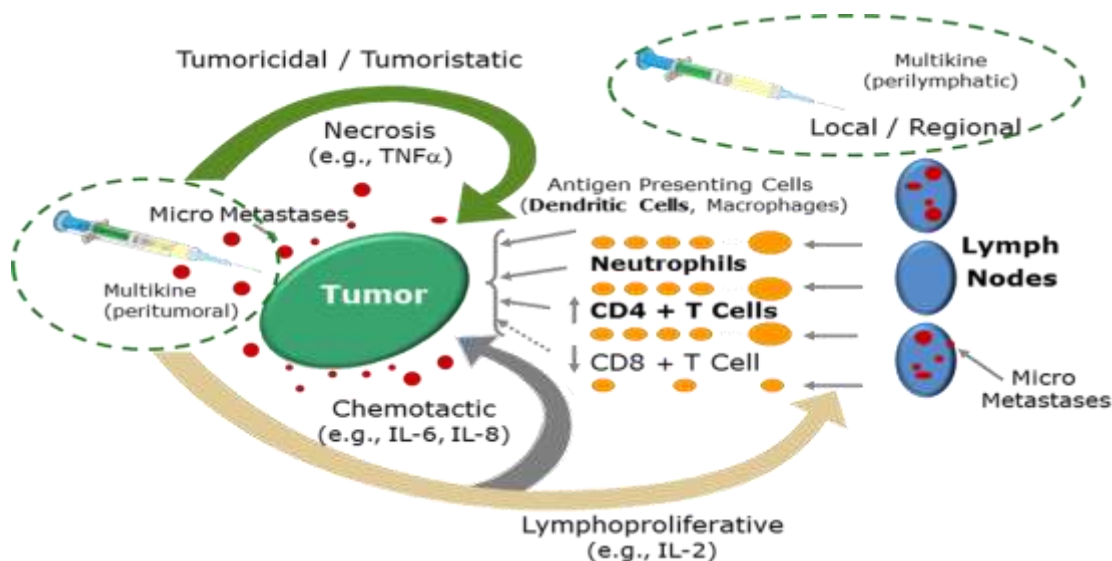
- 1) Multikine, an investigational immunotherapy under development for the potential treatment of certain head and neck cancers;
- 2) L.E.A.P.S. (Ligand Epitope Antigen Presentation System) technology, or LEAPS, with two investigational therapies, CEL-2000 and CEL-4000, vaccine product candidates under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

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 FDA, in connection with CEL-SCI's future anticipated regulatory submission for approval in the United States. 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, and neither its safety nor its efficacy been established.

Multikine is an immunotherapy product candidate comprised of a patented defined mixture of 14 human natural cytokines. If commercial approval is obtained, CEL-SCI intends to manufacture it in a proprietary manner in CEL-SCI's manufacturing facility. CEL-SCI spent over 10 years and more than \$80 million developing and validating the manufacturing process for Multikine. The pro-inflammatory cytokine mixture includes interleukins, interferons, chemokines and colony-stimulating factors, which contain elements of the body's natural mix of defenses against cancer.

Multikine is designed to be used in a different way than cancer immunotherapy is generally being used. Generally, cancer immunotherapy is given to patients who have already failed other treatments such as surgery, radiation and/or chemotherapy and most of the time it is administered systemically. Multikine on the other hand is administered locally to treat tumors and their microenvironment before any other therapy has been administered because it is believed that this is the time when the immune system would be most amenable to activation against the tumor. For example, during the dosing phase of the ongoing Phase 3 clinical trial, Multikine was injected locally around the tumor and near the adjacent draining lymph nodes as a first line of treatment before surgery, radiation and/or chemotherapy. 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 surgery, chemotherapy and radiation will result in better anti-tumor response than if Multikine were administered as a second- or later-line therapy. In clinical studies of Multikine, administration of the investigational therapy to head and neck cancer patients has demonstrated the potential for lesser or no appreciable toxicity.



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

The first indication CEL-SCI is pursuing for its investigational drug product candidate Multikine is an indication for the neoadjuvant therapy in patients with squamous cell carcinoma of the head and neck, or SCCHN (hereafter also referred to as advanced primary head and neck cancer).

SCCHN represents one type of head and neck cancer, and CEL-SCI believes that there is a large, unmet medical need among head and neck cancer patients as a whole. 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 650,000 patients diagnosed worldwide each year, of which approximately 60,000 patients diagnosed annually are in the United States and approximately 105,000 patients diagnosed annually are in Europe. Multikine investigational immunotherapy has been 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. The assessment of whether the primary study endpoint was met can only be made when a certain number of events (deaths) have occurred in these two main comparator groups of the study.

The primary endpoint for the protocol for this Phase 3 head and neck cancer study required that a 10% increase in overall survival be obtained in the Multikine group which also is administered with CIZ (CIZ = low dose (non-chemotherapeutic) of cyclophosphamide, indomethacin and Zinc-multivitamins) all of which are thought to enhance Multikine activity), plus SOC (Surgery + Radiotherapy or Chemoradiotherapy) arm of the study over the control comparator (SOC alone) arm. As the study was designed, the final determination of whether this endpoint had been successfully reached can only be determined when 298 events 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 across 24 countries 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 Phase 3 study protocol assumed an overall survival rate of about 55% at 3 years for the SOC treatment group alone. An analysis conducted using the Surveillance, Epidemiology, and End Results, or SEER U.S. government data base for the same study population as CEL-SCI enrolled in this Phase 3 study and covering the years 2011-2016 (when the patients were enrolled), shows that the standard of care for these patients has not resulted in an improvement in survival. In fact, the U.S. survival of the specific type of patients enrolled in the Phase 3 study during the study years was only about 47% at 3 years and about 37% at 5 years. At this point, all patients enrolled in the study are being followed-up as required by the study protocol.

This trial is currently 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 \$55.8 million as of September 30, 2019 on direct costs for the Phase 3 clinical trial. CEL-SCI estimates it will incur additional expenses of approximately \$4.5 million for the remainder of the Phase 3 clinical trial. It should be noted that this estimate is based only on the information currently from the CROs responsible for managing the Phase 3 clinical trial and does not include other related costs, e.g., preparations for the potential commercial manufacture 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 may 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. 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.

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 conditions, allergies, transplantation rejection and cancer, when it cannot do so on its own. Intended to be 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 and Musculoskeletal and Skin Diseases, or NIAMS, which is part of the U.S. 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 for a Phase 1 safety study, by funding IND enabling studies and additional mechanism of action studies, among other preclinical development activities. Work on CEL-4000 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., Jorge O. Galante Professor of Orthopedic Surgery and Katalin Mikecz, MD, Ph.D. Professor of Orthopedic Surgery & Biochemistry. The SBIR 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 May 2019, CEL-SCI announced that a newly discovered LEAPS conjugate vaccine acts alone and can complement CEL-4000 therapeutically when administered in combination to an animal model of Rheumatoid Arthritis (RA). This new LEAPS conjugate appears to act on T cell pathways by a new mechanism that is different from the pathways used by the CEL-4000 vaccine. The data was presented at the American Association of Immunologists 103th Annual Meeting (Immunology 2019) by Daniel Zimmerman, Ph.D., CEL-SCI's Senior Vice President of Research, Cellular Immunology. The work was performed in conjunction with researchers at Rush University Medical Center, Chicago, Illinois and was funded by the SBIR Phase 2 Grant.

