SECURITIES & EXCHANGE COMMISSION EDGAR FILING

CEL SCI CORP

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FORM 10-K

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
(Mark One)

(X) ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended September 30, 2019.

OR

( ) TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____.

Commission file number 1-11889

CEL-SCI CORPORATION

(Exact name of registrant as specified in its charter)

COLORADO	84-0916344
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
8229 Boone Blvd., Suite 802 Vienna, Virginia	22182
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: (703) 506-9460

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock	CVM	NYSE American

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. [ ]

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. [ ]

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes [X] No [ ]

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes [X] No [ ]

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an "emerging growth company". See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☒
Non-accelerated filer	☐	Smaller reporting company	☒
		Emerging Growth Company	☐

If an emerging growth company, indicate by checkmark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. [ ]

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act): Yes [ ] No [X]

The aggregate market value of the voting stock held by non-affiliates of the Registrant, based upon the closing sale price of the registrant's common stock on March 31, 2019, as quoted on the NYSE American, was $100,321,037.

As of December 11, 2019, the Registrant had 35,379,956 issued and outstanding shares of common stock.

Documents Incorporated by Reference: None

PART I

ITEM 1. BUSINESS

CEL-SCI Corporation (CEL-SCI) is a clinical-stage biotechnology company focused on finding the best way to activate the immune system to fight cancer and infectious diseases. Its lead investigational therapy Multikine® (Leukocyte Interleukin, Injection) is currently in a pivotal Phase 3 clinical trial for patients who are newly diagnosed with advanced primary squamous cell carcinoma of the head and neck, for which CEL-SCI has received Orphan Drug Status from the U.S. Food and Drug Administration, or FDA. The study was fully enrolled with 928 patients in September 2016. The study's primary end-point is a 10% increase in overall survival of patients between the two main comparator groups in favor of the group receiving the Multikine treatment regimen. The determination if the study's primary end-point is met will occur when there are a total of 298 deaths in those two groups. If the primary end-point of this global study is achieved, CEL-SCI expects to use the results to support a Biologics License Application, or BLA, to the FDA for Multikine for neoadjuvant therapy in patients with squamous cell carcinoma of the head and neck, or SCCHN (hereafter also referred to as advanced primary head and neck cancer).

CEL-SCI's investigational immunotherapy, Multikine, is being used in a different way than cancer immunotherapy is usually used. It is given before any other therapy has been administered because that is when the immune system is thought to be strongest (i.e., as a neoadjuvant). It is also administered locally around the tumors and near the draining lymph node. For example, in the Phase 3 clinical trial, Multikine was given locally for three weeks, five days per week as a first line treatment before surgery, radiation and/or chemotherapy. The goal is to help the intact immune system kill the micro metastases that usually cause recurrence of the cancer. In short, CEL-SCI believes that local administration of this neoadjuvant therapy and administration before weakening of the immune system by surgery, chemotherapy and radiation will result in improved outcomes and better overall survival rates for patients suffering from head and neck cancer.

CEL-SCI is also investigating a peptide-based immunotherapy as a vaccine for rheumatoid arthritis using its LEAPS technology platform. CEL-SCI was awarded a Phase 2 Small Business Innovation Research (SBIR) grant in the amount of $1.5 million from the National Institutes of Health (NIH) in September 2017. This grant will provide funding to allow CEL-SCI to advance its first LEAPS product candidate, CEL-4000, towards an Investigational New Drug (IND) application.

CEL-SCI was formed as a Colorado corporation in 1983. CEL-SCI's principal office is located at 8229 Boone Boulevard, Suite 802, Vienna, VA 22182. CEL-SCI's telephone number is 703-506-9460 and its website is www.cel-sci.com. CEL-SCI does not incorporate the information on its website into this report, and you should not consider it part of this report.

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

CEL-SCI'S PRODUCTS

CEL-SCI is a clinical-stage biotechnology company dedicated to research and development directed at improving the treatment of cancer and other diseases by using the immune system, the body's natural defense system. CEL-SCI is currently focused on the development of the following product candidates and technologies:

1) Multikine, an investigational immunotherapy under development for the potential treatment of certain head and neck cancers;

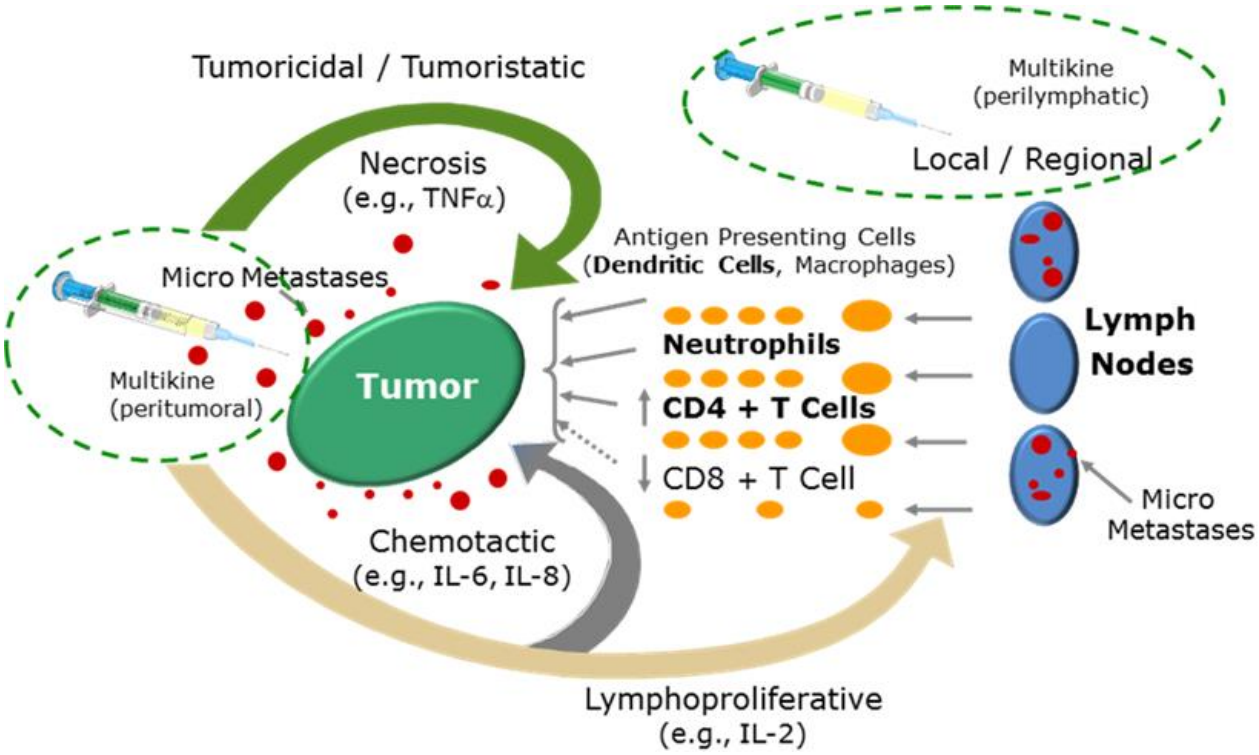
2) L.E.A.P.S. (Ligand Epitope Antigen Presentation System) technology, or LEAPS, with two investigational therapies, CEL-2000 and CEL-4000, vaccine product candidates under development for the potential treatment of rheumatoid arthritis, and LEAPS-H1N1-DC, a product candidate under development for the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

