



# **Annual Report**

## **2020**

## 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 an increase in overall survival of patients between the two main comparator groups in favor of the group receiving the Multikine treatment regimen. To prove an overall survival benefit, the study required CEL-SCI to wait until 298 events had occurred among the two main comparator groups. This study milestone occurred in late April 2020. The study is currently in the statistical analysis phase. If the primary end-point of this global study is achieved and/or the study shows clinical benefit for the patients, 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). This disease represents a clear unmet medical need with no new FDA approved drug in approximately 60 years.

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. 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 or radiochemotherapy. The goal is to help the intact immune system "see" the cancer and kill the micro metastases that usually cause recurrence of the cancer. In short, CEL-SCI believes that local administration and administration of Multikine before weakening of the immune system by surgery, radiation and chemotherapy will result in improved outcomes and better overall survival rates for patients suffering from head and neck cancer.

CEL-SCI is investigating a peptide-based immunotherapy (CEL-4000) 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 is in the process of completing pre-IND studies for CEL-4000 and hopes to start human studies with CEL-4000 in 2021.

CEL-SCI is also investigating LEAPS COVID-19 conjugates as a potential treatment of COVID-19 in hospitalized and at-high-risk patients. Initial animal experiments showed that LEAPS COVID-19 conjugates induced faster and much higher than expected antibody responses against a non-mutating region of the virus that causes COVID-19 after only one injection.

On December 1, 2020, CEL-SCI announced that LEAPS COV-19 peptides, delivered as a therapeutic treatment following SARS-CoV-2 virus challenge, achieved a 40% survival rate in transgenic mouse models as compared to 0% survival in the two control groups in studies conducted at the University of Georgia Center for Vaccines and Immunology. The animals were therapeutically treated with CEL-SCI's LEAPS COV-19 peptides one day after infection with a lethal dose of SARS-CoV-2. Of the LEAPS treated mice, forty percent (40%) were alive, recovering and regained lost weight, attaining > 90% of their starting weight, by the study's end. In contrast, mice in the two control groups lost 20% or more of their body weight by day 8 and all of them died between day 5 and day 8 post challenge. The success of this therapy was statistically significant at a 95% level.

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](http://www.cel-sci.com). CEL-SCI does not incorporate the information on its website into this report, and you should not consider it part of this report.

CEL-SCI makes its electronic filings with the Securities and Exchange Commission (SEC), including its annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to these reports available on its website free of charge as soon as practicable after they are filed or furnished to the SEC.

In this annual report, unless otherwise specified or the context requires otherwise, 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, product candidates under development for the potential treatment of rheumatoid arthritis, and LEAPS COV-19, a product candidate under development to potentially treat COVID-19 coronavirus.

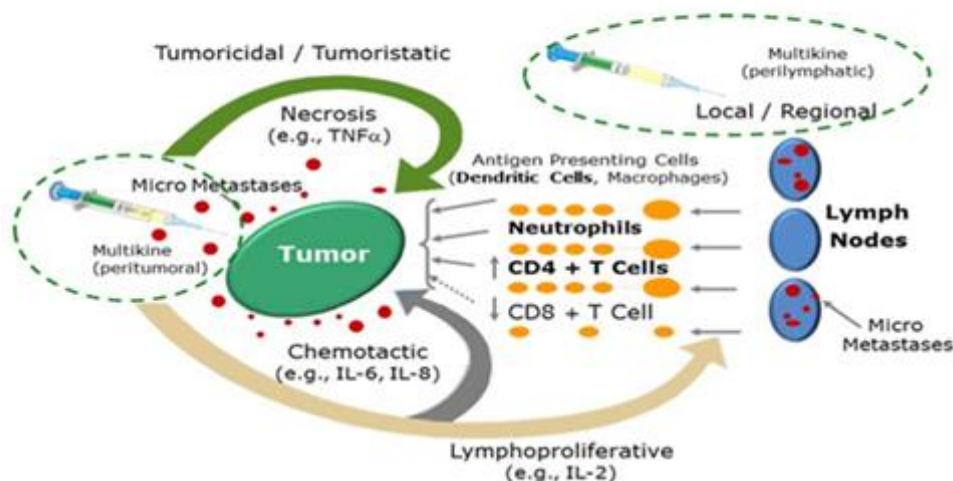
### **MULTIKINE**

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 have 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 Multikine 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 strongest and most amenable to activation against the tumor. For example, in the Phase 3 clinical trial, Multikine was injected locally around the tumor and near the adjacent draining lymph nodes for three weeks, five days a week as a first 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 of Multikine before weakening of the immune system by surgery, chemotherapy and radiation will result in better anti-tumor response than if Multikine were administered after surgery, radiation and chemotherapy. 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 the most prevalent type of head and neck cancer, and CEL-SCI believes that there is a large, unmet medical need among head and neck cancer patients. CEL-SCI believes the last FDA approval of a therapy indicated for the treatment of advanced primary head and neck cancer was over 60 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 are diagnosed annually in the United States and approximately 105,000 patients are diagnosed annually 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 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), 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. This study milestone occurred in late April 2020 and the Phase 3 study is currently in the analysis phase.

Nine hundred twenty-eight (928) newly diagnosed head and neck cancer patients have been enrolled in this Phase 3 cancer study and all the patients who have completed treatment continue to be followed for protocol-specific outcomes in accordance with the study protocol. The last patient was enrolled in the study in September 2016. Approximately 135 patients were enrolled in the study from 2011 to 2013, about 195 were enrolled in 2014, about 340 in 2015, and about 260 in 2016. An analysis conducted using the SEER (Surveillance, Epidemiology, and End Results) 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.

This trial is currently under the management of two clinical research organizations, or CROs: ICON plc., 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 \$58.9 million as of September 30, 2020 on direct costs for the Phase 3 clinical trial. CEL-SCI estimates it will incur additional expenses of approximately \$5.9 million for the remainder of the Phase 3 clinical trial and the filing of the clinical study report to the FDA. It should be noted that this estimate is based only on the information currently available 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 estimate may be affected by the 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. However, CEL-SCI does not believe that this is likely.

## **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. 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.

### **LEAPS Candidate: LEAPS COV-19**

CEL-SCI began developing an immunotherapy with the potential to treat the COVID-19 coronavirus using its patented LEAPS peptide technology. On March 23, 2020, CEL-SCI signed a collaboration agreement with the University of Georgia's Center for Vaccines and Immunology to develop LEAPS COV-19 immunotherapy. The LEAPS peptides will utilize conserved regions of coronavirus proteins to stimulate protective cell mediated T cell responses and reduce viral load. The LEAPS peptide technology can be used to construct immunotherapeutic peptides that exhibit both antiviral and anti-inflammatory properties. Consequently, these products not only target the virus infection against which they are directed, but also elicit the appropriate protective response(s) against it.

On July 24, 2020, CEL-SCI announced it had concluded animal experiments using its LEAPS COV-19 conjugate that provide the basis for moving forward into animal challenge studies with live virus SARS-CoV-2, the causative agent of COVID-19, at the UGA's Center for Vaccines and Immunology. The animal experiments showed that LEAPS COV-19 conjugates induced faster and much higher than expected antibody responses against a non-mutating region of the virus that causes COVID-19, after only one injection. It is important to note that IgG antibodies response was generated within 10 days of a single immunization. Generation of IgG requires activation of dendritic, T and B cells in order to promote the class switch from IgM to IgG antibody.

On December 1, 2020, CEL-SCI announced that LEAPS COV-19 peptides, delivered as a therapeutic treatment following SARS-CoV-2 virus challenge, achieved a 40% survival rate in transgenic mouse models as compared to 0% survival in the two control groups in studies conducted at the University of Georgia Center for Vaccines and Immunology. The animals were therapeutically treated with CEL-SCI's LEAPS COV-19 peptides one day after infection with a lethal dose of SARS-CoV-2. Of the LEAPS treated mice, forty percent (40%) were alive, recovering



and regained lost weight, attaining > 90% of their starting weight, by the study's end. In contrast, mice in the two control groups lost 20% or more of their body weight by day 8 and all of them died between day 5 and day 8 post challenge. The success of this therapy was statistically significant at a 95% level. An additional study conducted using LEAPS as a vaccine to prevent disease resulted in similar findings to the above described study, but with a slightly lower level of statistical significance. In this study, the Human(h) ACE2 transgenic mice were dosed twice with the LEAPS conjugate 28 and 14 days prior to being challenged with a lethal dose of SARS-CoV-2 virus. CEL-SCI's next step is to leverage the findings from these two animal studies into future studies that will optimize treatment dosing and test additional LEAPS peptides as a therapy.