In July 2019, one of CEL-SCI's collaborators from Rush, Dr. Adrienn Markovics presented new LEAPS data at i-Chem2019, International Conference on Immunity and Immunochemistry. Data presented was for a new second RA vaccine discovered which acts alone and can complement the existing CEL-4000 RA vaccine in an animal model of RA. The combination of the two RA vaccines provided not only broader epitope coverage, but also a greater therapeutic effect than either vaccine alone. The LEAPS work was performed in conjunction with researchers at CEL-SCI on CEL-4000 and a newly discovered LEAPS conjugate, DerG-PG275Cit. Both vaccines were evaluated alone and in combination in the model of proteoglycan [PG] induced arthritis (PGIA) called recombinant PG G1 domain-induced arthritis (GIA), an autoimmune mouse model of RA.

Prior to the SBIR Phase 2 grant, CEL-SCI was awarded a Phase 1 SBIR grant in the amount of \$225,000 from NIAMS. This 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 these SBIR grants, 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 suggests that it could be used 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 preclinical data for CEL-4000 indicates it could be used against rheumatoid arthritis where a Th1 signature cytokine (IFN- γ) is dominant. CEL-2000 and CEL-4000 each have the potential to become a personalized, disease-specific therapy, that acts at an earlier step in the disease process than current therapies, and

which 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.

Using the LEAPS technology, CEL-SCI has also tested in preclinical studies 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.

Accordingly, 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 activity 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, once developed and approved as safe and effective for humans, 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.

MANUFACTURING FACILITY

Before starting the Phase 3 clinical trial, for reasons related to regulatory considerations, CEL-SCI built a dedicated manufacturing facility to produce its investigational biological product candidate Multikine. This facility produced multiple clinical lots for the Phase 3 clinical trial and has also passed quality systems review by a European Union Qualified Person on several occasions. At the present time, while clinical supplies of Multikine are no longer needed and commercial approval remains subject to the completion of CEL-SCI’s Phase 3 trial and submission of marketing applications to the FDA and other regulatory authorities, this manufacturing facility is not actively engaged in the production of any drug or biological products. CEL-SCI is currently preparing the manufacturing facility for the potential commercial manufacture of Multikine.

CEL-SCI’s lease on the manufacturing facility expires on October 31, 2028. CEL-SCI completed validation of its manufacturing facility in January 2010.

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

As of September 30, 2019, there were approximately 700 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>
12/31/2017	\$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
12/31/2018	\$4.39	\$2.60
3/31/2019	\$3.55	\$2.37
6/30/2019	\$8.99	\$3.77
9/30/2019	\$9.93	\$5.80

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.

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 has fully enrolled 928 patients in a Phase 3 clinical trial for its lead investigational therapy, Multikine, 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

During the year ended September 30, 2019, grant income decreased by approximately \$14,000 compared to the year ended September 30, 2018. The income relates to a Phase 2 Small Business Innovation Research (SBIR) grant in the amount of \$1.5 million received in September 2017 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 IND enabling studies, and additional mechanism of action studies, among other preclinical development activities.

During the year ended September 30, 2019, research and development expenses increased by approximately \$1.7 million compared to the year ended September 30, 2018. The majority of CEL-SCI's research and development expense relates to its on-going Phase 3 clinical trial. During the year ended September 30, 2019, research and development expenses related to the Phase 3 study increased approximately \$0.6 million and stock-based compensation increased by approximately \$0.7 million compared to the prior year. Other components of the increase includes approximately \$0.4 million in other research and development expenses as a result of CEL-SCI preparing the manufacturing facility for the potential commercial manufacture of Multikine.

During the year ended September 30, 2019, general and administrative expenses increased by approximately \$1.7 million compared to the year ended September 30, 2018. A major component of the increase is an approximate \$1.0 million increase in employee stock compensation costs. Costs associated with employee stock options increased approximately \$1.7 million due to more options from option plans approved by shareholders granted during the year ended September 30, 2019, compared to the number of options granted in the prior year and a higher fair value of the options due to an increase in the market price of the CEL-SCI's common stock. These costs were offset by a decrease of approximately \$0.7 million in expenses associated with CEL-SCI's Incentive Stock Bonus Plan, for which the prior year costs were higher due to the achievement of the second milestone under that plan during the year ended September 30, 2018. Another component of the increase was an approximate \$0.7 million increase in public relations costs, of which approximately \$0.3 million was related to an increase in the value of non-employee stock compensation costs for consultants.

During the years ended September 30, 2019 and 2018, CEL-SCI recorded derivative losses of approximately \$0.8 million and \$8.6 million, respectively. This variation was the result of the change in fair value of the derivative liabilities during the period which was caused by fluctuations in the share price of CEL-SCI's common stock.

Net interest expense decreased approximately \$2.4 million during the year ended September 30, 2019 compared to the year ended September 30, 2018. The decrease was primarily due to interest incurred relating to CEL-SCI's convertible debt, all of which was converted by September 30, 2018. Interest expense for the year ended September 30, 2018 includes approximately \$2.0 million relating to the accrual of interest and the write-off of the discount on notes payable, as well as approximately \$0.3 million to record the issuance of warrants granted to induce conversion. Interest expense on CEL-SCI's leased facility remained relatively consistent at approximately \$1.9 million during each year.

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,	
	2019	2018
Multikine	\$ 11,623,050	\$ 10,082,972
LEAPS	1,036,237	831,559
Total research and development	\$ 12,659,287	\$ 10,914,531

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.

CEL-SCI is 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 for CEL-SCI's laboratory and manufacturing 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 2019 and 2018, CEL-SCI raised net proceeds of approximately \$14.8 million and \$21.4 million, respectively, through a combination of the sale of common stock and the exercise of warrants and options.

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 \$1.8 million during the twelve months ended September 30, 2019.

During the year ended September 30, 2018, note holders converted all outstanding Series MM and Series NN Notes (the 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. These Notes were issued during the year ended September 30, 2017, bore interest at 4% and were originally due on December 22, 2017.

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, 2019, 125,941 Series RR warrants had been exercised for total proceeds of approximately \$208,000.

On June 11, 2018, as an inducement to convert the Notes, 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. As of September 30, 2019, 32,752 Series UU warrants had been exercised for total proceeds of approximately \$92,000.

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, 2019, 806,834 Series SS warrants had been exercised for total proceeds of approximately \$1.7 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, 2019, 1,316,171 Series TT Warrants had been exercised for total proceeds of approximately \$2.9 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, were 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, were exercisable on January 2, 2019 and expire on July 2, 2023. As of September 30, 2019, 3,817,500 Series VV Warrants had been exercised for total proceeds of approximately \$6.7 million and 195,000 Series WW Warrants had been exercised for total proceeds of approximately \$317,000.

The following charts list the warrants that were exercised and the proceeds received during the years ended September 30, 2019 and 2018.