MULTIKINE

CEL-SCI's lead investigational therapy, Multikine, is currently being developed as a potential therapeutic agent directed at using the immune system to produce an anti-tumor immune response. Data from Phase 1 and Phase 2 clinical trials suggest that Multikine may help the immune system "see" the tumor and then attack it, enabling the body's own anti-tumor immune response to fight the tumor. Multikine is the trademark that CEL-SCI has registered for this investigational therapy, and this proprietary name is subject to review by the FDA, in connection with CEL-SCI's future anticipated regulatory submission for approval in the United States. Multikine has not been licensed or approved for sale, barter or exchange by the FDA or any other regulatory agency, such as the European Medicine Agency, or EMA, and neither its safety nor its efficacy been established.

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

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



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

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

SCCHN represents one type of head and neck cancer, and CEL-SCI believes that there is a large, unmet medical need among head and neck cancer patients as a whole. CEL-SCI believes the last FDA approval of a therapy indicated for the treatment of advanced primary head and neck cancer was over 50 years ago. In the aggregate, head and neck cancer represents about 6% of the world's cancer cases, with approximately 650,000 patients diagnosed worldwide each year, of which approximately 60,000 patients diagnosed annually in the United States and approximately 105,000 patients 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) arm of the study over the control comparator (SOC alone) arm. As the study was designed, the final determination of whether this endpoint had been successfully reached can only be determined when 298 events have occurred in the combined comparator arms of the study.

Nine hundred twenty-eight (928) newly diagnosed head and neck cancer patients have been enrolled in this Phase 3 cancer study across 24 countries and all the patients who have completed treatment continue to be followed for protocol-specific outcomes in accordance with the study protocol. The last patient was enrolled in the study in September 2016. Approximately 135 patients were enrolled in the study from 2011 to 2013, about 195 were enrolled in 2014, about 340 in 2015, and about 260 in 2016. The Phase 3 study protocol assumed an overall survival rate of about 55% at 3 years for the SOC treatment group alone. An analysis conducted using the Surveillance, Epidemiology, and End Results, or SEER U.S. government data base for the same study population as CEL-SCI enrolled in this Phase 3 study and covering the years 2011-2016 (when the patients were enrolled), shows that the standard of care for these patients has not resulted in an improvement in survival. In fact, the U.S. survival of the specific type of patients enrolled in the Phase 3 study during the study years was only about 47% at 3 years and about 37% at 5 years. At this point, all patients enrolled in the study are being followed-up as required by the study protocol.

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

Since CEL-SCI launched its Phase 3 clinical trial for Multikine, CEL-SCI has incurred expenses of approximately $55.8 million as of September 30, 2019 on direct costs for the Phase 3 clinical trial. CEL-SCI estimates it will incur additional expenses of approximately $4.5 million for the remainder of the Phase 3 clinical trial. It should be noted that this estimate is based only on the information currently available in CEL-SCI's contracts with the CROs responsible for managing the Phase 3 clinical trial and does not include other related costs, e.g., preparations for the potential commercial manufacture of the drug. This number may be affected by the rate and speed of death accumulation in the study, foreign currency exchange rates, and many other factors, some of which cannot be foreseen today. It is therefore possible that the cost of the Phase 3 clinical trial may be higher than currently estimated.

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

Development Agreements for Multikine

In August 2008, CEL-SCI signed an agreement with Teva Pharmaceutical Industries Ltd., or Teva, that gives Teva the exclusive right and license to market, distribute and sell Multikine, if approved, in Israel and Turkey for treatment of head and neck cancer. The agreement terminates on a country-by-country basis 10 years after the product launch in each country or upon a material breach or upon bankruptcy of either party. The agreement will automatically extend for additional two year terms unless either party gives notice of its intent not to extend the agreement. If CEL-SCI develops Multikine for other oncology indications and Teva indicates a desire to participate, the parties have agreed to negotiate in good faith with respect to Teva's participation and contribution in future clinical trials.

Teva has agreed to use all reasonable efforts to obtain regulatory approval to market and sell Multikine in its territory at its own cost and expense. Pursuant to the agreement, it is CEL-SCI's responsibility to supply Multikine and Teva's responsibility to sell Multikine, if approved by regulatory authorities in the relevant countries. Net sales will be divided 50/50 between the two parties. Teva also initially agreed to fund certain activities relating to the conduct of a clinical trial in Israel as part of the global Phase 3 trial for Multikine. In January 2012, pursuant to an assignment and assumption agreement between CEL-SCI, Teva and GCP Clinical Studies Ltd., or GCP, Teva transferred all of its rights and obligations concerning the Phase 3 trial in Israel to GCP. GCP is now operating the Phase 3 trial in Israel pursuant to a service agreement with CEL-SCI.

In July 2011, Serbia and Croatia were added to Teva's territory, pursuant to a joinder agreement between CEL-SCI and PLIVA Hrvatska d.o.o., or PLIVA, an affiliate of Teva's, subject to similar terms as described above.

In consideration for the rights granted by CEL-SCI to PLIVA under the joinder agreement, CEL-SCI will be paid by PLIVA (in U.S. dollars):

- $100,000 upon EMA grant of Marketing Authorization for Multikine;
- $50,000 upon Croatia's grant of reimbursement status for Multikine in Croatia; and
- $50,000 upon Serbia's grant of reimbursement status for Multikine in Serbia.

In November 2000, CEL-SCI signed an agreement with Orient Europharma Co., Ltd., or Orient Europharma, of Taiwan, which was amended in October 2008 and again in June 2010. Pursuant to this agreement, as amended, Orient Europharma has the exclusive marketing and distribution rights to Multikine, if approved by regulatory authorities, for head and neck cancer, naso-pharyngeal cancer and potentially cervical cancer indications in Taiwan, Singapore, Malaysia, Hong Kong, the Philippines, South Korea, Australia and New Zealand. CEL-SCI has granted Orient Europharma the first right of negotiation with respect to Thailand and China.