Predictions of success using the LEAPS peptides against COVID-19 coronavirus are based on previous studies conducted in collaboration with the National Institutes for Allergies and Infectious Diseases (NIAID) with another respiratory virus, pandemic influenza (H1N1). In those studies, LEAPS peptides elicited protection of mice from morbidity and mortality after the introduction of infection by activating appropriate T cell responses rather than an inflammatory response. These SARS-CoV-2 challenge studies at the University of Georgia's Center for Vaccines and Immunology seek to repeat the success of animal challenge studies conducted previously at the NIAID emerging diseases laboratory during the threatened H1N1 flu pandemic. LEAPS is in the early stages for treating COVID-19 coronavirus and there is no guarantee that CEL-SCI will be able to replicate the results from its prior studies.

#### LEAPS Candidates: CEL-2000, CEL-4000 and DerG-PG275(Cit)

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 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 103rd 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 University, Dr. Adrienn Markovics presented new LEAPS data at i-Chem2019, International Conference on Immunity and Immunochemistry. Data presented was for a new second RA conjugate 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 conjugates provided not only broader epitope coverage, but also a greater therapeutic effect than either conjugate 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 conjugates 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.

In February 2017 and November 2016, CEL-SCI announced preclinical data that demonstrate its investigational new drug candidate CEL-4000 has the potential to treat rheumatoid arthritis. This study was supported in part by the SBIR Phase I Grant and was conducted in collaboration with Drs. Katalin Mikecz and Tibor Glant, and their research team at Rush University Medical Center in Chicago, IL. This work was published in an article entitled "*An epitope-specific DerG-PG70 LEAPS vaccine modulates T cell responses and suppresses arthritis progression in two related murine models of rheumatoid arthritis*" and can be found online at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5568759/>.

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 several new drug candidates, CEL-2000 and CEL-4000, as potential rheumatoid arthritis therapeutic treatments. The data from animal studies using the CEL-2000 treatment 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- $\alpha$ . The preclinical data indicates these peptides could be used against rheumatoid arthritis where a Th1 signature cytokine (IFN- $\gamma$ ) 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.

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

#### Other LEAPS experiments: LEAPS-H1N1-DC

Using the LEAPS technology, CEL-SCI has also tested in preclinical studies a potential peptide treatment for H1N1 (swine flu) hospitalized patients, a disease which does not represent a problem any more. Therefore CEL-SCI is no longer developing a treatment against H1N1. This LEAPS flu treatment was 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.

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

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

Accordingly, even though the various LEAPS 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.

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. CEL-SCI is currently expanding the manufacturing facility so CEL-SCI will be able to meet the expected demand for Multikine if a license is granted. CEL-SCI's lease on the manufacturing facility expires on October 31, 2028.

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

As of September 30, 2020, there were approximately 617 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.

Quarter Ending	High	Low
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
12/31/2019	\$9.74	\$6.00
3/31/2020	\$17.80	\$6.35
6/30/2020	\$18.00	\$9.64
9/30/2020	\$15.10	\$11.29

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. The pivotal Phase 3 study reached the targeted threshold of 298 events (deaths) required to conduct the data evaluation. CEL-SCI is now in the phase that involves final analysis of the trial results. CEL-SCI will continue to remain blinded to the study results throughout this process. CEL-SCI will be advised of the results when the analysis is completed and the study results will be announced to the public at that time.

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, 2020, grant income increased by approximately \$0.1 million compared to the year ended September 30, 2019. 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, 2020, research and development expenses increased by approximately \$5.2 million, or 41%, compared to the year ended September 30, 2019. Major components of this increase include approximately \$2.1 million in expenses to prepare for the potential filing of a Biologics License Application (BLA) and commercial manufacture of Multikine. Additional components of the increase include, \$2.7 million increase in employee stock compensation expense, of which \$0.7 million was incurred under the 2020 Non-Qualified Stock Option Plan, \$1.2 million increase in depreciation expense resulting from the adoption of the new leasing standard, and an increase of approximately \$0.4 million in other miscellaneous research and development expenses. These increases were offset by a decrease of approximately \$1.2 million in expenses related to CEL-SCI's on-going Phase 3 clinical trial.

During the year ended September 30, 2020, general and administrative expenses increased by approximately \$3.7 million, or 46%, compared to the year ended September 30, 2019. A major component of the increase is an approximate \$3.0 million increase in employee stock compensation costs, of which approximately \$1.4 million was incurred under the 2020 Non-Qualified Stock Option Plan. Additionally, depreciation on leased assets increased by approximately \$0.3 million as a result of the adoption of the new leasing standard effective October 1, 2019, and an approximately \$0.4 million net increase in other general and administrative costs.

During the years ended September 30, 2020 and 2019, CEL-SCI recorded derivative losses of approximately \$0.3 million and \$0.8 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.

Other non-operating gain increased by approximately \$0.3 million for the year ended September 30, 2020 as compared to the year ended September 30, 2019. This gain relates to the Securities Purchase Agreement described in Note 12 to the financial statements included as part of this report. The amount of the gain or loss is a result of the timing of shares issued to Ergomed and the subsequent re-sale of those shares. During the years ended September 30, 2020 and 2019, the Company issued 150,000 and 750,000 shares, respectively, to Ergomed and recorded a non-operating loss

equal to the fair value of those shares of approximately \$1.8 million and \$3.4 million, respectively. During the year ended September 30, 2020 and 2019, Ergomed received approximately \$2.7 million and \$3.9 million, respectively, from the resale of these shares.

During the year ended September 30, 2020, the Company issued Series XX and Series YY warrants to induce holders of Series V warrants to exercise their warrants. Upon acceptance of the warrant inducement offer, the aggregate value of the inducement warrants of approximately \$0.8 million was recorded as an expense. All unexercised Series V warrants expired in September 2020.

Net interest expense decreased by approximately \$0.8 million for the year ended September 30, 2020 compared to the year ended September 30, 2019 due to a reduction in the interest rate applied to the Company's finance leases that were re-measured in connection with the adoption of ASC 842, *Leases*, effective October 1, 2019.

### **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.

	<b>Year ended September 30,</b>	
	<b>2020</b>	<b>2019</b>
Multikine	\$ 16,146,248	\$ 11,623,050
LEAPS	1,694,042	1,036,237
Total research and development	<u>\$ 17,840,290</u>	<u>\$ 12,659,287</u>

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 primarily 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 primarily 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 2020 and 2019, CEL-SCI raised net proceeds of approximately \$25.8 million and \$14.8 million, respectively, through a combination of the sale of common stock and the exercise of warrants and options. In December 2020, the CEL-SCI sold 1,000,000 shares of common stock at a public offering price of \$14.65 per share and received aggregate net proceeds of approximately \$13.6 million. Under the terms of the Underwriting Agreement the Company granted the Underwriters a 30-day option to purchase up to an additional 150,000 shares of common stock at the public offering price to cover over-allotments.

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 \$1.9 million during the twelve months ended September 30, 2020.



In March 2020, the Company sold 630,500 shares of common stock at a public offering price of \$12.22 per share and received aggregate net proceeds of approximately \$7.1 million. Under the terms of the Underwriting Agreement the Company granted the Underwriters a 45-day option to purchase up to an additional 94,575 shares of common stock solely to cover over-allotments. The underwriter fully exercised this option in May 2020 resulting in additional net proceeds to the Company of approximately \$1.1 million.

In December 2019, the Company sold 606,395 shares of common stock at a public offering price of \$9.07 per share and received aggregate net proceeds of approximately \$5.0 million. In January 2020, the underwriters of that offering fully exercised an option to purchase 90,959 additional shares of common stock at the public offering price of \$9.07 per share for aggregate net proceeds to the Company of approximately \$0.8 million.

The following charts list the warrants that were exercised and the proceeds received during the years ended September 30, 2020 and 2019.