Fiscal Year 2019

<u>Warrants</u>	<u>Warrants Exercised</u>	<u>Exercise Price</u>	<u>Proceeds</u>
Series CC	403,017	\$5.00	\$ 2,015,085
Series GG	200,000	\$3.00	600,000
Series HH	13,500	\$3.13	42,188
Series II	216,500	\$3.00	649,500
Series JJ	20,550	\$3.13	64,219
Series KK	213,870	\$3.04	649,095
Series NN	65,502	\$2.52	165,065
Series OO	10,000	\$2.52	25,200
Series PP	172,500	\$2.30	396,750
Series QQ	3,500	\$2.50	8,750
Series RR	98,254	\$1.65	162,119
Series SS	477,886	\$2.09	998,782
Series TT	737,188	\$2.24	1,651,301
Series UU	32,752	\$2.80	91,706
Series VV	3,817,500	\$1.75	6,680,625
Series WW	195,000	\$1.63	316,875
	<u>6,677,519</u>		<u>\$ 14,517,260</u>

Fiscal Year 2018

	Warrants Exercised	Exercise Price	Proceeds
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	522,674
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
	<u>4,072,109</u>		<u>\$ 9,412,964</u>

During the years ended September 30, 2019 and 2018, 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 amounts due Ergomed. Under the Agreements, CEL-SCI issued Ergomed shares of common stock in payment of amounts CEL-SCI owed Ergomed for providing these services. 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, 2019 and 2018, CEL-SCI issued Ergomed 750,000 and 2,260,000 shares, respectively. On December 31, 2018, the expiration date of the prior agreement, Ergomed returned 564,905 unsold shares for cancellation in accordance with the terms of the previous agreement. The following table summarizes the Other Non-Operating Gains (Loss) for the years ended September 30 relating to these agreements:

	2019	2018
Amount realized through the resale of shares	\$ 3,945,528	\$ 3,230,796
Fair value of shares upon issuance	3,400,000	5,507,400
Other non-operating gain (loss)	<u>\$ 545,528</u>	<u>\$ (2,276,604)</u>

As of September 30, 2019, Ergomed held 198,000 shares for resale. As of September 30, 2018, Ergomed held 918,900 shares.

During the year ended September 30, 2019, CEL-SCI's cash decreased by approximately \$1.9 million. Significant components of this decrease include: Gross proceeds received of approximately \$14.9 million from the combination of the sale of common stock to officers and directors and the exercise of warrants and stock options, offset by net cash used in operating activities of approximately \$16.3 million, purchases of capitalizable property, equipment and patents of approximately \$0.3 million, and approximately \$0.2 million for payments of stock issuance costs.

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

Future Capital Requirements

CEL-SCI'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 \$4.5 million for the remainder of the Phase 3 clinical trial. It should be noted that this estimate is based only on the information currently available in CEL-SCI's contracts with the CROs responsible for managing the Phase 3 clinical trial and does not include other related costs, e.g., the manufacturing of 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 is reached in the study. However, CEL-SCI will need to raise additional funds, either through the exercise of outstanding warrants/options, through a debt or equity financing or a partnering arrangement, to 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. 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 4 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.

Management believes that the following critical accounting policies affect the more significant judgments and estimates used in the preparation of CEL-SCI's financial statements.

Share-based Compensation – Share-based compensation cost to employees 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 and expected option life. The compensation cost is recognized 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 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.

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, 2019 and 2018, and
Report of Independent Registered Public Accounting Firm**

CEL-SCI CORPORATION

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Report of Independent Registered Public Accounting Firm

Shareholders and Board of Directors
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, 2019 and 2018, the related statements of operations, stockholders’ equity, 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, 2019 and 2018, 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.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (“PCAOB”), the Company's internal control over financial reporting as of September 30, 2019, based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (“COSO”) and our report dated December 16, 2019, except as to the effect of the material weakness identified, which is dated December 23, 2019, expressed an adverse opinion thereon.

Amendment of Financial Statements

The accompanying financial statements have been amended to include the entire statements of cash flows; a portion of which was inadvertently omitted during the EDGARization process in connection with the original filing of the Form 10-K.

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 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.

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.
Potomac, Maryland

December 16, 2019, except as to the inclusion of the entire statements of cash flows which is dated December 23, 2019

Report of Independent Registered Public Accounting Firm

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

Opinion on Internal Control over Financial Reporting

We have audited CEL-SCI Corporation's (the "Company's") internal control over financial reporting as of September 30, 2019, based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (the "COSO criteria"). In our opinion, the Company did not maintain, in all material respects, effective internal control over financial reporting as of September 30, 2019, based on the COSO criteria. In our report dated December 16, 2019, we expressed an unqualified opinion on the effectiveness of internal control over financial reporting as of September 30, 2019. Subsequent to December 16, 2019, the Company discovered that the statements of cash flows for the years ended September 30, 2019 and 2018 were not included, in its entirety, in the EDGAR filed Form 10-K report filed on December 16, 2019. As a result of the omission, revised its assessment of internal control over financial reporting due to the identification of a material weakness, as described below, in connection with the financial statement amendment. Accordingly, our opinion on the effectiveness of the Company's internal control over financial reporting as of September 30, 2019 expressed herein is different from that expressed in our previous report.

We do not express an opinion or any other form of assurance on management's statements referring to any corrective actions taken by the Company after the date of management's assessment.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the balance sheets of the Company as of September 30, 2019 and 2018, the related consolidated statements of operations, stockholders' equity, and cash flows for the years then ended, and the related notes (collectively referred to as "the financial statements") and our report dated December 16, 2019, except as to inclusion of the entire statements of cash flows, which is dated December 23, 2019, expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying "Item 9A, Management's Report on Internal Control over Financial Reporting". Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit of internal control over financial reporting in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis. A material weakness regarding management's failure to design and maintain controls over the Company's review of EDGAR proofs to ensure the filings are accurate and complete has been identified and described in management's revised assessment. This material weakness was considered in determining the nature, timing, and extent of audit tests applied in our audit of the 2019 financial statements (as amended).

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly

reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

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

/s/ BDO USA, LLP

Potomac, Maryland

December 16, 2019, except as to the effect of the material weakness, which is dated December 23, 2019

CEL-SCI CORPORATION
BALANCE SHEETS
SEPTEMBER 30, 2019 and 2018

ASSETS	2019	2018
Current Assets:		
Cash and cash equivalents	\$8,444,774	\$10,310,044
Receivables	62,765	118,657
Prepaid expenses	524,953	364,622
Inventory used for R&D and manufacturing	782,363	645,238
Total Current Assets	9,814,855	11,438,561
Plant, property and equipment, net	15,825,636	16,218,851
Patent costs, net	311,586	258,093
Deposits	1,670,917	1,670,917
Total Assets	<u>\$27,622,994</u>	<u>\$29,586,422</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	\$1,586,478	\$5,743,913
Accrued expenses	34,432	205,310
Due to employees	709,442	764,941
Derivative instruments, current portion	674,442	2,498,606
Other current liabilities	14,956	14,029
Total Current Liabilities	3,019,750	9,226,799
Derivative instruments, net of current portion	5,813,868	6,818,458
Lease liability	13,508,156	13,379,962
Deferred income	125,000	126,795
Other liabilities	22,553	33,492
Total Liabilities	22,489,327	29,585,506
Commitments and Contingencies		
STOCKHOLDERS' EQUITY		
Preferred stock, \$.01 par value- 200,000 shares authorized; -0- shares issued and outstanding	-	-
Common stock, \$.01 par value - 600,000,000 shares authorized; 35,231,776 and 28,034,487 shares issued and outstanding at September 30, 2019 and 2018, respectively	352,318	280,346
Additional paid-in capital	358,507,603	331,312,184
Accumulated deficit	(353,726,254)	(331,591,614)
Total Stockholders' Equity	5,133,667	916
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	<u>\$27,622,994</u>	<u>\$29,586,422</u>

See notes to financial statements.