The agreement requires Orient Europharma to fund 10% of the cost of the clinical trials needed to obtain marketing approvals in these countries for head and neck cancer, naso-pharyngeal cancer and potentially cervical cancer. Orient Europharma has set up clinical centers for the Phase 3 trial in Taiwan, Malaysia, the Philippines and Thailand and has made further financial contributions towards the cost of the Phase 3 clinical trial.

If Multikine is approved for sale, Orient Europharma will purchase Multikine from CEL-SCI for 35% of the gross selling price in each country. Orient Europharma is obligated to use the same diligent efforts to develop, register, market, sell and distribute Multikine in its territory as with its own products or other licensed products.

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

CEL-SCI has a licensing agreement with Byron Biopharma LLC, or Byron, under which CEL-SCI granted Byron an exclusive license to market and distribute Multikine in the Republic of South Africa, if approved. This license will terminate 20 years after marketing approval in South Africa or after bankruptcy or uncured material breach. After the 20-year period has expired, the agreement will be automatically extended for successive two year periods, unless either party gives notice of its intent not to extend the agreement.

Pursuant to the agreement, Byron will be responsible for registering Multikine in South Africa. If Multikine is approved for sale in South Africa, CEL-SCI will be responsible for manufacturing the product, while Byron will be responsible for sales in South Africa. Sales revenues will be divided between CEL-SCI and Byron. CEL-SCI will be paid fifty (50%) percent of the net sales of Multikine.

LEAPS

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

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

On September 19, 2017, CEL-SCI announced that it had been awarded a Phase 2 Small Business Innovation Research (SBIR) grant in the amount of $1.5 million from the National Institute of Arthritis and Musculoskeletal and Skin Diseases, or NIAMS, which is part of the U.S. National Institutes of Health (NIH). This grant will provide funding to allow CEL-SCI to advance its first LEAPS product candidate, CEL-4000, towards an Investigational New Drug (IND) application for a Phase 1 safety study, by funding IND enabling studies and additional mechanism of action studies, among other preclinical development activities. Work on CEL-4000 is being conducted at CEL-SCI's research laboratory and Rush University Medical Center in Chicago, Illinois in the laboratories of Tibor Glant, MD, Ph.D., Jorge O. Galante Professor of Orthopedic Surgery and Katalin Mikecz, MD, Ph.D. Professor of Orthopedic Surgery & Biochemistry. The SBIR grant was awarded based on published data described below by Dr. Glant's team in collaboration with CEL-SCI showing that the administration of a proprietary peptide using CEL-SCI's LEAPS technology prevented the development, and lessened the severity, including inflammation, of experimental proteoglycan induced arthritis (PGIA or GIA) when it was administered after the disease was induced in animals.

In May 2019, CEL-SCI announced that a newly discovered LEAPS conjugate vaccine acts alone and can complement CEL-4000 therapeutically when administered in combination to an animal model of Rheumatoid Arthritis (RA). This new LEAPS conjugate appears to act on T cell pathways by a new mechanism that is different from the pathways used by the CEL-4000 vaccine. The data was presented at the American Association of Immunologists 103th Annual Meeting (Immunology 2019) by Daniel Zimmerman, Ph.D., CEL-SCI's Senior Vice President of Research, Cellular Immunology. The work was performed in conjunction with researchers at Rush University Medical Center, Chicago, Illinois and was funded by the SBIR Phase 2 Grant.

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

Prior to the SBIR Phase 2 grant, CEL-SCI was awarded a Phase 1 SBIR grant in the amount of $225,000 from NIAMS. This grant funded the development of CEL-SCI's LEAPS technology as a potential treatment for rheumatoid arthritis, an autoimmune disease of the joints. The work was conducted at Rush University Medical Center in Chicago, Illinois in the laboratories of Tibor Glant, MD, Ph.D., Katalin Mikecz, MD, Ph.D., and Allison Finnegan, Ph.D. Professor of Medicine.

With the support of these SBIR grants, CEL-SCI is developing two new drug candidates, CEL-2000 and CEL-4000, as potential rheumatoid arthritis therapeutic vaccines. The data from animal studies using the CEL-2000 treatment vaccine suggests that it could be used against rheumatoid arthritis with fewer administrations than those required by other anti-rheumatoid arthritis treatments currently on the market for arthritic conditions associated with the Th17 signature cytokine TNF-a. The preclinical data for CEL-4000 indicates it could be used against rheumatoid arthritis where a Th1 signature cytokine (IFN-c) 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 February 2017 and November 2016, CEL-SCI announced preclinical data that demonstrate its investigational new drug candidate CEL-4000 has the potential for use as a therapeutic vaccine to treat rheumatoid arthritis. This study was supported in part by the SBIR Phase I Grant and was conducted in collaboration with Drs. Katalin Mikecz and Tibor Glant, and their research team at Rush University Medical Center in Chicago, IL.

In March 2015, CEL-SCI and its collaborators published a review article on vaccine therapies for rheumatoid arthritis based in part on work supported by the SBIR 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.

Using the LEAPS technology, CEL-SCI has also tested in preclinical studies a potential peptide treatment for H1N1 (swine flu) hospitalized patients. This LEAPS flu treatment is designed to focus on the conserved, non-changing epitopes of the different strains of Type A Influenza viruses (H1N1, H5N1, H3N1, etc.), including "swine", "avian or bird", and "Spanish Influenza", in order to minimize the chance of viral "escape by mutations" from immune recognition. Therefore one should think of this treatment not really as an H1N1 treatment, but as a potential pandemic flu treatment. CEL-SCI's LEAPS flu treatment contains epitopes known to be associated with immune protection against influenza in animal models.

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

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

Accordingly, even though the various LEAPS vaccine candidates have not yet been given to humans, they have been tested in vitro with human cells. They have induced similar cytokine responses that were seen in these animal models, which may indicate that the LEAPS technology might translate to humans. The LEAPS candidates have demonstrated protection against lethal herpes simplex virus (HSV1) and H1N1 influenza infection, as a prophylactic or therapeutic agent in animals. They have also shown some level of activity in animals in two autoimmune conditions, curtailing and sometimes preventing disease progression in arthritis and myocarditis animal models. CEL-SCI's belief is that the LEAPS technology, once developed and approved as safe and effective for humans, may be a significant alternative to the vaccines currently available on the market for these diseases.

None of the LEAPS investigational products have been approved for sale, barter or exchange by the FDA or any other regulatory agency for any use to treat disease in animals or humans. The safety or efficacy of these products has not been established for any use. Lastly, no definitive conclusions can be drawn from the early-phase, preclinical-trials data involving these investigational products. Before obtaining marketing approval from the FDA in the United States, and by comparable agencies in most foreign countries, these product candidates must undergo rigorous preclinical and clinical testing which is costly and time consuming and subject to unanticipated delays. There can be no assurance that these approvals will be granted.