Fiscal Year 2020

Warrants	Warrants Exercised	Exercise Price	Proceeds
Series CC	128,820	\$5.00	\$ 644,100
Series FF	68,048	\$3.91	265,812
Series HH	6,300	\$3.13	19,687
Series JJ	9,450	\$3.13	29,531
Series LL	26,398	\$3.59	94,867
Series MM	95,858	\$1.86	178,296
Series NN	124,956	\$2.52	314,889
Series OO	50,000	\$2.52	126,000
Series RR	39,467	\$1.65	65,121
Series SS	156,580	\$2.09	327,252
Series TT	188,125	\$2.24	421,400
Series UU	61,207	\$2.80	171,380
Series V	674,164	\$13.75	9,269,755
Series VV	82,500	\$1.75	144,375
	<u>1,711,873</u>		<u>\$ 12,072,465</u>

Fiscal Year 2019

Warrants	Warrants Exercised	Exercise Price	Proceeds
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>

CEL-SCI entered into Securities Purchase Agreements (SPAs) with Ergomed plc, one of CEL-SCI's Clinical Research Organizations responsible for managing the Phase 3 clinical trial, to facilitate payment of amounts due Ergomed. Under the Agreements, CEL-SCI issued Ergomed shares of common stock and the net proceeds from the sales of those shares reduces outstanding amounts due Ergomed. Upon issuance, CEL-SCI 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.

During the year ended September 30, 2020 and 2019, CEL-SCI issued Ergomed 150,000 and 750,000 shares, respectively.

The following table summarizes the Other Non-operating gains for the years ended September 30 relating to these agreements:

	2020	2019
Amount realized through the resale of shares	\$ 2,652,605	\$ 3,945,528
Fair value of shares upon issuance	1,769,500	3,400,000
Other non-operating gain (loss)	\$ 883,105	\$ 545,528

As of September 30, 2020, Ergomed held 102,521 shares for resale. As of September 30, 2019, Ergomed held 198,000 shares for resale.

During the year ended September 30, 2020, CEL-SCI's cash increased by approximately \$7.1 million. Significant components of this increase include: Net proceeds received of approximately \$25.8 million from the sale of common stock and the exercise of warrants and stock options, offset by net cash used in operating activities of approximately \$15.2 million, purchases of capitalizable property, equipment and patents of approximately \$2.7 million, and approximately \$0.8 million in lease payments.

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 and making required lease payments. Additionally, the Company is currently upgrading the manufacturing facility to prepare for the potential commercial production of Multikine. Estimated costs to complete the upgrade are \$7.4 million, \$2.4 million of which the landlord of the property has contingently agreed to finance.

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 \$5.9 million for the remainder of the Phase 3 clinical trial and the filing of the clinical study report to the FDA. It should be noted that this estimate is based only on the information currently available from the CROs responsible for managing the Phase 3 clinical trial and does not include other related costs, e.g., the manufacturing of the drug.

On May 4, 2020, CEL-SCI announced that the pivotal Phase 3 head and neck cancer study of Multikine immunotherapy had reached the targeted threshold of 298 events (deaths) required to conduct the data evaluation. CEL-SCI is now in the phase that involves final analysis of the trial results. CEL-SCI may or may not need to raise additional funds to reach the final read-out of the Phase 3 trial depending on the length of time it takes. 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 25 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 foreign currency exchange rates.

### **Critical Accounting Policies**

CEL-SCI's significant accounting policies are more fully described in Note 3 to the financial statements included as part of this report. However, certain accounting policies are particularly important to the portrayal of CEL-SCI's financial position and results of operations and require the application of significant judgments by management. As a result, the financial statements are subject to an inherent degree of uncertainty. In applying those policies, management uses its judgment to determine the appropriate assumptions to be used in the determination of certain estimates. These estimates are based on CEL-SCI's historical experience, terms of existing contracts, observance of trends in the industry and information available from outside sources, as appropriate.

Management believes that the following critical accounting policies require the most significant judgments and estimates with respect 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. Performance-based options are valued using a Monte-Carlo simulation model, which requires inputs based on estimates, including the likelihood of the occurrence of performance and market conditions, volatility and expected option life.

In October 2019, the Company adopted ASU 2018-07, *Compensation — Stock Compensation (Topic 718)*, which expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees, and thus, the accounting for share-based payments to non-employees will be substantially aligned. Adoption of the new guidance had no impact on the financial statements and related disclosures.

*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, 2020 and 2019, and**

**Report of Independent Registered Public Accounting Firm**

## **CEL-SCI CORPORATION**

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## **Report of Independent Registered Public Accounting Firm**

Stockholders 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, 2020 and 2019, 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, 2020 and 2019, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

### **Going Concern Uncertainty**

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, since inception the Company has suffered recurring losses from operations and expects to continue incurring losses. In addition, the Company is dependent on raising additional capital to continue to fund its operations. These factors raise substantial doubt about the Company's 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.

### **Change in Accounting Principle**

As discussed in Note 3 to the consolidated financial statements, the Company has changed its method of accounting for leases as of October 1, 2019 due to the adoption of Accounting Standards Codification (ASC) 842, *Leases*.

### **Basis for Opinion**

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

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

/s/ BDO USA, LLP

We have served as the Company's auditor since 2005.

Potomac, Maryland  
December 29, 2020

CEL-SCI CORPORATION  
BALANCE SHEETS  
SEPTEMBER 30, 2020 and 2019

ASSETS	2020	2019
Current Assets:		
Cash and cash equivalents	\$ 15,508,909	\$ 8,444,774
Receivables	54,922	62,765
Prepaid expenses	1,313,432	524,953
Supplies used for R&D and manufacturing	820,052	782,363
Total current assets	17,697,315	9,814,855
Finance lease right of use assets	13,811,849	-
Operating lease right of use assets	1,198,958	-
Property and equipment, net	5,843,993	15,825,636
Patent costs, net	313,422	311,586
Deposits	1,670,917	1,670,917
Total assets	\$ 40,536,454	\$ 27,622,994
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	\$ 2,023,067	\$ 1,586,478
Accrued expenses	510,515	34,432
Due to employees	448,022	709,442
Derivative instruments, current portion	213,787	674,442
Lease liabilities, current portion	1,070,123	-
Other current liabilities	-	14,956
Total current liabilities	4,265,514	3,019,750
Derivative instruments, net of current portion	3,551,826	5,813,868
Finance lease liabilities, net of current portion	11,753,100	13,508,156
Operating lease liabilities, net of current portion	1,114,340	-
Other liabilities	125,000	147,553
Total liabilities	20,809,780	22,489,327
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; 38,730,150 and 35,231,776 shares issued and outstanding at September 30, 2020 and 2019, respectively	387,302	352,318
Additional paid-in capital	401,174,675	358,507,603
Accumulated deficit	(381,835,303)	(353,726,254)
Total stockholders' equity	19,726,674	5,133,667
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 40,536,454	\$ 27,622,994

See notes to financial statements.



CEL-SCI CORPORATION  
STATEMENTS OF OPERATIONS  
YEARS ENDED SEPTEMBER 30, 2020 and 2019

	2020	2019
Grant income	\$ 558,664	\$ 462,754
Operating expenses:		
Research and development	17,840,290	12,659,287
General and administrative	11,703,429	7,998,573
Total operating expenses	29,543,719	20,657,860
Operating loss	(28,985,055)	(20,195,106)
Other income	38,763	73,022
Loss on derivative instruments	(349,078)	(760,603)
Warrant inducement expense	(805,753)	-
Other non-operating gain	887,604	545,528
Interest expense, net	(1,041,725)	(1,797,481)
Net loss	(30,255,244)	(22,134,640)
Modification of warrants	(21,734)	-
Net loss available to common shareholders	\$ (30,276,978)	\$ (22,134,640)
Net loss per common share, basic and diluted	\$ (0.82)	\$ (0.71)
Weighted average common shares outstanding, basic and diluted	36,759,115	31,174,394

See notes to financial statements.