CEL-SCI CORPORATION
STATEMENTS OF OPERATIONS
YEARS ENDED SEPTEMBER 30, 2019 and 2018

	<u>2019</u>	<u>2018</u>
Grant income	\$462,754	\$476,556
Operating expenses:		
Research and development	12,659,287	10,914,531
General & administrative	<u>7,998,573</u>	<u>6,334,271</u>
Total operating expenses	<u>20,657,860</u>	<u>17,248,802</u>
Operating loss	(20,195,106)	(16,772,246)
Other income	73,022	70,896
Loss on derivative instruments	(760,603)	(8,643,561)
Other non-operating gain (loss)	545,528	(2,276,604)
Interest expense, net	<u>(1,797,481)</u>	<u>(4,215,690)</u>
Net loss	(22,134,640)	(31,837,205)
Modification of warrants	<u>-</u>	<u>(14,368)</u>
Net loss available to common shareholders	<u><u>\$(22,134,640)</u></u>	<u><u>\$(31,851,573)</u></u>
Net loss per common share, basic and diluted	\$(0.71)	\$(1.87)
Weighted average common shares outstanding, basic and diluted	31,174,394	17,004,722

See notes to financial statements.

CEL-SCI CORPORATION
STATEMENTS OF STOCKHOLDERS' EQUITY
YEARS ENDED SEPTEMBER 30, 2019 and 2018

	<u>Common Shares</u>	<u>Stock Amount</u>	<u>Additional Paid-In Capital</u>	<u>Accumulated Deficit</u>	<u>Total</u>
BALANCE, OCTOBER 1, 2017	11,903,133	\$119,031	\$296,298,401	\$(299,754,409)	\$(3,336,977)
Sale of common stock	7,690,623	76,906	11,715,335	-	11,792,241
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
Purchase of stock by officers and directors	463,855	4,639	380,361	-	385,000
Stock issuance costs	-	-	(206,583)	-	(206,583)
Warrants issued with notes payable	-	-	947,616	-	947,616
Conversion of notes payable and interest to common stock	1,194,930	11,950	2,363,066	-	2,375,016
Shares issued for settlement of clinical research costs	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
Warrant exercises	6,677,519	66,775	18,039,842	-	18,106,617
401(k) contributions paid in common stock	30,996	310	143,568	-	143,878
Stock issued to nonemployees for service	199,977	1,999	876,589	-	878,588
Equity based compensation - employees	(7,500)	(75)	4,428,249	-	4,428,174
Option exercises	65,997	660	149,822	-	150,482
Purchase of stock by officers and directors	45,205	452	291,545	-	291,997
Stock issuance costs	-	-	(132,345)	-	(132,345)
Shares issued for settlement of clinical research costs	185,095	1,851	3,398,149	-	3,400,000
Net loss	-	-	-	(22,134,640)	(22,134,640)
BALANCE, SEPTEMBER 30, 2019	<u>35,231,776</u>	<u>\$352,318</u>	<u>\$358,507,603</u>	<u>\$(353,726,254)</u>	<u>\$5,133,667</u>

See notes to financial statements.

CEL-SCI CORPORATION
STATEMENTS OF CASH FLOWS
YEARS ENDED SEPTEMBER 30, 2019 and 2018

	2019	2018
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$(22,134,640)	\$(31,837,205)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	633,529	650,131
Share based payments for services	856,025	530,736
Share based payments for interest	-	80,716
Equity based compensation	4,428,174	2,743,267
Common stock contributed to 401(k) plan	143,878	145,090
Shares issued for settlement of clinical research costs	3,400,000	5,507,400
Loss on prepaid research and development	-	471,157
Gain on derivative instruments	760,603	8,643,561
Amortization of debt discount	-	1,956,424
Inducement expense	-	291,234
Capitalized lease interest	128,194	168,037
(Increase)/decrease in assets:		
Receivables	55,892	99,824
Prepaid expenses	(137,768)	153,102
Inventory used for R&D and manufacturing	(137,125)	27,284
Deposits	-	150,000
Increase/(decrease) in liabilities:		
Accounts payable	(4,084,410)	(2,514,488)
Accrued expenses	(170,878)	(731,388)
Due to employees	(55,499)	71,110
Other liabilities	(6,660)	4,450
Net cash used in operating activities	(16,320,685)	(13,389,558)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of equipment	(177,779)	(1,015)
Expenditures for patent costs	(158,060)	(57,125)
Net cash used in investing activities	(335,839)	(58,140)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock and warrants	-	11,792,241
Payments of stock issuance costs	(163,364)	(195,589)
Proceeds from exercise of warrants	14,517,260	9,412,964
Proceeds from exercises of options	150,482	-
Proceeds from the purchase of stock by officers and directors	291,997	385,000
Payments on obligations under capital lease	(5,121)	(6,312)
Net cash provided by financing activities	14,791,254	21,388,304
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(1,865,270)	7,940,606
CASH AND CASH EQUIVALENTS, BEGINNING OF YEAR	10,310,044	2,369,438
CASH AND CASH EQUIVALENTS, END OF YEAR	\$8,444,774	\$10,310,044

See notes to financial statements.

CEL-SCI CORPORATION
STATEMENTS OF CASH FLOWS
YEARS ENDED SEPTEMBER 30, 2019 and 2018

SUPPLEMENTAL SCHEDULE OF NON-CASH INVESTING AND FINANCING ACTIVITIES:

	2019	2018
Plant, property and equipment purchases included in accounts payable	\$ 17,329	\$ -
Prepaid consulting services paid with issuance of common stock	\$ 22,563	\$ 162,452
Notes payable converted into common shares	\$ -	\$ 2,294,300
Exercise of derivative liabilities	\$ 3,589,357	\$ 1,379,899
Capital lease obligation included in accounts payable	\$ 441	\$ 415
Stock issuance costs included in current liabilities	\$ 15,580	\$ 46,599
Cash paid for interest	\$ 1,809,242	\$ 1,750,897

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 Company expects to use the results to support applications to regulatory agencies around the world for worldwide commercial marketing approvals for Multikine for neoadjuvant therapy in patients with squamous cell carcinoma of the head and neck.

The Company's investigational immune therapy, Multikine, is being used in a different way than other 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 at the site of the tumors. 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 of this neoadjuvant therapy and administration before weakening of the immune system by surgery, chemotherapy and radiation will result in improved outcomes and better overall survival rates for patients suffering from head and neck cancer.