INTELLECTUAL PROPERTY

Patents and other proprietary rights are essential to CEL-SCI's business. CEL-SCI files patent applications to protect its technologies, inventions and improvements to its inventions that CEL-SCI considers important to the development of its business. CEL-SCI'S intellectual property portfolio covers its proprietary technologies, including Multikine and LEAPS, by multiple issued patents and pending patent applications in the United States and in key foreign markets.

Multikine is protected by a U.S. patent, which is a composition-of-matter patent issued in May 2005 that, in its current format, expires in 2023. Additional composition-of-matter patents for Multikine have been issued in Germany (issued in June 2011 and currently set to expire in 2025), China (issued in May 2011 and currently set to expire in 2024), Japan (issued in November 2012 and currently set to expire in 2025), and three in Europe (issued in September 2015, May 2016 and October 2017, currently set to expire in 2025 and 2026). The most recent patent issued in October 2017, patent # EP 1 879 618 B1, titled "A Method for Modulating HLA Class II Tumor Cell Surface Expression With A Cytokine Mixture," addresses Multikine's mechanism of action to make tumors more visible to the immune system. This new patent is important because, along with the other Multikine issued patents, it addresses how Multikine enables the immune system to recognize and attack the tumor. One way tumor cells evade the immune system is by expressing human leukocyte antigens (HLA) on the tumor cell surface, thus appearing as 'self' to the immune cells and therefore the tumor cells are not attacked. It is important to note that the tumors of the Multikine-treated responders in CEL-SCI's prior Phase 2 studies had no HLA Class II expressed on the cell surface following Multikine treatment as compared to controls. This points to Multikine's ability to modulate HLA expression on the tumor cell surface, thereby allowing the immune system to recognize and attack the tumor.

In addition to the patents that offer certain protections for Multikine, the method of manufacture for Multikine, a complex biological product, is held by CEL-SCI as a trade secret.

LEAPS is protected by patents in the United States issued in February 2006, April 2007, August 2007, January 2019 and March 2019. The LEAPS patents, which expire in 2021, 2022, 2021 and three in 2032, respectively, include overlapping claims, with composition of both matter (new chemical entity), process and methods-of-use, to maximize and extend the coverage in their current format. One issued U.S. application is a joint application with Northeast Ohio Medical University ("Neoucom") and CEL-SCI will share the ability to use the patent, unless CEL-SCI licenses the rights to the patent from Neoucom. In October 2017, a patent was issued in Europe for LEAPS, which expires in 2029.

CEL-SCI has four patent applications pending in the United States and one in Europe for LEAPS, which, if issued, would extend protection through 2034, subject to any potential patent term extensions.

As of December 12, 2019, there were no contested proceedings and/or third party claims with respect to CEL-SCI's patents or patent applications.

MANUFACTURING FACILITY

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

CEL-SCI's lease on the manufacturing facility expires on October 31, 2028. CEL-SCI completed validation of its manufacturing facility in January 2010. See Item 2 of this report for more information concerning the terms of this lease.

GOVERNMENT REGULATION

The FDA and other regulatory authorities at federal, state and local levels and in foreign countries extensively regulate, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, record keeping, approval, advertising, promotion, marketing and post-approval monitoring and reporting of biologics such as those CEL-SCI is developing. CEL-SCI, along with third party contractors, will be required to navigate the various preclinical, clinical and commercial approval requirements of the governing regulatory agencies of the countries in which it wishes to conduct studies or seek approval or licensure of its product candidates. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local, and foreign statutes and regulations requires the expenditure of substantial time and financial resources.

U.S. Food and Drug Administration Regulation of Biological Products

In the United States, the FDA regulates biological products under the Federal Food, Drug, and Cosmetic Act, or FDCA, and the Public Health Service Act, or PHSA, and their implementing regulations. The process required by the FDA before biological product candidates may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests and animal studies performed in accordance with the FDA's Good Laboratory Practice, or GLP, regulations;
- submission to the FDA of an investigational new drug application, or IND, which must become effective before clinical trials may begin and must be updated annually;
- approval by an independent Institutional Review Board, or IRB, or ethics committee at each clinical site before the trial is initiated;
- performance of adequate and well-controlled human clinical trials in compliance with Good Clinical Practice, or GCP, regulations to establish the safety, purity and potency of the proposed biologic product candidate for its intended purpose;
- preparation of and submission to the FDA of a Biologics License Application, or BLA, after completion of clinical trials;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- a determination by the FDA within 60 days of its receipt of a BLA to file the application for review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the proposed product is produced to assess compliance with current Good Manufacturing Practice, or cGMP, requirements and to assure that the facilities, methods and controls are adequate to preserve the biological product's continued safety, purity and potency, and of selected clinical investigations to assess compliance with GCPs; and
- FDA review and approval of the BLA to permit commercial marketing of the product for particular indications for use in the United States.

Prior to commencing the first clinical trial with a product candidate in the U.S., CEL-SCI must submit an IND to the FDA. An IND is a request for authorization from the FDA to administer an investigational product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for human studies. The IND also includes results of animal and in vitro studies assessing the toxicology, pharmacokinetics, pharmacology, and pharmacodynamic characteristics of the product; chemistry, manufacturing, and controls information; and any available human data or literature to support the use of the investigational product. An IND must become effective before human clinical trials may begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises safety concerns or questions about the proposed clinical trial. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Submission of an IND therefore may or may not result in FDA authorization to commence a clinical trial.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical study. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. Furthermore, an independent IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial commences at that site, and must monitor the study until completed. Regulatory authorities, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board (DSMB) or independent data monitoring committee (IDMC), which provides recommendations for whether or not a study should move forward at designated check points based on access to certain data from the study and may suggest halting the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. There are also requirements governing the reporting of ongoing clinical studies and clinical study results to public registries.

For purposes of approval of a Biologics License Application, or BLA, human clinical trials are typically conducted in three or four sequential phases that may overlap.

● Phase 1 — The investigational product is initially introduced into healthy human subjects or patients with the target disease or condition. These studies are designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans, the side effects associated with increasing doses.

● Phase 2 — The investigational product is administered to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.

● Phase 3 — The investigational product is administered to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval.

● Phase 4 — In some cases, the FDA may require, or companies may voluntarily pursue, additional clinical trials after a product is approved to gain more information about the product. FDA may also make these so-called Phase 4 or post-marketing studies a condition to approval of the BLA.