CEL-SCI CORPORATION  
STATEMENTS OF STOCKHOLDERS' EQUITY  
YEARS ENDED SEPTEMBER 30, 2020 and 2019

	Common Shares	Stock Amount	Additional Paid-In Capital	Accumulated Deficit	Total
BALANCE, OCTOBER 1, 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
Stock 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	35,231,776	\$ 352,318	\$ 358,507,603	\$ (353,726,254)	\$ 5,133,667
Adoption of new accounting principle (ASC 842)				2,146,195	2,146,195
Proceeds from the sale of common stock	1,422,429	14,225	13,978,214	-	13,992,439
Warrant issuances	-	-	805,753	-	805,753
Warrant exercises	1,711,873	17,118	15,127,122	-	15,144,240
Modification of warrants	-	-	5,554	-	5,554
401(k) contributions paid in common stock	13,870	139	163,201	-	163,340
Stock issued to nonemployees for service	79,950	799	971,868	-	972,667
Equity based compensation - employees	-	-	10,112,968	-	10,112,968
Stock option exercises	99,740	998	337,330	-	338,328
Purchase of stock by officers and directors	20,512	205	184,785	-	184,990
Stock issuance costs	-	-	(787,723)	-	(787,723)
Shares issued for settlement of clinical research costs	150,000	1,500	1,768,000	-	1,769,500
Net loss	-	-	-	(30,255,244)	(30,255,244)
BALANCE, SEPTEMBER 30, 2020	38,730,150	\$ 387,302	\$ 401,174,675	\$ (381,835,303)	\$ 19,726,674

See notes to financial statements.

CEL-SCI CORPORATION  
STATEMENTS OF CASH FLOWS  
YEARS ENDED SEPTEMBER 30, 2020 and 2019

	2020	2019
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$ (30,255,244)	\$ (22,134,640)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,159,729	633,529
Share based payments for services	862,796	856,025
Equity based compensation	10,112,968	4,428,174
Common stock contributed to 401(k) plan	163,340	143,878
Shares issued for settlement of clinical research costs	1,769,500	3,400,000
Loss on derivative instruments	349,078	760,603
Warrant inducement expense	805,753	-
Modification of warrants	5,554	-
Capitalized lease interest	-	128,194
(Increase)/decrease in assets:		
Receivables	7,843	55,892
Prepaid expenses	(623,608)	(137,768)
Supplies used for manufacturing	(37,689)	(137,125)
Increase/(decrease) in liabilities:		
Accounts payable	(766,073)	(4,084,410)
Accrued expenses	406,083	(170,878)
Due to employees	(261,420)	(55,499)
Other liabilities	25,229	(6,660)
Net cash used in operating activities	(15,276,161)	(16,320,685)
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Purchases of property and equipment	(2,654,906)	(177,779)
Expenditures for patent costs	(39,975)	(158,060)
Net cash used in investing activities	(2,694,881)	(335,839)
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from issuance of common stock	13,992,439	-
Payments of stock issuance costs	(752,804)	(163,364)
Proceeds from exercise of warrants	12,072,465	14,517,260
Proceeds from exercises of options	338,328	150,482
Proceeds from the purchase of stock by officers and directors	184,990	291,997
Payments on obligations under finance leases	(800,241)	(5,121)
Net cash provided by financing activities	25,035,177	14,791,254
<b>NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS</b>	<b>7,064,135</b>	<b>(1,865,270)</b>
<b>CASH AND CASH EQUIVALENTS, BEGINNING OF YEAR</b>	<b>8,444,774</b>	<b>10,310,044</b>
<b>CASH AND CASH EQUIVALENTS, END OF YEAR</b>	<b>\$ 15,508,909</b>	<b>\$ 8,444,774</b>



CEL-SCI CORPORATION  
STATEMENTS OF CASH FLOWS  
YEARS ENDED SEPTEMBER 30, 2020 and 2019

SUPPLEMENTAL SCHEDULE OF NON-CASH INVESTING AND FINANCING ACTIVITIES:

	2020	2019
Property and equipment purchases included in accounts payable	\$ 1,184,723	\$ 17,329
Prepaid consulting services paid with issuance of common stock	\$ 164,871	\$ 22,563
Right of use assets acquired and liabilities incurred	\$ 399,032	\$ -
Exercise of derivative liabilities	\$ 3,071,775	\$ 3,589,357
Lease obligation included in accounts payable	\$ 790	\$ 441
Stock issuance costs included in current liabilities	\$ 50,499	\$ 15,580
Capitalizable patent costs included in current liabilities	\$ 15,000	\$ -
Accrued consulting services to be paid with common stock	\$ 55,000	\$ -
Cash paid for interest	\$ 1,155,026	\$ 1,809,242

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. The Company has recently reached the end of the pivotal Phase 3 study for its lead investigational therapy, Multikine® (Leukocyte Interleukin, Injection), involving head and neck cancer, for which the Company has received Orphan Drug Status from the United States Food and Drug Administration (FDA). The Phase 3 study is in the final statistical analysis phase. Unlike other immune therapies, Multikine is administered locally at the site of the tumor as a first line treatment right after diagnosis, 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.

CEL-SCI is investigating a peptide-based immunotherapy (CEL-4000) as a vaccine for rheumatoid arthritis using its LEAPS technology platform. CEL-SCI is in the process of completing pre-IND studies for CEL-4000 and hopes to start human studies with CEL-4000 in 2021.

CEL-SCI is also investigating LEAPS COVID-19 conjugates as a potential treatment of COVID-19 in hospitalized and at-high-risk patients at the University of Georgia's Center for Vaccines and Immunology. Initial animal experiments showed that LEAPS COVID-19 conjugates induced faster and much higher than expected antibody responses against a non-mutating region of the virus that causes COVID-19, after only one injection. These experiments provide the basis for moving forward into animal challenge studies with live virus SARS-CoV-2, the causative agent of COVID-19. These SARS-CoV-2 challenge studies being conducted at UGA's Center for Vaccines and Immunology seek to repeat the success of animal challenge studies conducted previously at the National Institutes for Allergies and Infectious Diseases (NIAID) emerging diseases laboratory during the threatened H1N1 flu pandemic.

### **2. OPERATIONS AND FINANCING**

On May 4, 2020, the Company announced that the pivotal Phase 3 head and neck cancer study of Multikine immunotherapy had reached the targeted threshold of 298 events (deaths) required to conduct the data evaluation. Database lock is completed and the Phase 3 study is now in the final statistical analysis phase. The Company will continue to remain blinded to the study results throughout this process. The Company will be advised of the results when the analysis is completed, and the study results will be announced to the public at that time.

The Company has incurred significant costs since its inception for the acquisition of certain proprietary technology and scientific knowledge relating to the human immunological defense system, patent applications, research and development, administrative costs, construction of laboratory facilities and participation in clinical trials. The Company has funded such costs primarily 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 to continue with its research efforts. The ability to raise capital may be dependent upon market conditions that are outside the control of the Company. 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 believes there is a high likelihood that it will continue to receive funds from private and public offerings and warrant exercises similarly to the way it has substantially funded operations for the past 12 months. However, there can be no assurance that the Company will be able to raise sufficient capital to support its operations.

To finance the Company through marketing approval, the Company plans to raise additional capital in the form of warrant exercises, corporate partnerships, and 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 the Multikine Phase 3 study has ended and is only awaiting final results. 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.

On January 30, 2020, the World Health Organization (“WHO”) announced a global health emergency because of a new strain of coronavirus originating in Wuhan, China (the “COVID-19 outbreak”) and the risks to the international community as the virus spread globally beyond its point of origin. In March 2020, because of the rapid increase in exposure globally, the WHO classified the COVID-19 outbreak as a pandemic. The full impact of the COVID-19 outbreak continues to evolve as of the date of this report. As such, it is uncertain as to the full magnitude that the pandemic will have on the Company’s financial condition, liquidity and future results of operations. Management is actively monitoring the risks to public health and the impact of overall global business activity on its financial condition, liquidity, operations, suppliers, industry, and workforce.

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.

### 3. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

*Cash and Cash Equivalents* – 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.

*Property and Equipment* – Property and 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. Property and equipment is reviewed on a quarterly basis to determine if any of the assets are impaired.