The Company is also investigating a different peptide-based immunotherapy as a vaccine for Rheumatoid Arthritis. The Company 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 provides 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 2019 and 2018, the Company received net proceeds of approximately \$14.8 million and \$21.4 million, respectively, through the sale of stock and the exercise of warrants and options. 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 warrant exercises, 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 \$55.8 million as of September 30, 2019 on direct costs for the Phase 3 clinical trial. The Company estimates it will incur additional expenses of approximately \$4.5 million for the remainder of the Phase 3 clinical trial. It should be noted that this estimate is based only on the information currently available from 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's primary 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 were paid to Lake Whillans Litigation Finance. As a result of the arbitrator's ruling, during the year ended September 30, 2018, the Company wrote off approximately \$471,000, which will no longer be realized.

3. REVISION OF PRIOR PERIOD FINANCIAL STATEMENTS FOR CORRECTION OF IMMATERIAL ERRORS

In November 2019, CEL-SCI discovered an error in the classification of certain employee compensation on the statement of operations. Costs associated with employees considered to be in the research and development function of the business were incorrectly classified as general and administrative costs. The total amount of expenses recorded is not impacted by this error. This misclassification has no impact on the earnings of CEL-SCI or its financial position. The error does not impact total compensation costs, total operating costs, net operating loss, net loss, net loss per share, cash flows or stockholders' deficit.

Employee related expenses of approximately \$1.5 million were incorrectly recorded as general and administrative expenses and should have been recorded as research and development expenses in the prior year. Prior year amounts have been revised in the current year financial statements to reflect this change.

	Year ended 9/30/2018		
	Originally Reported	Reclassification	Corrected
Operating Expenses			
Research and development	\$ 9,400,306	\$ 1,514,225	\$10,914,531
General and administrative	7,848,496	(1,514,225)	6,334,271
Total Operating Expenses	\$ 17,248,802	\$ -	\$17,248,802

4. 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 12.

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, and considering 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 from the Company's 2014 Incentive Stock Bonus Plan, 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, 2019.

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, 2019 and 2018.

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 15 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 over which options granted are expected to be outstanding and has been determined using 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.

Reclassifications-

Approximately \$2.3 million loss on a financing transaction in the prior year was reclassified from net interest expense to other non-operating loss to conform with the current year presentation. The current year statement of operations has been restated to reflect this reclassification.

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 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 a right-of-use asset and a lease liability. Leases will be classified as operating or financing. 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 ASU 2016-02 is effective for fiscal years and interim periods, within those fiscal years, beginning after December 15, 2018, but early adoption is permitted. The Company is currently evaluating the effect of the new standard on its financial statements and related disclosures. In July 2018, the FASB issued ASU No. 2018-11, Leases (Topic 842): Targeted Improvements which allows entities to initially apply the new leases standard at the adoption date and recognize a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. ASU 2016-02 also requires expanded financial statement disclosures on leasing activities. These changes will become effective for the Company on October 1, 2019.

The new lease guidance as codified in ASC 842, provides for several optional practical expedients in transition. The Company will adopt the following practical expedients:

- The optional transition method set forth in ASU 2018-11 noted above – Upon adopting the standard effective October 1, 2019, the Company will recognize a cumulative-effect adjustment to the opening balance of retained earnings without recasting comparative periods.
- The election to apply a “package of practical expedients,” which allows management to not reassess whether any expired or existing contracts are or contain leases under the new standard, or to reassess prior conclusions on lease identification, lease classification and the recording of initial direct costs. As required, these practical expedients must be elected as a package and must be applied to all leases.
- The option not to separate lease and non-lease components within the lease and account for all lease components as a single lease component.

The Company estimates the impact of adopting ASC 842 on October 1, 2019 will be to record a \$13.1 million right-to-use asset, to decrease property and equipment by approximately \$13.4 million and to increase lease liabilities by approximately \$0.3 million. This will result in an approximate \$0.6 million adjustment to opening retained earnings as of October 1, 2019. Management is evaluating the appropriate lease classification and expects to complete this evaluation by the end of the first quarter of fiscal year 2020. The adoption of ASC 842 is not expected to result in significant changes to the Company’s statements of operations or cash flows.

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.

5. WARRANTS AND NON-EMPLOYEE OPTIONS

The following warrants and non-employee options are outstanding at September 30, 2019:

<u>Warrant</u>	<u>Issue Date</u>	<u>Shares Issuable upon Exercise of Warrants</u>	<u>Exercise Price</u>	<u>Expiration Date</u>
Series N	8/18/2008	85,339	\$3.00	2/18/2020
Series V	5/28/2015	810,127	\$19.75	5/28/2020
Series UU	6/11/2018	154,810	\$2.80	6/11/2020
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
Series CC	12/8/2016	277,463	\$5.00	12/8/2021
Series HH	2/23/2017	6,500	\$3.13	2/16/2022
Series AA	8/26/2016	200,000	\$13.75	2/22/2022
Series JJ	3/14/2017	9,450	\$3.13	3/8/2022
Series LL	4/30/2017	26,398	\$3.59	4/30/2022
Series MM	6/22/2017	893,491	\$1.86	6/22/2022
Series NN	7/24/2017	473,798	\$2.52	7/24/2022

Series OO	7/31/2017	50,000	\$2.52	7/31/2022
Series RR	10/30/2017	457,116	\$1.65	10/30/2022
Series SS	12/19/2017	482,644	\$2.09	12/18/2022
Series TT	2/5/2018	559,689	\$2.24	2/5/2023
Series VV	7/2/2018	82,500	\$1.75	1/2/2024
Consultants	7/28/17	10,000	\$2.18	7/27/2027

The following warrants and non-employee options were 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>
Series S	10/11/13- 10/24/14	327,729	\$31.25	10/11/2018
Series DD	12/8/2016	1,360,960	\$4.50	12/10/2018
Series EE	12/8/2016	1,360,960	\$4.50	12/10/2018
Series N	8/18/2008	85,339	\$3.00	2/18/2020
Series V	5/28/2015	810,127	\$19.75	5/28/2020
Series UU	6/11/2018	187,562	\$2.80	6/11/2020
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
Series CC	12/8/2016	680,480	\$5.00	12/8/2021
Series HH	2/23/2017	20,000	\$3.13	2/16/2022
Series AA	8/26/2016	200,000	\$13.75	2/22/2022
Series JJ	3/14/2017	30,000	\$3.13	3/8/2022
Series LL	4/30/2017	26,398	\$3.59	4/30/2022
Series MM	6/22/2017	893,491	\$1.86	6/22/2022
Series NN	7/24/2017	539,300	\$2.52	7/24/2022
Series OO	7/31/2017	60,000	\$2.52	7/31/2022
Series QQ	8/22/2017	3,500	\$2.50	8/22/2022
Series GG	2/23/2017	200,000	\$3.00	8/23/2022
Series II	3/14/2017	216,500	\$3.00	9/14/2022
Series RR	10/30/2017	555,370	\$1.65	10/30/2022
Series KK	5/3/2017	213,870	\$3.04	11/3/2022
Series SS	12/19/2017	960,530	\$2.09	12/18/2022
Series TT	2/5/2018	1,296,877	\$2.24	2/5/2023
Series PP	8/28/2017	172,500	\$2.30	2/28/2023
Series WW	7/2/2018	195,000	\$1.63	6/28/2023
Series VV	7/2/2018	3,900,000	\$1.75	1/2/2024
Consultants	1/1/16 - 7/28/17	30,400	\$2.18- \$11.50	12/31/18- 7/27/27