Phase 1, Phase 2 and Phase 3 testing may not be completed successfully within a specified period, if at all, and there can be no assurance that the data collected will support FDA approval or licensure of the product. Concurrent with clinical trials, companies may complete additional animal studies and develop additional information about the biological characteristics of the product candidate, and must finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

BLA Submission and Review by the FDA

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, nonclinical studies and clinical trials are submitted to the FDA as part of a BLA requesting approval to market the product for one or more indications. The BLA must include all relevant data available from pertinent preclinical and clinical studies, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls, and proposed labeling, among other things. Data can come from company-sponsored clinical studies intended to test the safety and effectiveness of a use of the product, or from a number of alternative sources, including studies initiated by investigators.

In most cases, the submission of a BLA is subject to a substantial application user fee. Under the goals and policies agreed to by the FDA under the Prescription Drug User Fee Act, or PDUFA, for original BLAs, the FDA's goal is to review the BLA within ten months after it accepts the application for filing, or, if the product relates to an unmet medical need in a serious or life-threatening indication and has received a priority review designation, six months after the FDA accepts the application for filing. The FDA does not always meet its PDUFA goal dates, and the review process is often significantly extended by FDA requests for additional information or clarification and a sponsor's process to respond to such inquiries. This FDA review typically takes twelve months from the date the BLA is submitted to the FDA (for a standard review) and eight months from the date the BLA is submitted (for a priority review) because the FDA has approximately two months after BLA submission to make a "filing" decision.

After filing the marketing application, the FDA reviews a BLA to determine, among other things, whether a product is safe, pure and potent and the facility in which it is manufactured, processed, packed, or held meets standards designed to assure the product's continued safety, purity and potency. Before approving a BLA, the FDA will typically inspect the facility or facilities where the product is manufactured. The FDA will not approve a biological product for marketing unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCPs. If the FDA determines that the data provided in the application, or the manufacturing process or manufacturing facilities for the product are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. The FDA also may refer applications for novel biologic candidates which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions, if any. The FDA is not bound by recommendations of an advisory committee, but it considers such recommendations when making decisions on approval.

After the FDA evaluates a BLA and conducts inspections of manufacturing facilities where the biological product and/or its drug substance will be produced, the FDA may issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete but the application is not ready for approval. A Complete Response Letter may request additional information or clarification, including new clinical studies. The FDA may delay or refuse approval of a BLA if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product. If a Complete Response Letter is issued, the applicant may either resubmit the BLA, addressing all of the deficiencies identified in the letter, or withdraw the application. Even if such data and information are submitted, the FDA may decide that the re-submitted BLA does not satisfy the criteria for approval.

If a product receives regulatory approval, such approval is limited to the conditions of use (e.g., patient population, indication) described in the application. Further, depending on the specific risk(s) to be addressed, the FDA may require that contraindications, warnings or precautions be included in the product labeling, require that post-approval trials, including Phase 4 clinical trials, be conducted to further assess a product's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution and use restrictions or other risk management mechanisms under a Risk Evaluation and Mitigation Strategy, or REMS, plan if it determines that a REMS is necessary to ensure that the benefits of the product outweigh its risks and to assure the safe use of the biological product, which can materially affect the potential market and profitability of the product. The REMS plan could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing regulatory standards is not maintained or if problems occur after the product reaches the marketplace. The FDA may prevent or limit further marketing of a product based on the results of post- marketing trials or surveillance programs. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Expedited Review and Approval

A sponsor may seek approval of its product candidate under programs designed to accelerate the FDA's review and approval of new drugs and biological products that meet certain criteria. Specifically, new drugs and biological products are eligible for fast track designation if they are intended to treat a serious or life-threatening condition and demonstrate the potential to address unmet medical needs for the condition. For a fast track product, the FDA may consider sections of the BLA for review on a rolling basis before the complete application is submitted if relevant criteria are met. A fast track designated product candidate may also qualify for priority review, under which the FDA sets the PDUFA target date for FDA action on the BLA at six months after the FDA accepts the application for filing. Priority review is granted where there is evidence that the proposed product would be a significant improvement in the safety or effectiveness of the treatment, diagnosis, or prevention of a serious condition. If criteria are not met for priority review, the application is subject to the standard FDA review period of 10 months after FDA accepts the application for filing. Priority review designation does not change the scientific/medical standard for approval or the quality of evidence necessary to support approval.

Under the accelerated approval program, the FDA may approve a BLA on the basis of either a surrogate endpoint that is reasonably likely to predict a clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. Post-marketing studies or completion of ongoing studies after marketing approval are generally required to verify the biologic's clinical benefit in relationship to the surrogate endpoint or ultimate outcome in relationship to the clinical benefit. In addition, the Food and Drug Administration Safety and Innovation Act, or FDASIA, which was enacted and signed into law in 2012, established the new Breakthrough Therapy designation. A sponsor may seek FDA designation of its product candidate as a breakthrough therapy if the product candidate is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the therapy may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Sponsors may request the FDA to designate a breakthrough therapy at the time of or any time after the submission of an IND, but ideally before an end-of-phase 2 meeting with the FDA. If the FDA designates a breakthrough therapy, it may take actions appropriate to expedite the development and review of the application, which may include holding meetings with the sponsor and the review team throughout the development of the therapy; providing timely advice to, and interactive communication with, the sponsor regarding the development of the drug to ensure that the development program to gather the nonclinical and clinical data necessary for approval is as efficient as practicable; involving senior managers and experienced review staff, as appropriate, in a collaborative, cross-disciplinary review; assigning a cross-disciplinary project lead for the FDA review team to facilitate an efficient review of the development program and to serve as a scientific liaison between the review team and the sponsor; and considering alternative clinical trial designs when scientifically appropriate, which may result in smaller trials or more efficient trials that require less time to complete and may minimize the number of patients exposed to a potentially less efficacious treatment.

Fast Track designation, priority review and breakthrough therapy designation do not change the standards for approval but may expedite the development or approval process.

Post-Approval Requirements

All therapeutic products manufactured or distributed pursuant to FDA approval or licensure are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing, annual user fee requirements under PDUFA for any marketed products and the establishments at which such products are manufactured, as well as new application fees for supplemental applications containing clinical data. Biologic manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP requirements, which impose significant procedural and documentation requirements. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements on manufacturers. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance. CEL-SCI cannot be certain that it, or CEL-SCI's present or future suppliers, will be able to comply with the cGMP regulations and other FDA regulatory requirements. If CEL-SCI is not able to comply with these requirements, the FDA may, among other things, take enforcement action or seek sanctions against use, impose restrictions on a product or its manufacturer, require us to recall a product from distribution, or withdraw approval of the BLA.