*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* – On October 1, 2019, the Company adopted Accounting Standards Update (“ASU”) 2016-02, *Leases* and its related amendments (collectively referred to as Topic 842 and codified as “ASC 842”). ASC 842 requires that lessees recognize right-of-use assets and lease liabilities measured at the present value of the future lease payments at the lease commencement date. The Company adopted the new leases standard utilizing the modified retrospective transition method, under which amounts in prior periods presented were not restated. For contracts existing at the time of adoption, the Company elected to not reassess (i) whether any are or contain leases, (ii) lease classification, and (iii) initial direct costs. The Company’s lease portfolio includes both finance and operating leases. The impact of adopting ASC 842 was to increase long term assets by approximately \$3.0 million, increase total liabilities by approximately \$0.9 million and record a cumulative effect adjustment of approximately \$2.1 million to the opening accumulated deficit balance. The adoption of ASC 842 did not have a significant impact on the Company’s statements of operations or cash flows.

In connection with the preparation of our financial statements for the year ended September 30, 2020, we identified an error relating to the manufacturing facility lease on the adoption of ASC 842 at October 1, 2019. The error impacted the finance lease right-of-use asset and total stockholders’ equity, both of which were understated by approximately \$2.0 million on adoption. We concluded the impact on the interim financial statements during fiscal 2020 was immaterial to the statement of operations but material to the balance sheet and will correct the balances for the quarterly reporting periods at December 31, 2019, March 31, 2020, and June 30, 2020. All adjustments have been reflected in the accompanying financial statements. Additional information has been disclosed in the 8-K filed on December 29, 2020.



*Derivative Instruments* – The Company has financing arrangements that consist of freestanding derivative instruments that contain embedded derivative features. The Company accounts for these arrangements in accordance with ASC 815, “Accounting for Derivative Instruments and Hedging Activities.” In accordance with ASC 815, derivative instruments and hybrid instruments are recognized as either assets or liabilities in 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 considering all the rights and obligations of each instrument. The derivative liabilities are re-measured at fair value at the end of each interim period.

In August 2018, the FASB issued ASU 2018-13, “Fair Value Measurement - Disclosure Framework-Changes to the Disclosure Requirements for Fair Value Measurement (Topic 820).” Under the new standard, the amount and reason for a transfer between Level 1 and Level 2 of the fair value hierarchy is no longer required to be disclosed, but public companies are required to disclose a range and weighted average of significant unobservable inputs for Level 3 fair value measurements. The Company adopted the new standard on July 1, 2020; however, it had an insignificant impact to the disclosures in the Company’s financial statements.

*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.

In June 2018, the Financial Accounting Standards Board (“FASB”) issued ASU 2018-07, *Compensation — Stock Compensation (Topic 718)*, which expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees, and thus, the accounting for share-based payments to non-employees will be substantially aligned. The Company adopted ASU 2018-07 as of October 1, 2019 with no impact on its financial statements and related disclosures.

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

The Company’s stock options are not transferable, and the actual value of the stock options that an employee may realize, if any, will depend on the excess of the market price on the date of exercise over the exercise price. For options issued with service conditions only, 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 the term equal to the expected life of the option. Forfeitures are accounted for when they occur. The expected term of options represents the period that options granted are expected to be outstanding and has been determined based on an analysis of historical exercise behavior. 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 and options granted under the 2020 Non-Qualified Stock Option Plan are subject to service, performance and market conditions and meets the classification of equity awards. These awards were measured at market value on the grant-dates for issuances where the attainment of performance criteria is likely 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.

*Research and Development Costs* - Research and development costs are expensed as incurred. Management accrues Clinical Research Organization (“CRO”) expenses and clinical trial study expenses based on services performed and relies on the CROs to provide estimates of those costs applicable to the completion stage of a study. Estimated accrued CRO costs are subject to revisions as such studies progress to completion. The Company charges revisions to estimated expense in the period in which the facts that give rise to the revision become known.

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

*Net Loss Per Common Share* – The Company calculates net loss per common share in accordance with ASC 260 "Earnings Per Share" (ASC 260). Basic and diluted net loss per common share was determined by dividing net loss applicable to common shareholders by the weighted average number of common shares outstanding during the period. The Company's potentially dilutive shares, which include outstanding common stock options, unvested restricted 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, 2020.

*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, 2020 and 2019.

*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.

#### *New Accounting Pronouncements*

In December 2019, the FASB issued ASU No. 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*. The new standard includes several provisions that simplify accounting for income taxes by removing certain exceptions to the general principles in Topic 740 and increasing consistency and clarity for the users of financial statements. This standard will be effective for the Company on October 1, 2021. Early adoption is permitted. We are currently evaluating the impact this ASU will have on our financial statements.

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

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

The following warrants and non-employee options are outstanding at September 30, 2020:



<u>Warrant</u>	<u>Issue Date</u>	Shares Issuable upon Exercise of <u>Warrants</u>	<u>Exercise Price</u>	<u>Expiration Date</u>
Series N	8/18/2008	85,339	\$3.00	2/18/2021
Series UU	6/11/2018	93,603	\$2.80	12/31/2020
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 CC	12/8/2016	148,643	\$5.00	12/8/2021
Series HH	2/23/2017	200	\$3.13	2/16/2022
Series AA	8/26/2016	200,000	\$13.75	2/22/2022
Series MM	6/22/2017	797,633	\$1.86	6/22/2022
Series NN	7/24/2017	348,842	\$2.52	7/24/2022
Series RR	10/30/2017	417,649	\$1.65	10/30/2022
Series SS	12/19/2017	326,064	\$2.09	12/18/2022
Series TT	2/5/2018	371,564	\$2.24	2/5/2023
Consultants	7/28/17	10,000	\$2.18	7/27/2027

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

<u>Warrant</u>	<u>Issue Date</u>	Shares Issuable upon Exercise of <u>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

#### A. Warrant Liabilities

Warrant liabilities outstanding at September 30 are as follows:



	2020	2019
Series V warrants	\$ -	\$ 674,442
Series W warrants	73,570	1,193,507
Series Z warrants	1,207,902	1,109,545
Series ZZ warrants	75,044	77,638
Series AA warrants	1,082,212	916,908
Series BB warrants	65,173	63,966
Series CC warrants	1,259,712	1,710,898
Series FF warrants	-	446,185
Series HH warrants	2,000	45,657
Series JJ warrants	-	66,599
Series LL warrants	-	182,965
Total warrant liabilities	\$ 3,765,613	\$ 6,488,310

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

	2020	2019
Series S Warrants	\$ -	\$ 33
Series V warrants	185,652	95,994
Series W warrants	1,119,937	(194,426)
Series Z warrants	(98,357)	(621,778)
Series ZZ warrants	2,594	(43,423)
Series AA warrants	(165,304)	(536,434)
Series BB warrants	(1,207)	(35,510)
Series CC warrants	(875,040)	(1,198,836)
Series DD warrants	-	1,249,287
Series EE warrants	-	1,249,287
Series FF warrants	(319,706)	(257,264)
Series GG warrants	-	195,228
Series HH warrants	(34,589)	(24,465)
Series II warrants	-	(442,040)
Series JJ warrants	(64,992)	(35,301)
Series KK warrants	-	(55,622)
Series LL warrants	(98,066)	(105,333)
Net loss on warrant liabilities	\$ (349,078)	\$ (760,603)

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.

#### *Changes in Warrant Liabilities*

On May 26, 2020, the Company lowered the exercise price of 810,127 Series V warrants from \$19.75 to \$13.75 per share and extended the expiration dates of the Series V warrants from May 28, 2020 to June 25, 2020. The incremental cost of this modification was approximately \$664,000, which was included in the net loss on derivatives for the year ended September 30, 2020. On June 25, 2020, 135,963 Series V warrants, with an exercise price of \$13.75 expired. The warrants were valued at approximately \$211,000 on the date of expiration.

On December 10, 2018, 1,360,960 Series DD and 1,360,960 Series EE warrants, with an exercise price of \$4.50 expired.

On October 11, 2018, 327,729 Series S warrants, with an exercise price of \$31.25 expired.