1. Warrant Liabilities

Warrant liabilities outstanding at September 30 are as follows:

	<u>2019</u>	<u>2018</u>
Series S warrants	\$ -	\$ 33
Series V warrants	674,442	770,436
Series W warrants	1,193,507	999,081
Series Z warrants	1,109,545	487,767
Series ZZ warrants	77,638	34,215
Series AA warrants	916,908	380,474
Series BB warrants	63,966	28,456
Series CC warrants	1,710,898	1,779,724
Series DD warrants	-	1,249,287
Series EE warrants	-	1,249,287
Series FF warrants	446,185	188,921
Series GG warrants	-	607,228

Series HH warrants	45,657	58,816
Series II warrants	-	660,135
Series JJ warrants	66,599	88,642
Series KK warrants	-	656,930
Series LL warrants	<u>182,965</u>	<u>77,632</u>
Total warrant liabilities	<u>\$ 6,488,310</u>	<u>\$ 9,317,064</u>

The (losses)/gains on the warrant liabilities for the years ended September 30 are as follows:

	2019	2018
Series S Warrants	\$ 33	\$ (751,378)
Series V warrants	95,994	(697,526)
Series W warrants	(194,426)	(915,327)
Series Z warrants	(621,778)	(410,551)
Series ZZ warrants	(43,423)	(29,461)
Series AA warrants	(536,434)	(315,387)
Series BB warrants	(35,510)	(24,134)
Series CC warrants	(1,198,836)	(1,385,504)
Series DD warrants	1,249,287	(1,243,795)
Series EE warrants	1,249,287	(1,243,795)
Series FF warrants	(257,264)	(141,767)
Series GG warrants	195,228	(408,555)
Series HH warrants	(24,465)	(42,802)
Series II warrants	(442,040)	(462,519)
Series JJ warrants	(35,301)	(64,439)
Series KK warrants	(55,622)	(449,470)
Series LL warrants	<u>(105,333)</u>	<u>(57,151)</u>
Net loss on warrant liabilities	<u>\$ (760,603)</u>	<u>\$ (8,643,561)</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.

Exercise of Warrant Liabilities

The following warrants recorded as liabilities were exercised during the year ended September 30, 2019:

<u>Warrants</u>	<u>Warrants Exercised</u>	<u>Exercise Price</u>	<u>Proceeds</u>
Series CC	403,017	\$5.00	\$2,015,085
Series GG	200,000	\$3.00	600,000
Series HH	13,500	\$3.13	42,188
Series II	216,500	\$3.00	649,500
Series JJ	20,550	\$3.13	64,219
Series KK	213,870	\$3.04	649,095
	<u>1,067,437</u>		<u>\$4,020,087</u>

The following warrants recorded as liabilities were exercised during the year ended September 30, 2018:

<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	<u>182,100</u>	<u>\$3.04</u>	<u>552,674</u>

1,474,991

\$3,544,608

Expiration of Warrants

On December 10, 2018, 1,360,960 Series DD and 1,360,960 Series EE warrants with exercise prices of \$4.50 expired. The expiration dates of these warrants had been previously extended and such modifications were reflected in the fair value measurement of the warrants on the dates of modification.

On October 11, 2018, 327,729 Series S warrants, with an exercise price of \$31.25, expired. The exercise price of these warrants had been previously repriced under temporarily revised terms and such modifications were reflected in the fair value measurement of the warrants.

On October 17, 2017, 17,821 Series U warrants, with an exercise price of \$43.75, expired.

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 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 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.

During the year ended September 30, 2019, 3,817,500 and 195,000 Series VV and WW warrants were exercised, respectively, for total gross proceeds of approximately \$7.0 million. During the year ended September 30, 2018 no Series VV or WW warrants were exercised. As of September 30, 2019, 82,500 Series VV and 0 Series WW warrants were outstanding.

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 8). The Series UU warrants are exercisable at a fixed price of \$2.80 per share and expire on June 11, 2020. The Company recognized an expense equal to the excess of the fair value of the consideration transferred in the transaction over 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 for the year ended September 30, 2018. The Series UU warrants qualify for equity treatment in accordance with ASC 815.

During the year ended September 30, 2019, 32,752 Series UU warrants were exercised for total gross proceeds of approximately \$0.1 million. During the year ended September 30, 2018 no Series UU warrants were exercised. As of September 30, 2019, 154,810 Series UU warrants were outstanding.

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 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 years ended September 30, 2019 and 2018, 737,188 and 578,983, respectively, Series TT warrants were exercised for total gross proceeds of approximately \$1.6 million and \$1.3 million, respectively. As of September 30, 2019, 559,689 Series TT warrants were outstanding.

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. 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 years ended September 30, 2019 and 2018, 477,886 and 328,948, respectively, Series SS warrants were exercised for total gross proceeds of approximately \$1.0 million and \$0.7 million, respectively. As of September 30, 2019, 482,644 Series SS warrants were outstanding.

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 8.

During the years ended September 30, 2019 and 2018, 98,254 and 27,687, respectively, Series RR warrants were exercised for total gross proceeds of approximately \$160,000 and \$50,000, respectively. As of September 30, 2019, 457,116 Series RR warrants were outstanding.

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 expiration date of the Series N warrants was extended to February 18, 2020. The incremental cost of this extension was approximately \$14,000, which was recorded as a deemed dividend in the financial statements for the year ended September 30, 2018.

Exercise of Equity Warrants

The following equity warrants were exercised during the year ended September 30, 2019.

<u>Warrants</u>	<u>Warrants Exercised</u>	<u>Exercise Price</u>	<u>Proceeds</u>
Series NN	65,502	\$2.52	\$165,065
Series OO	10,000	\$2.52	25,200
Series PP	172,500	\$2.30	396,750
Series QQ	3,500	\$2.50	8,750
Series RR	98,254	\$1.65	162,119
Series SS	477,886	\$2.09	998,782
Series TT	737,188	\$2.24	1,651,301
Series UU	32,752	\$2.80	91,706
Series VV	3,817,500	\$1.75	6,680,625
Series WW	195,000	\$1.63	316,875
	<u>5,610,082</u>		<u>\$10,497,173</u>

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

<u>Warrants</u>	<u>Warrants Exercised</u>	<u>Exercise Price</u>
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			Proceeds
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, 2019 and 2018 the Company issued 199,977 and 356,197 shares, respectively, of common stock to consultants of which 199,977 and 353,197 shares, respectively, were restricted shares. Under these arrangements, the common stock was issued with stock prices ranging between \$0.85 and \$8.76 per share. The weighted average grant price was \$4.25 and \$1.95, respectively, for stock issued during the years and September 30, 2019 and 2018.

During the years ended September 30, 2019 and 2018, the Company recorded total expense of approximately \$856,000 and \$531,000, respectively, relating to these consulting agreements. At September 30, 2019 and 2018, approximately \$230,000 and \$207,000, respectively, are included in prepaid expenses. During the year ended September 30, 2019, 10,000 options issued to consultants were exercised and 10,400 options expired. As of September 30, 2019, 10,000 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.