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- injunctions or the imposition of civil or criminal penalties; and
- consent decrees, corporate integrity agreements, debarment, or exclusion from federal healthcare programs; or mandated modification of promotional materials and labeling and the issuance of corrective information.

The FDA closely regulates the marketing, labeling, advertising and promotion of drugs and biologics. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of unapproved, or "off-label," uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs or biologics intended to treat a rare disease or condition that affects fewer than 200,000 individuals in the United States, or if it affects more than 200,000 individuals in the United States, there is no reasonable expectation that the cost of developing and making the drug for this type of disease or condition will be recovered from sales in the United States.

In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. In addition, if a product receives the first FDA approval for the indication for which it has orphan designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other application to market the same drug for the same indication for a period of 7 years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity. Orphan drug exclusivity also could block the approval of one of CEL-SCI's products for seven years if a competitor obtains approval of the same product before CEL-SCI does, as defined by the FDA, for the same indication CEL-SCI is seeking, or if CEL-SCI's product candidate is determined to be contained within the scope of the competitor's product for the same indication or disease. If one of CEL-SCI's products designated as an orphan drug receives marketing approval for an indication broader than that which is designated, it may not be entitled to orphan drug exclusivity. Orphan drug status in the European Union has similar, but not identical, requirements and benefits.

Orphan drug designation must be requested before submitting a BLA to the FDA for review and approval. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

Other U.S. Health Care Laws

CEL-SCI's sales, promotion, medical education and other activities following product approval will be subject to regulation by numerous regulatory and law enforcement authorities in the United States in addition to the FDA, including potentially the Federal Trade Commission, the Department of Justice, the Centers for Medicare and Medicaid Services, other divisions of the Department of Health and Human Services and state and local governments. CEL-SCI's promotional and scientific/educational programs must comply with the anti-kickback provisions of the Social Security Act, the Foreign Corrupt Practices Act, the False Claims Act, the Physician Payments Sunshine Act, the Veterans Health Care Act and similar state laws.

Depending on the circumstances, failure to meet these applicable regulatory requirements can result in criminal prosecution, fines or other penalties, exclusion from government health care programs, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of pre-marketing product approvals, private "qui tam" actions brought by individual whistleblowers under the False Claims Act in the name of the government or refusal to allow us to enter into supply contracts, including government contracts.

Coverage, Pricing and Reimbursement in the U.S.

Sales of pharmaceutical products depend significantly on the availability of third-party coverage and reimbursement. Third-party payors include government health administrative authorities, managed care providers, private health insurers and other organizations. These third-party payors are increasingly challenging the price and examining the cost-effectiveness of medical products and services. In addition, significant uncertainty exists as to the reimbursement status of newly approved healthcare products and new drug classes, including biological products such as CEL-SCI's product candidates. CEL-SCI may need to conduct expensive clinical studies to demonstrate the comparative cost-effectiveness of its products. The product candidates that CEL-SCI develops may not be considered cost-effective. It is time consuming and expensive for us to seek reimbursement from third- party payors. Reimbursement may not be available or sufficient to allow CEL-SCI to sell its products on a competitive and profitable basis.

The United States and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals to change the healthcare system in ways that could affect CEL-SCI's ability to sell its products profitably. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

Foreign Regulation

In addition to regulations in the United States, CEL-SCI will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of its products to the extent CEL-SCI chooses to develop or sell any products outside of the United States. The approval process varies from country to country and the time may be longer or shorter than that required to obtain FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country.

ITEM 1B. RISK FACTORS

The risks described below could adversely affect the price of CEL-SCI's common stock.

Risks Related to CEL-SCI

CEL-SCI has incurred significant losses since inception, and CEL-SCI anticipates that it will continue to incur significant losses for the foreseeable future and may never achieve or maintain profitability.

CEL-SCI has a history of net losses, expects to incur substantial losses and have negative operating cash flow for the foreseeable future, and may never achieve or maintain profitability. Since the date of its formation and through September 30, 2019, CEL-SCI incurred net losses of approximately $354 million. CEL-SCI has relied principally upon the proceeds from the public and private sales of its securities to finance its activities to date. To date, CEL-SCI has not commercialized any products or generated any revenue from the sale of products, and CEL-SCI does not expect to generate any product revenue for the foreseeable future. CEL-SCI does not know whether or when it will generate product revenue or become profitable.

CEL-SCI is heavily dependent on the success of Multikine which is under clinical development. CEL-SCI cannot be certain that Multikine will receive regulatory approval or be successfully commercialized even if CEL-SCI receives regulatory approval. Multikine is the only product candidate in late-stage clinical development, and CEL-SCI's business currently depends heavily on its successful development, regulatory approval and commercialization. CEL-SCI has no drug products for sale currently and may never be able to develop approved and marketable drug products.

Even if CEL-SCI succeeds in developing and commercializing one or more of its product candidates, CEL-SCI expects to continue to incur significant operating and capital expenditures as CEL-SCI:

- continues to undertake preclinical development and clinical trials for product candidates;
- seeks regulatory approvals for product candidates; and
- implements additional internal systems and infrastructure.

To become and remain profitable, CEL-SCI must succeed in developing and commercializing product candidates which must generate significant revenue. This will require CEL-SCI to be successful in a range of challenging activities, including completing preclinical testing and clinical trials of its product candidates, discovering or acquiring additional product candidates, obtaining regulatory approval for these product candidates and manufacturing, marketing and selling any products for which CEL-SCI may obtain regulatory approval. CEL-SCI is only in the preliminary stages of most of these activities. CEL-SCI may never succeed in these activities and, even if CEL-SCI does, may never generate revenue that is significant enough to achieve profitability.

Even if CEL-SCI does achieve profitability, it may not be able to sustain or increase profitability on a quarterly or annual basis. The failure to become and remain profitable could depress the value of CEL-SCI and could impair its ability to raise capital, expand its business, maintain research and development efforts, diversify product offerings or even continue in operation. A decline in the value of CEL-SCI could cause its stockholders to lose all or part of their investment.

CEL-SCI's financial statements include an explanatory paragraph that expresses substantial doubt about its ability to continue as a going concern, indicating the possibility that CEL-SCI may not be able to operate in the future.

Primarily as a result of CEL-SCI's losses incurred to date, CEL-SCI's expected continued future losses, and limited cash balances, CEL-SCI has included an explanatory paragraph 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. CEL-SCI's ability to continue as a going concern is contingent upon, among other factors, the sale of the shares of its common stock or obtaining alternate financing.

CEL-SCI's Independent Registered Public Accountants have included in their report on CEL-SCI's financial statements a paragraph stating that we may be unable to continue as a going concern.