#### *Exercise of Warrant Liabilities*

The following warrants recorded as liabilities were exercised during the year ended September 30, 2020:

<u>Warrants</u>	<u>Warrants Exercised</u>	<u>Exercise Price</u>	<u>Proceeds</u>
Series V	674,164	\$13.75	\$ 9,269,755
Series CC	128,820	\$5.00	644,100
Series FF	68,048	\$3.91	265,812
Series HH	6,300	\$3.13	19,687
Series JJ	9,450	\$3.13	29,531
Series LL	26,398	\$3.59	94,867
	<u>913,180</u>		<u>\$10,323,752</u>

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>

## **B. Equity Warrants**

### *Changes in Equity Warrants*

On May 26, 2020, the Company provided that for each Series V liability warrant exercised on or before June 10, 2020, the former holder of the Series V warrant received one Series XX warrant. Each Series XX warrant allowed the holder to purchase one share of the Company's common stock at a price of \$18.00 per share at any time on or before September 10, 2020. For each Series V liability warrant exercised after June 10, 2020 but on or before June 25, 2020, the former holder of the Series V warrant received one Series YY warrant. Every two Series YY warrants allowed the holder to purchase one share of the Company's common stock at a price of \$20.00 per share at any time on or before September 25, 2020. In June 2020, 461,953 Series XX warrants and 101,839 Series YY warrants were issued to the former holders of the Series V warrants. The Series XX and YY warrants qualified for equity treatment in accordance with ASC 815. The Company recognized a warrant inducement expense equal to the fair value of the Series XX and Series YY warrants issued as of the date the inducement offers were accepted. The fair values of the Series XX and Series YY warrants were calculated to be approximately \$629,000 and \$177,000, respectively. The total expense of approximately \$806,000 is reported as warrant inducement expense in the statement of operations for the year ended September 30, 2020. All Series XX and YY warrants expired in September 2020.

On May 8, 2020, the expiration dates of 93,593 Series UU warrants were extended from June 11, 2020 to December 31, 2020. These warrants were previously issued as an inducement to convert notes payable into shares of common stock. The incremental cost of this extension was approximately \$6,000 and was recorded as interest expense during the year ended September 30, 2020. The Series UU warrants are held by Geert Kersten, Patricia Prichep (current Officers of the Company) and the de Clara Trust, of which the Company's CEO, Geert Kersten, is a beneficiary.

On January 23, 2020, the expiration date of the Series N warrants was extended to February 18, 2021. The incremental cost of this extension was approximately \$22,000, which was recorded as a deemed dividend in the financial statements for the year ended September 30, 2020. The Series N warrants are held by the de Clara Trust.

#### *Exercise of Equity Warrants*

The following equity warrants were exercised during the year ended September 30, 2020.

<u>Warrants</u>	<u>Warrants Exercised</u>	<u>Exercise Price</u>	<u>Proceeds</u>
Series MM	95,858	\$1.86	\$ 178,296
Series NN	124,956	\$2.52	314,889
Series OO	50,000	\$2.52	126,000
Series RR	39,467	\$1.65	65,121
Series SS	156,580	\$2.09	327,252
Series TT	188,125	\$2.24	421,400
Series UU	61,207	\$2.80	171,380
Series VV	82,500	\$1.75	144,375
	<u>798,693</u>		<u>\$1,748,713</u>

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>

#### **C. 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, 2020 and 2019 the Company issued 79,950 and 199,977 shares, respectively, of common stock to consultants, all of which were restricted shares. Under these arrangements, the common stock was issued with stock prices ranging between \$2.66 and \$17.60 per share. The weighted average grant price was \$12.01 and \$4.25, respectively, for stock issued during the years ended September 30, 2020 and 2019.

During the years ended September 30, 2020 and 2019, the Company recorded total expense of approximately \$863,000 and \$856,000, respectively, relating to these consulting agreements. At September 30, 2020 and 2019, costs of approximately \$395,000 and \$230,000, respectively, are included in prepaid expenses. No options were issued to consultants during the year ended September 30, 2020. During the year ended September 30, 2019, 10,000 options issued to consultants were exercised and 10,400 options expired. As of September 30, 2020, 10,000 options issued to consultants as payment for services remained outstanding, all of which were issued from the Non-Qualified Stock Option plan and are fully vested.

#### **5. PLANT, PROPERTY AND EQUIPMENT**

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



	2020	2019
Leased manufacturing facility	\$ -	\$ 21,183,756
Research equipment	3,898,242	3,320,358
Furniture and equipment	99,768	125,872
Leasehold improvements	5,519,161	149,239
	9,517,171	24,779,225
Accumulated depreciation and amortization	(3,673,178)	(8,953,589)
Net plant, property and equipment	\$ 5,843,993	\$ 15,825,636

The Company leases its manufacturing facility under a finance lease. Prior to the adoption of ASC 842 effective October 1, 2019, the Company accounted for the manufacturing facility lease under the build-to-suit provisions of ASC 840. This guidance required the Company to record an asset and liability for construction costs incurred because it was involved in the construction of structural improvements and took construction risk prior to the commencement of the lease. Upon occupancy of the facility, the Company determined that because the lease did not meet the criteria to qualify for a sale-leaseback transaction, the established asset and liability would remain on the Company's balance sheet and is included with property and equipment at September 30, 2019. As of September 30, 2019, accumulated depreciation on the manufacturing facility approximated \$5.6 million.

On October 1, 2019, the Company adopted ASC 842 and elected the optional transition method that allows for a cumulative-effect adjustment in the period of adoption and no restatement to prior periods. Under ASC 842, the manufacturing facility lease no longer meets the criteria for a build-to-suit lease and is instead is classified as a finance lease. Under the provisions of ASC 842, the Company recognized a right-of-use asset and lease liability for this facility. These balances are classified with other leased assets and liabilities and are no longer included with plant and equipment on the September 30, 2020 balance sheet.

Depreciation expense for the year ended September 30, 2020 totaled approximately \$2.1 million. Depreciation expense for the year ended September 30, 2019 totaled approximately \$588,000 and includes depreciation on the leased manufacturing building of approximately \$514,000.

## 6. PATENTS

Patents consist of the following at September 30:

	2020	2019
Patents	\$ 896,372	\$ 841,397
Accumulated amortization	(582,950)	(529,811)
Patents, net	\$ 313,422	\$ 311,586

During the years ended September 30, 2020 and 2019, there was no impairment of patent costs. Amortization expense for the years ended September 30, 2020 and 2019 totaled approximately \$53,000 and \$45,000, respectively. The total estimated future amortization is as follows:

Years ending September 30,	
2021	52,000
2022	48,000
2023	38,000
2024	30,000
2025	28,000
Thereafter	117,000
	<u>\$ 313,000</u>

## 7. INCOME TAXES

At September 30, 2020 and 2019, the Company had net deferred tax assets of \$35.5 million and \$28.8 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, 2020. The Company's Section 382 estimated analysis was completed through September 30, 2020. 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 \$51.5 million and \$36.7 million at September 30, 2020 and 2019, respectively. Approximately \$19.2 million of the NOL carryforwards begin to expire during the year ended September 30, 2021 and become fully expired by 2039 and approximately \$32.3 million of NOL carryforwards, which were generated post Tax Cuts and Jobs Act, have an indefinite life. 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, 2020 and 2019. The R&D credit begins to expire during the year ended September 30, 2021 and becomes fully expired during the fiscal year ended 2029.

Significant components of the Company's deferred tax assets as of September 30, 2020 and 2019 are listed below:

	<u>2020</u>	<u>2019</u>
NOL carryforwards	\$ 13,407,000	\$ 9,698,000
Lease liabilities	3,631,000	-
R&D credit	1,221,000	1,221,000
Stock-based compensation	5,297,000	3,165,000
Capitalized R&D	15,853,000	14,777,000
Vacation and other	125,000	544,000
Total deferred tax assets	39,534,000	29,405,000
Right of use assets	(3,911,000)	-
Fixed assets and intangibles	(169,000)	(586,000)
Total deferred tax liability	(4,080,000)	(586,000)
Net deferred tax asset	35,454,000	28,819,000
Valuation allowance	(35,454,000)	(28,819,000)
Ending Balance	\$ -	\$ -

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:

	<b>2020</b>	<b>2019</b>
Federal Rate	21.00%	21.00%
Federal rate change	(1.40)	(2.8)
State tax rate, net of federal benefit	5.15	5.31
Other adjustments	(3.24)	(4.77)
Permanent differences	0.42	(0.57)
Change in valuation allowance	(21.93)	(18.17)
Effective tax rate	0.00%	0.00%

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 2019. These years remain open to examination by the major domestic taxing jurisdictions to which the Company is subject.