6. PLANT, PROPERTY AND EQUIPMENT

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

	2019	2018
Leased manufacturing facility	\$ 21,183,756	\$ 21,183,756
Research equipment	3,320,358	3,162,151
Furniture and equipment	125,872	124,369
Leasehold improvements	149,239	131,910
	<u>24,779,225</u>	<u>24,602,186</u>
Accumulated depreciation and amortization	<u>(8,953,589)</u>	<u>(8,383,335)</u>
Net plant, property and equipment	<u>\$ 15,825,636</u>	<u>\$ 16,218,851</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 12, Commitments and Contingencies—Lease Obligations, for additional information. As of September 30, 2019 and 2018, accumulated depreciation on the manufacturing building is approximately \$5.6 million and \$5.1 million, respectively. Depreciation expense for the years ended September 30, 2019 and 2018 totaled approximately \$588,000 and, \$575,000, 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.

7. PATENTS

Patents consist of the following at September 30:

	2019	2018
Patents	\$ 841,397	\$ 742,698
Accumulated amortization	<u>(529,811)</u>	<u>(484,605)</u>
Patents, net	<u>\$ 311,586</u>	<u>\$ 258,093</u>

During the years ended September 30, 2019 and 2018, there was no impairment of patent costs. Amortization expense for the years ended September 30, 2019 and 2018 totaled approximately \$45,000 and \$75,000, respectively. The total estimated future amortization is as follows:

Years ending September 30,	
2020	51,000
2021	48,000
2022	44,000
2023	33,000
2024	26,000
Thereafter	110,000
	<u>\$ 312,000</u>

8. 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) along with Series MM and Series NN warrants (See Note 5). 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. During the year ended September 30, 2018, note holders converted the remaining outstanding Notes with an aggregate principal amount of \$2,294,300, into 1,166,105 shares of common stock. 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.

As an inducement to convert, on June 11, 2018, 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 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 excess of the fair value of the consideration transferred in the transaction over 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 for the year ended September 30, 2018.

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 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 October 2017 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.

During the year ended September 30, 2018, the Company recorded approximately \$2.0 million in interest expense relating to the amortization of the debt discount.

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.

9. INCOME TAXES

At September 30, 2019 and 2018, the Company had net deferred tax assets of \$28.8 million and \$24.8 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. No limitations on NOL carryforwards relating to change in ownership were imposed during the year ended September 30, 2019. The Company’s Section 382 estimated analysis was completed through September 30, 2018. If additional changes in ownership occur after 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 \$36.7 million and \$18.6 million at September 30, 2019 and 2018, respectively. The NOL carryforwards begin to expire during the year ended September 30, 2021 and become fully expired by the end of the fiscal year ended 2039. 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, 2019 and 2018. 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, 2019 and 2018 are listed below:

	<u>2019</u>	<u>2018</u>
NOL carryforwards	\$ 9,698,000	\$ 5,052,000
R&D credit	1,221,000	1,221,000
Stock-based compensation	3,165,000	3,097,000
Capitalized R&D	14,777,000	15,518,000
Vacation and other	544,000	544,000
Total deferred tax assets	<u>29,405,000</u>	<u>25,432,000</u>
Fixed assets and intangibles	<u>(586,000)</u>	<u>(634,000)</u>
Total deferred tax liability	<u>(586,000)</u>	<u>(634,000)</u>
Net deferred tax asset	28,819,000	24,798,000
Valuation allowance	<u>(28,819,000)</u>	<u>(24,798,000)</u>
Ending Balance	<u><u>\$ -</u></u>	<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>2019</u>	<u>2018</u>
Federal Rate	21.00%	24.28%
Federal rate change	(2.8)	(88.94)
State tax rate, net of federal benefit	5.31	4.47
Net operating loss – write-off	-	(161.21)
Other adjustments	(4.77)	(5.95)
Permanent differences	(0.57)	(5.79)
Change in valuation allowance	<u>(18.17)</u>	<u>233.14</u>
Effective tax rate	<u><u>0.00%</u></u>	<u><u>0.00%</u></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.

10. STOCK COMPENSATION

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

	Year Ended September 30,	
	<u>2019</u>	<u>2018</u>
Employees	\$4,428,174	\$2,743,267
Non-employees	\$856,025	\$ 530,736

During the years ended September 30, 2019 and 2018, non-employee stock compensation excluded approximately \$230,000 and \$207,000, respectively, for future services to be performed (Note 5).

During the years ended September 30, 2019 and 2018 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>2019</u>	<u>2018</u>
Expected stock price volatility	87.67 – 92.84%	89.90 – 94.32%
Risk-free interest rate	1.62 – 2.82%	2.30 – 3.04%
Expected life of options	9.67 – 9.68 Years	9.67 – 9.70 Years
Expected dividend yield	-	-

Non-Qualified Stock Option Plans – At September 30, 2019, the Company has collectively authorized the issuance of 6,387,200 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, 2019, 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, 2019 is summarized as follows:

Non-Qualified and Incentive Stock Option Plans

	Outstanding				Exercisable			
	Number of Shares	Weighted Average Exercise Price	Weighted Ave Remaining Contractual Term (Years)	Aggregate Intrinsic Value	Number of Shares	Weighted Average Exercise Price	Weighted Ave Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding at 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
Vested					945,359	\$2.56		
Granted	3,271,362	\$5.40						
Exercised (a)	65,997	\$2.28			65,997	\$2.28		
Forfeited	82,461	\$17.89						
Expired (b)	64,815	\$71.86			64,815	\$71.86		
Cancelled								
Outstanding at September 30, 2019	6,218,216	\$5.54	8.88	\$29,562,594	1,392,241	\$9.15	7.68	\$7,869,555

(a) Includes 10,000 stock options exercised by consultants

(b) Includes 10,400 stock options to consultants

A summary of the status of the Company's non-vested options for the two years ended September 30, 2019 is presented below:

	Number of Options	Weighted Average Grant Date Fair Value
Unvested at October 1, 2017	963,862	\$ 4.91
Vested	(334,111)	
Granted	1,958,108	
Forfeited	(5,426)	
Unvested at September 30, 2018	2,582,433	\$ 2.48
Vested	(945,359)	
Granted	3,271,362	
Forfeited	(82,461)	
Unvested at September 30, 2019	4,825,975	\$ 3.79

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, 2019 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, 2019 and 2018, the Company recorded expense relating to the issuance of restricted stock pursuant to the plan of approximately \$0.3 million and \$1.4 million, respectively. At September 30, 2019, the Company has unrecognized compensation expense of approximately \$0.7 million which is expected to be recognized over a weighted average period of 2.3 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, 2019 is presented below:

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested at September 30, 2017	468,000	\$13.75
Vested	(156,000)	
Unvested at September 30, 2018	312,000	\$13.75
Forfeited	(7,500)	
Vested	-	
Unvested at September 30, 2019	304,500	\$13.75

Stock Bonus Plans – At September 30, 2019, 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, 2019, the Company has issued a total of 33,226 shares of common stock from the Stock Bonus Plans.

Stock Compensation Plans – At September 30, 2019, 634,000 shares were authorized for use in the Company's Stock Compensation Plans. During the years ended September 30, 2019, and 2018, no shares were issued from the Stock Compensation Plans to consultants for payment of services. As of September 30, 2019, the Company has issued 130,183 shares of common stock from the Stock Compensation Plans.

11. 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, 2019, 30,996 shares were issued to the Company's 401(k) plan for a cost of approximately \$144,000. 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.