As a result of CEL-SCI's recurring losses from operations, CEL-SCI's independent registered public accounting firm, BDO USA, LLP, has issued a report in connection with their audit of CEL-SCI's financial statements for the year ended September 30, 2019, that included an explanatory paragraph referring to CEL-SCI's recurring losses from operations and expressing substantial doubt in CEL-SCI's ability to continue as a going concern without additional capital becoming available. The doubt about CEL-SCI's ability to continue as a going concern could have an adverse impact on CEL-SCI's ability to execute CEL-SCI's business plan, result in the reluctance on the part of certain suppliers to do business with CEL-SCI, or adversely affect CEL-SCI's ability to raise additional debt or equity capital.

CEL-SCI will require substantial additional capital to remain in operation. A failure to obtain this necessary capital when needed could force CEL-SCI to delay, limit, reduce or terminate the product candidates' development or commercialization efforts.

As of September 30, 2019, CEL-SCI had cash and cash equivalents of approximately $8.4 million. CEL-SCI believes that it will continue to expend substantial resources for the foreseeable future developing Multikine, LEAPS and any other product candidates or technologies that it may develop or acquire. These expenditures will include costs associated with research and development, potentially obtaining regulatory approvals and having the products manufactured, as well as marketing and selling products approved for sale, if any. In addition, other unanticipated costs may arise. Because the outcome of the current and anticipated clinical trials is highly uncertain, CEL-SCI cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of the product candidates.

CEL-SCI's future capital requirements depend on many factors, including:

- the rate of progress of, results of and cost of completing Phase 3 clinical development of Multikine for the treatment of certain head and neck cancers;
- the results of the applications to and meetings with the FDA, the EMA and other regulatory authorities and the consequential effect on operating costs;
- assuming favorable Phase 3 clinical results, the cost, timing and outcome of the efforts to obtain marketing approval for Multikine in the United States, Europe and in other jurisdictions, including the preparation and filing of regulatory submissions for Multikine with the FDA, the EMA and other regulatory authorities;
- the scope, progress, results and costs of additional preclinical, clinical, or other studies for additional indications for Multikine, LEAPS and other product candidates and technologies that CEL-SCI may develop or acquire;
- the timing of, and the costs involved in, obtaining regulatory approvals for LEAPS if clinical studies are successful;
- the cost and timing of future commercialization activities for the products, if any of the product candidates are approved for marketing, including product manufacturing, marketing, sales and distribution costs;
- the revenue, if any, received from commercial sales of the product candidates for which CEL-SCI receives marketing approval;
- the cost of having the product candidates manufactured for clinical trials and in preparation for commercialization;
- the ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of such agreements;
- the costs involved in preparing, filing and prosecuting patent applications and maintaining, defending and enforcing its intellectual property rights, including litigation costs, and the outcome of such litigation; and
- the extent to which CEL-SCI acquires or in-licenses other products or technologies.

CEL-SCI will need to raise additional funds in order to continue its operations and additional funds may not be available when CEL-SCI needs them on terms that are acceptable to CEL-SCI, or at all. If adequate funds are not available to CEL-SCI on a timely basis, CEL-SCI may be required to delay, limit, reduce or terminate preclinical studies, clinical trials or other development activities for Multikine, LEAPS, or any other product candidates or technologies that CEL-SCI develops or acquires, or delay, limit, reduce or terminate its sales and marketing capabilities or other activities that may be necessary to commercialize its product candidates. Due to recurring losses from operations and future liquidity needs, there is substantial doubt about CEL-SCI's ability to continue as a going concern without additional capital becoming available. The doubt about CEL-SCI's ability to continue as a going concern could have an adverse impact on CEL-SCI's ability to execute its business plan, result in the reluctance on the part of certain suppliers to do business with CEL-SCI, or adversely affect CEL-SCI's ability to raise additional debt or equity capital.

The costs of the product candidates development and clinical trials are difficult to estimate and will be very high for many years, preventing CEL-SCI from making a profit for the foreseeable future, if ever.

Clinical and other studies necessary to obtain approval of a new drug or biologic can be time consuming and costly, especially in the United States, but also in foreign countries. The estimates of the costs associated with future clinical trials and research may be substantially lower than what CEL-SCI actually experiences. It is impossible to predict what CEL-SCI will face in the development of a complex product candidate, such as Multikine. The purpose of clinical trials is to provide both CEL-SCI and regulatory authorities with safety and efficacy data in humans. The difficult and often complex steps necessary to obtain regulatory approval, especially that of the FDA and the EMA, involve significant costs and may require several years to complete. CEL-SCI expects that it will need substantial additional financing over an extended period of time in order to fund the costs of future clinical trials, related research, and general and administrative expenses.

The extent of the clinical trials and research programs are primarily based upon the amount of capital available to CEL-SCI and the extent to which CEL-SCI receives regulatory approvals for clinical trials. CEL-SCI has established estimates of the future costs of the Phase 3 clinical trial for Multikine, but, as explained above, the estimates may not prove correct.

Completion of modifications to its manufacturing facility may delay submission of CEL-SCI's Biologics License Application to the FDA with respect to Multikine as a neoadjuvant treatment of advanced head and neck cancer.

If CEL-SCI's ongoing Phase 3 clinical trial is successful, some modifications to CEL-SCI's manufacturing facility will have to be made in order to prepare the facility to produce Multikine for commercial purposes and before CEL-SCI's Biologics License Application (BLA) can be approved by the FDA. Although these modifications are in process, they may not be completed prior to the time CEL-SCI's Phase 3 clinical trial ends, the BLA is submitted and the FDA would seek to conduct a pre-approval inspection of the manufacturing facility and its processes. In that case, and assuming a positive outcome for CEL-SCI's Phase 3 clinical trial, submission of CEL-SCI's marketing application to the FDA and/or the approval of such a BLA for Multikine as a treatment for advanced head and neck cancer may be delayed.

An adverse determination in any future legal proceedings could have a material adverse effect on CEL-SCI.

CEL-SCI may be the target of claims asserting violations of securities fraud and derivative actions, or other litigation or arbitration proceedings in the future. Any future litigation could result in substantial costs and divert management's attention and resources. These legal proceedings may result in large judgments or settlements against CEL-SCI, any of which could have a material adverse effect on its business, operating results, financial condition and liquidity.

Compliance with changing regulations concerning corporate governance and public disclosure may result in additional expenses.