On March 27, 2020, the United States enacted the Coronavirus Aid, Relief and Economic Security Act (CARES Act). The CARES Act is an emergency economic stimulus package that includes spending and tax breaks to strengthen the United States economy and fund a nationwide effort to curtail the effect of COVID-19. The Company does not expect the enactment of the CARES Act to directly impact its financial position, results of operations or cash flows.

## 8. STOCK COMPENSATION

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

	<b>Year Ended September 30,</b>	
	<b>2020</b>	<b>2019</b>
Employees	\$ 10,112,968	\$ 4,428,174
Non-employees	\$ 862,796	\$ 856,025

During the years ended September 30, 2020 and 2019 the fair value of each option grant was estimated on the date of grant using the Black-Scholes option-pricing model with the following assumptions.

	<b>2020</b>	<b>2019</b>
Expected stock price volatility	87.36 – 90.26%	87.67 – 92.84%
Risk-free interest rate	0.62 – 1.87%	1.62 – 2.82%
Expected life of options	9.68 – 9.69 Years	9.67 – 9.68 Years
Expected dividend yield	-	-

**Non-Qualified Stock Option Plans** – During the year ended September 30, 2020, the Company adopted the 2020 Non-Qualified Stock Option Plan, which provides for the issuance of up to 3,600,000 options to purchase shares of common stock. On April 20, 2020, the Company granted 1,872,000 performance-based stock options from the 2020 Non-Qualified Stock Option Plan to officers and directors. Each option entitles the holder to purchase one share of the Company's common stock at a price of \$10.93 per share, the fair value on the date of issuance. The stock options vest upon the achievement of the following performance goals: i) 25% of the options will vest when the closing price of the Company's common stock exceeds \$20.00 for ten consecutive trading days; ii) 50% of the options will vest when the closing price of the Company's common stock exceeds \$25.00 for ten consecutive trading days; iii) 75% of the options will vest when the closing price of the Company's common stock exceeds \$30.00 for ten consecutive trading days; and iv) 100% of the options will vest when either (a) the filing of the first marketing application for any pharmaceutical based upon the Company's Multikine technology, in the US, Canada, UK, Germany, France, Italy, Spain, Japan, or Australia or (b) the closing price of the Company's common stock exceeds \$40.00 for ten consecutive trading days. All Options which have not vested as of April 19, 2030,



will be canceled and will no longer be exercisable. The options were recorded as equity in accordance with ASC 718, Compensation – Stock Compensation. On the grant date, the options were valued using a Monte Carlo Simulation approach. Monte Carlo Simulation is a statistical technique that is used to model probabilistic systems and establish the probabilities for a variety of outcomes. That valuation resulted in a per share fair value of \$4.21 and an aggregate value of \$7,881,120 on the grant date. The aggregate value will be expensed over the implicit life of the options, which was determined to be 1.7 years. This resulted in compensation expense of approximately \$2.1 million recorded during the year ended September 30, 2020. The remaining \$5.8 million will be expensed over the next 1.25 years.

At September 30, 2020, the Company has collectively authorized the issuance of 9,987,200 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, 2020, 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, 2020 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, 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		
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
Vested					2,014,501	\$4.06		
Granted	2,563,000	\$10.93						
Exercised	99,740	\$3.39			99,740	\$3.39		
Forfeited	18,000	\$10.34						
Expired	9,773	\$132.75			9,773	\$132.75		
Outstanding at September 30, 2020	8,653,703	\$7.01	8.39	\$56,193,415	3,297,229	\$5.85	7.48	\$29,090,662

(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, 2020 is presented below:

	Number of Options	Weighted Average Grant Date Fair Value
Unvested at October 1, 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
Vested	(2,014,501)	
Granted	2,563,000	
Forfeited	(18,000)	
Unvested at September 30, 2020	5,356,474	\$ 4.76

**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, 2020 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 each of the years ended September 30, 2020 and 2019, the Company recorded expense relating to the issuance of restricted stock pursuant to the plan of approximately \$0.3 million. At September 30, 2020, the Company has unrecognized compensation expense of approximately \$0.4 million which is expected to be recognized over a weighted average period of 1.2 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, 2020 is presented below:

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested at September 30, 2018	312,000	\$13.75
Forfeited	(7,500)	
Vested	-	
Unvested at September 30, 2019	304,500	\$13.75
Forfeited	-	
Vested	-	
Unvested at September 30, 2020	304,500	\$13.75

**Stock Bonus Plans** – As of September 30, 2020, the Company has issued a total of 345,096 shares of common stock from the Stock Bonus Plans and 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.

**Stock Compensation Plans** – On September 30, 2020, 634,000 shares were authorized for use in the Company's Stock Compensation Plans. No shares were issued from the Stock Compensation Plans to consultants for payment of services during the years ended September 30, 2020, and 2019. As of September 30, 2020, the Company has issued 150,695 shares of common stock from the Stock Compensation Plans.

## 9. EMPLOYEE BENEFIT PLAN

The Company maintains a defined contribution retirement plan, qualifying under Section 401(k) of the Internal Revenue Code, subject to the Employee Retirement Income Security Act of 1974, as amended, and covering substantially all Company employees. Each participant's contribution is matched by the Company with shares of common stock that have a value equal to 100% of the participant's contribution, not to exceed the lesser of



\$10,000 or 6% of the participant's total compensation. The Company's contribution of common stock is valued each quarter based upon the closing bid price of the Company's common stock. During the year ended September 30, 2020, 13,870 shares were issued to the Company's 401(k) plan for a cost of approximately \$163,000. 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.

## 10. 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 \$33.4 million related to Ergomed's services. This amount is net of Ergomed's discount of approximately \$11.1 million. During the years ended September 30, 2020 and 2019, the Company recorded approximately \$2.0 million and \$2.8 million, respectively, as research and development expense related to Ergomed's services. These amounts were net of Ergomed's discount of approximately \$0.6 million and \$1.0 million during the years ended September 30, 2020 and 2019, respectively.

### *Lease Agreements*

If a contract conveys the right to control the use of identified property, plant or equipment over a period of time in exchange for consideration, the Company accounts for the contract as a lease upon inception. The Company leases certain real estate, machinery, laboratory equipment and office equipment over varying periods. Many of these leases include an option to either renew or terminate the lease. For purposes of calculating lease liabilities, these options are included in the lease term when it is reasonably certain that the Company will exercise such options. The incremental borrowing rate utilized to calculate the lease liabilities is based on the information available at commencement date, as most of the leases do not provide an implicit borrowing rate. Short-term leases, defined as leases with initial terms of 12 months or less, are not reflected on the balance sheet. Lease expense for such short-term leases is not material. For purposes of calculating lease liabilities, lease and non-lease components are combined.

The Company leases a manufacturing facility near Baltimore, Maryland (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, which expires in October 2028.

Upon adoption of ASC 842 on October 1, 2019, the Company recorded a finance lease right of use asset of approximately \$16.5 million and a finance lease liability of approximately \$13.5 million. As of September 30, 2020, the net book value of the finance lease right of use asset is approximately \$13.8 million and the balance of the finance lease liability is approximately \$12.7 million, of which approximately \$0.9 million is current. These amounts include the San Tomas lease as well as several other smaller finance leases for office equipment. The finance right of use assets are being depreciated using a straight-line method over the underlying lease terms. Total cash paid related to finance leases during the year ended September 30, 2020 was approximately \$1.9 million, of which approximately \$1.2 million was for interest. The weighted average discount rate of the Company's finance leases is 8.8% and the weighted average time to maturity is 8.1 years.



In August 2020, the Company entered into an amendment to the lease agreement under which the landlord agreed to allow the Company to substantially upgrade the manufacturing facility in preparation for the potential commercial production of Multikine. The estimated cost of the upgrades is \$10.5 million, of which approximately \$3.1 million has been incurred to date. Pursuant to the amendment, the landlord agreed to finance the final \$2.4 million of the costs incurred, i.e., after the Company has financed the initial \$8.1 million. Per the terms of the financing, upon completion of the project, the \$2.4 million will be repaid as through increased lease payments over the remaining lease term.

The Company was required to deposit the equivalent of one year of base rent in accordance with the lease. When the Company meets the minimum cash balance required by the lease, the deposit will be returned to the Company. The approximate \$1.7 million deposit is included in non-current assets at September 30, 2020 and 2019.