12. COMMITMENTS AND CONTINGENCIES

Clinical Research Agreements

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 \$30.9 million related to Ergomed's services. This amount is net of Ergomed's discount of approximately \$10.5 million. During the years ended September 30, 2019 and 2018, the Company recorded approximately \$2.8 million and \$3.1 million, respectively, as research and development expense related to Ergomed's services. These amounts were net of Ergomed's discount of approximately \$1.0 million during the years ended September 30, 2019 and 2018.

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 building 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, 2019 and 2018, the leased building asset has a net book value of approximately \$15.6 million and \$16.1 million, respectively, and the landlord liability has a balance of \$13.5 million and \$13.4 million, respectively. The leased building 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, 2019 and 2018.

Approximate future minimum lease payments under the San Tomas lease as of September 30, 2019 are as follows:

Years ending September 30,		
2020	\$	1,872,000
2021		1,937,000
2022		2,004,000
2023		2,073,000
2024		2,145,000
Thereafter		9,540,000
Total future minimum lease obligation		19,571,000
Less: imputed interest on financing obligation		(6,063,000)
Net present value of lease financing obligation	\$	13,508,000

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, 2019 and 2018 was approximately \$73,000 and \$71,000, 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, 2019 and 2018, the Company has recorded a deferred rent liability of approximately \$14,000 and \$12,000, 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, 2019 and 2018, the Company has recorded a deferred rent liability of approximately \$7,000 and \$14,000, 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%. Amortization of this capital lease is combined with depreciation expense.

Approximate future minimum annual lease payments due under non-cancelable operating leases, excluding the San Tomas lease, for the years ending after September 30, 2019 are as follows:

Years ending September 30,		
2020	\$	238,000
2021		163,000
2022		69,000
Total future minimum lease obligation	\$	470,000

Rent expense, for the years ended September 30, 2019 and 2018, excluding the rent paid on the San Tomas lease, was approximately \$253,000 for both fiscal years.

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 \$4.5 million for the remainder of the Phase 3 clinical trial. It should be noted that this estimate is based only on the information currently available from 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.

13. RELATED PARTY TRANSACTIONS

On October 30, 2017, in consideration for an extension of the maturity date of the Series MM and Series NN convertible notes, which had been issued in the prior year, the Company issued a total of 583,057 Series RR warrants to the note holders who agreed to the extension. Geert Kersten, the Company's Chief Executive Officer, a trust in which Mr. Kersten holds a beneficial interest and Patricia B. Prichep, the Company's Senior Vice President of Operations 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. The terms of the related party notes and warrants were identical to the other participants.

On June 11, 2018, Mr. Kersten, the trust and Ms. Prichep converted the outstanding notes payable balances of \$250,000, \$250,000 and \$25,000, respectively, into 147,929, 109,170 and 10,917 shares, respectively, of common stock in accordance with the original conversion terms, which were identical to those of the other participants. To induce conversion of the Series MM and NN Notes, all note holders, including Mr. Kersten, the trust 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 had 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. 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 for the year ended September 30, 2018. The Series UU warrants qualified 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 in June 2018, 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, 2019 and 2018.

During the year ended September 30, 2019, officers and a director of the Company purchased 45,205 restricted shares of the Company's common stock at an aggregate market value of approximately \$292,000. During the year ended September 30, 2018, officers of the Company purchased 463,855 restricted shares of the Company's common stock from the Company for an aggregate fair market value of \$385,000. The shares are subject to the conditions of Rule 144 under the Securities Act of 1933.

14. STOCKHOLDERS' EQUITY

Exercise of Warrants

During the years ended September 30, 2019 and 2018, the Company received proceeds of approximately \$14.5 million and \$9.4 million, respectively, from the exercise of warrants, as detailed in Note 5. Upon exercise, 6,677,519 and 4,072,109 shares of common stock, respectively, were issued during the years ended September 30, 2019 and 2018.

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 and 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 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 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 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.

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 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 expire on December 18, 2022. 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.

Other Equity Transactions

The Company has entered into Securities Purchase Agreements with Ergomed plc, one of its Clinical Research Organizations responsible for managing the Company's Phase 3 clinical trial, to facilitate a partial payment of the amounts due Ergomed. Under the Agreements, the Company issued Ergomed shares of common stock that would reduce Ergomed's bills in an amount equal to the net proceeds from the sales of the shares issued to Ergomed. Upon issuance, the Company expenses the full value of the shares as Other non-operating gain/loss and subsequently offsets the expense as amounts are realized through the sale by Ergomed and reduces accounts payable to Ergomed. Any amounts received from the sale of the shares in excess of the amounts due Ergomed will be applied towards the satisfaction of any future amounts owed.

During the year ended September 30, 2019 and 2018, the Company issued Ergomed 750,000 and 2,260,000 shares, respectively. On December 31, 2018, the expiration date of the prior agreement, Ergomed returned 564,905 unsold shares for cancellation. The following table summarizes the Other Non-Operating Gains (Loss) for the years ended September 30 relating to these agreements:

	2019	2018
Amount realized through the resale of shares	\$ 3,945,528	\$ 3,230,796
Fair value of shares upon issuance	3,400,000	5,507,400
Other non-operating gain (loss)	\$ 545,528	\$ (2,276,604)

As of September 30, 2019, Ergomed holds 198,000 shares for resale. As of September 30, 2018, Ergomed held 918,900 shares.

15. 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, 2019:

	Quoted Prices in Active Markets for Identical Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Derivative Instruments	\$ -	\$ -	\$ 6,488,310	\$ 6,488,310

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	\$ 33	\$ -	\$ 9,317,031	\$ 9,317,064

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>2019</u>	<u>2018</u>
Beginning balance	\$ 9,317,031	\$ 2,020,629
Issuances	-	-
Exercises	(3,589,357)	(595,780)
Net realized and unrealized derivative loss (gain)	<u>760,636</u>	<u>7,892,182</u>
Ending balance	<u>\$ 6,488,310</u>	<u>\$ 9,317,031</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, 2019, the Company's Level 3 derivative instruments have a weighted average fair value of \$2.72 per share and a weighted average exercise price of \$15.17 per share. Fair values were determined using a weighted average risk free interest rate of 1.85% and 103% volatility. The instruments have a weighted average time to maturity of 1.86 years. 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.

16. 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>2019</u>	<u>2018</u>
Loss per share – basic and diluted		
Net loss available to common shareholders	\$ (22,134,640)	\$ (31,851,573)
Weighted average shares outstanding	<u>31,174,394</u>	<u>17,004,722</u>
Basic and diluted loss per common share	<u>\$ (0.71)</u>	<u>\$ (1.87)</u>

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>2019</u>	<u>2018</u>
Options and Warrants	7,164,544	11,794,603
Unvested Restricted Stock	304,500	312,000
Total	<u>7,469,044</u>	<u>12,106,603</u>

17. SUBSEQUENT EVENTS

In accordance with ASC 855, “Subsequent Events”, the Company has reviewed subsequent events through the date of the filing and determined there are no subsequent events that require disclosure.

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 and CEO
Juvare, LLC

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

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Independent Auditors

BDO USA, LLP
Potomac, MD

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 650 stockholders of record as of February 21, 2020. 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
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