Approximate future minimum lease payments under finance leases as of September 30, 2020 are as follows:

Year ending September 30,	
2021	\$ 1,953,000
2022	2,014,000
2023	2,083,000
2024	2,148,000
2025	2,218,000
Thereafter	7,322,000
Total future minimum lease obligation	17,738,000
Less imputed interest on finance lease obligations	(5,050,000)
Net present value of lease finance lease obligations	<u>\$ 12,688,000</u>

Effective April 30, 2020, the Company terminated a month-to-month arrangement with a sub-lessee as the sub-leased space is needed to prepare the facility to produce Multikine for commercial purposes and before the Company's Biologics License Application (BLA) can be submitted to the FDA. The sublease rental income for the years ended September 30, 2020 and 2019 was approximately \$39,000 and \$73,000, respectively.

The Company leases two facilities under 60-month operating leases – the lease for its research and development laboratory expires February 28, 2022 and the lease for its office headquarters was renewed on July 1, 2020 and will expire on November 30, 2025. During the year ended September 30, 2020, the Company incurred approximately \$80,000 in leasehold improvements costs for the research and development lab and is reasonably certain to renew the lease through February 28, 2027. The renewal period is included in the right of use asset and liability calculations. The operating leases include escalating rental payments. The Company is recognizing the related rent expense on a straight-line basis over the full 60-month terms of the leases. Upon adoption of ASC 842 on October 1, 2019, the Company recorded an operating lease right of use asset and an operating lease liability of approximately \$1.0 million. As of September 30, 2020, the net book value of the operating lease right of use asset is approximately \$1.2 million and the balance of the operating lease liability is approximately \$1.3 million, of which approximately \$0.1 million is current. The Company incurred lease expense under operating leases of approximately \$268,000 for the year ended September 30, 2020. Total cash paid related to operating leases during the year ended September 30, 2020 was approximately \$238,000.

As of September 30, 2020, future minimum lease payments on operating leases are as follows:

Year ending September 30,	
2021	\$ 241,000
2022	264,000
2023	272,000
2024	280,000
2025	288,000
Thereafter	286,000
Total future minimum lease obligation	1,631,000
Less imputed interest on operating lease obligation	(381,000)
Net present value of operating lease obligation	<u>\$ 1,250,000</u>

#### *Vendor Obligations*

The Company has contingent obligations with vendors for work that will be completed in relation to the Phase 3 clinical trial. The timing of these obligations cannot be determined at this time. The Company estimates it will incur additional expenses of approximately \$5.9 million for the remainder of the Phase 3 clinical trial and the filing of the clinical study report with the FDA. 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.

### **11. RELATED PARTY TRANSACTIONS**

During the year ended September 30, 2020, officers and directors of the Company purchased 20,512 shares of restricted common stock at market price at an aggregate fair market value of approximately \$185,000. 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 market price at an aggregate market value of approximately \$292,000. The shares are subject to the conditions of Rule 144 under the Securities Act of 1933.

On May 8, 2020, the expiration date of 93,593 Series UU warrants were extended from June 11, 2020 to December 31, 2020. The incremental cost of this extension was approximately \$6,000 and was recorded as interest expense for the year ended September 30, 2020. The Series UU warrants are held by the Company's officers and were originally issued with convertible debt.

On January 23, 2020, the expiration date of the Series N warrants was extended to February 18, 2021. The incremental cost of this extension was approximately \$22,000, which was recorded as a deemed dividend in the financial statements for the year ended September 30, 2020. The Series N warrants are held by the de Clara Trust.

### **12. STOCKHOLDERS' EQUITY**

#### *Exercise of Warrants*

During the years ended September 30, 2020 and 2019, the Company received proceeds of approximately \$12.1 million and \$14.5 million, respectively, from the exercise of warrants, as detailed in Note 4. Upon exercise, 1,711,873 and 6,677,519 shares of common stock were issued during the years ended September 30, 2020 and 2019, respectively.

#### *Sales of Securities*

In March 2020, the Company sold 630,500 shares of common stock at a public offering price of \$12.22 per share and received aggregate net proceeds of approximately \$7.1 million. Under the terms of the Underwriting Agreement the Company granted the Underwriters a 45-day option to purchase up to an additional 94,575 shares of common stock solely to cover over-allotments. The underwriter fully exercised this option in May 2020 resulting in additional net proceeds to the Company of approximately \$1.1 million.

In December 2019, the Company sold 606,395 shares of common stock at a public offering price of \$9.07 per share and received aggregate net proceeds of approximately \$5.0 million. In January 2020, the underwriters of that offering fully exercised the option to purchase 90,959 additional shares of common stock at the public offering price of \$9.07 per share for aggregate net proceeds to the Company of approximately \$0.8 million.

#### *Other Equity Transactions*

The Company entered into Securities Purchase Agreements (SPA) with Ergomed plc, one of the Company's Clinical Research Organizations responsible for managing the Company's Phase 3 clinical trial, to facilitate payment of amounts due Ergomed. Under the Agreements, the Company issued Ergomed shares of common stock and the net proceeds from the sales of those shares reduces outstanding amounts due 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.

During the year ended September 30, 2020 and 2019, the Company issued Ergomed 150,000 and 750,000 shares, respectively. On December 31, 2018, the expiration date of a prior agreement, Ergomed returned 564,905 unsold shares for cancellation. The current agreement has no expiration date, but after Ergomed has completed its work and all amounts due are paid any remaining shares will be returned to the Company.

The following table summarizes the Other Non-operating gains (losses) for the years ended September 30 relating to these agreements:

	2020	2019
Amount realized through the resale of shares	\$ 2,652,605	\$ 3,945,528
Fair value of shares upon issuance	1,769,500	3,400,000
Other non-operating gain (loss)	\$ 883,105	\$ 545,528

As of September 30, 2020, Ergomed held 102,521 shares for resale. As of September 30, 2019, Ergomed held 198,000 shares which were all subsequently sold.

### 13. FAIR VALUE MEASUREMENTS

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

As of September 30, 2020 and 2019, all of the Company's derivative liabilities are classified as Level 3.

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:

	2020	2019
Beginning balance	\$ 6,488,310	\$ 9,317,031
Issuances	-	-
Exercises	(3,071,775)	(3,589,357)
Net realized and unrealized derivative loss	349,078	760,636
Ending balance	\$ 3,765,613	\$ 6,488,310



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, 2020, the Company's Level 3 derivative instruments have a weighted average fair value of \$2.81 per share and a weighted average exercise price of \$14.32 per share. Fair values were determined using a weighted average risk free interest rate of 0.12% and volatility of 95%. The instruments have a weighted average time to maturity of 1.2 years. 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.

#### 14. NET LOSS PER COMMON SHARE

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

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

	Year ended September 30,	
	2020	2019
<b>Loss per share – basic and diluted</b>		
Net loss available to common shareholders	\$ (30,276,978)	\$ (22,134,640)
Weighted average shares outstanding	36,759,115	31,174,394
Basic and diluted loss per common share	\$ (0.82)	\$ (0.71)

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:

	2020	2019
Options and Warrants	7,221,696	7,164,544
Unvested Restricted Stock	308,814	304,500
Total	7,530,510	7,469,044

#### 15. SUBSEQUENT EVENTS

In December 2020, the Company sold 1,000,000 shares of common stock at a public offering price of \$14.65 per share and received aggregate net proceeds of approximately \$13.6 million. Under the terms of the Underwriting Agreement, the Company granted the Underwriters a 30-day option to purchase up to an additional 150,000 shares of common stock at the public offering price to cover over-allotments.

## ***CORPORATE INFORMATION***

### ***Board of Directors***

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

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

**Bruno Baillavoine**  
Director  
Pericles Group UK

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

### ***Corporate Officers***

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

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

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

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

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

### ***Corporate Headquarters***

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

Telephone: (703) 506-9460  
Facsimile: (703) 506-9471

Website: [www.cel-sci.com](http://www.cel-sci.com)

### ***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 570 stockholders of record as of May 7, 2021. CEL-SCI has not paid cash dividends on its Common Stock since its inception.

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

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

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

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8229 Boone Boulevard  
Suite 802  
Vienna, VA 22182  
USA

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