Changing laws, regulations and standards relating to corporate governance and public disclosure may create uncertainty regarding compliance matters. New or changed laws, regulations and standards are subject to varying interpretations in many cases. As a result, their application in practice may evolve over time. CEL-SCI is committed to maintaining high standards of corporate governance and public disclosure. Complying with evolving interpretations of new or changing legal requirements may cause CEL-SCI to incur higher costs as CEL-SCI revises current practices, policies and procedures, and may divert management time and attention from potential revenue-generating activities to compliance matters. If the efforts to comply with new or changed laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to practice, CEL-SCI's reputation may also be harmed. Further, CEL-SCI's board members, chief executive officer, and other executive officers could face an increased risk of personal liability in connection with the performance of their duties. As a result, CEL-SCI may have difficulty attracting and retaining qualified board members and executive officers, which could harm its business.

CEL-SCI has not established a definite plan for the marketing of Multikine, if approved.

CEL-SCI has not established a definitive plan for marketing nor has CEL-SCI established a price structure for any of its product candidates, if approved. However, CEL-SCI intends, if it is in a position to do so, to sell Multikine itself in certain markets where it is approved, and or to enter into written marketing agreements with various third parties with established sales forces in such markets. The sales forces in turn would, CEL-SCI believes, focus on selling Multikine to targeted cancer centers, physicians and clinics involved in the treatment of head and neck cancer. CEL-SCI has already licensed future sales of Multikine, if approved, to three companies: Teva Pharmaceutical Industries Ltd. in Israel, Turkey, Serbia and Croatia; Orient Europharma in Taiwan, Singapore, Hong Kong, Malaysia, South Korea, the Philippines, Australia and New Zealand; and Byron BioPharma, LLC in South Africa. CEL-SCI believes that these companies will have the resources to market Multikine appropriately in their respective territories, if approved, but there is no guarantee that they will. There is no assurance that CEL-SCI will be able to find qualified third-party partners to market its products in other areas, on terms that are favorable to CEL-SCI, or at all.

CEL-SCI may encounter problems, delays and additional expenses in developing marketing plans with third parties. In addition, even if Multikine, if approved, is cost-effective and demonstrated to increase overall patient survival, CEL-SCI may experience other limitations involving the proposed sale of Multikine, such as uncertainty of third-party coverage and reimbursement. There is no assurance that CEL-SCI can successfully market Multikine, if approved, or any other product candidates it may develop.

CEL-SCI hopes to expand its clinical development capabilities in the future, and any difficulties hiring or retaining key personnel or managing this growth could disrupt its operations.

CEL-SCI is highly dependent on the principal members of its management and development staff. If the Phase 3 clinical trial is successful, CEL-SCI expects to expand its clinical development and manufacturing capabilities, which will involve hiring additional employees. Future growth will require CEL-SCI to continue to implement and improve its managerial, operational and financial systems and continue to retain, recruit and train additional qualified personnel, which may impose a strain on its administrative and its operational infrastructure. The competition for qualified personnel in the biopharmaceutical field is intense. CEL-SCI is highly dependent on its ability to attract, retain and motivate highly qualified management and specialized personnel required for clinical development. Due to limited resources, CEL-SCI may not be able to manage effectively the expansion of its operations or recruit and train additional qualified personnel. If CEL-SCI is unable to retain key personnel or manage its future growth effectively, CEL-SCI may not be able to implement its business plan.

If product liability or patient injury lawsuits are brought against CEL-SCI, CEL-SCI may incur substantial liabilities and may be required to limit clinical testing or future commercialization of Multikine or its other product candidates.

CEL-SCI faces an inherent risk of product liability as a result of the clinical testing of Multikine and other product candidates, and will face an even greater risk if CEL-SCI is able to commercialize any of its product candidates. For example, CEL-SCI may be sued if its Multikine or LEAPS product candidates, or any other future product candidates, allegedly cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing or, if approved, marketing, sale or administration to patients. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product candidate, negligence, strict liability and a breach of warranties. Claims could also be asserted under state consumer protection acts.

Furthermore, Multikine is made, in part, from components of human blood. There are inherent risks associated with products that involve human blood such as possible contamination with viruses, including hepatitis or HIV. Any possible contamination could cause injuries to patients who receive contaminated Multikine, or could require CEL-SCI to destroy batches of Multikine, thereby subjecting CEL-SCI to possible financial losses, lawsuits and harm to its business.

If CEL-SCI cannot successfully defend itself against product liability claims, CEL-SCI may incur substantial liabilities or be required to limit or cease the clinical testing or commercialization of its product candidates, if approved. Even a successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for Multikine or other product candidates, if approved and commercialized, or clinical holds or suspension of the IND while the candidates are still in clinical development;
- injury to CEL-SCI's reputation;
- withdrawal of existing, or failure to enroll additional, clinical trial participants;
- costs to defend any related litigation;
- a diversion of management's time and resources;
- substantial monetary awards to trial participants or patients;
- recalls of approved products, withdrawal of BLA approvals or new labeling, marketing or promotional restrictions;
- loss of revenue;
- inability to commercialize Multikine or other product candidates; and
- a decline in the price of CEL-SCI's common stock.

Although CEL-SCI has product liability insurance for Multikine in the amount of $10 million, the successful prosecution of a product liability case against CEL-SCI could have a materially adverse effect upon its business if the amount of any judgment exceeds the insurance coverage. Any claim that may be brought against CEL-SCI could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by CEL-SCI's insurance or that is in excess of the limits of the insurance coverage. CEL-SCI's insurance policies also have various exclusions, and CEL-SCI may be subject to a claim for which CEL-SCI has no coverage. CEL-SCI may have to pay any amounts awarded by a court or negotiated in a settlement that exceed the coverage limitations or that are not covered by its insurance, and CEL-SCI may not have, or be able to obtain, sufficient capital to pay such amounts. CEL-SCI commenced the Phase 3 clinical trial for Multikine in December 2010. Although no claims have been brought to date, participants in the clinical trials could bring civil actions against CEL-SCI for any unanticipated harmful effects allegedly arising from the use of Multikine or any other product candidate that CEL-SCI may attempt to develop.

CEL-SCI's commercial success depends, in part, upon attaining significant market acceptance of its product candidates, if approved, among physicians, patients, healthcare payors and major operators of cancer clinics.

Even if CEL-SCI obtains regulatory approval for its product candidates, any resulting product may not gain market acceptance among physicians, healthcare payors, patients and the medical community, which are critical to commercial success. Market acceptance of any product candidate for which CEL-SCI receives approval depends on a number of factors, including:

- the efficacy and safety of the products as demonstrated in clinical trials;
- the timing of market introduction of such product as well as competitive products;
- the clinical indications for which the biological product is approved;
- the approval, availability, market acceptance and reimbursement for the companion diagnostic, if appropriate or necessary;
- acceptance by physicians, major operators of cancer clinics and patients of the biologic as a safe and effective treatment;
- the potential and perceived advantages of such product candidate over alternative treatments, especially with respect to patient subsets that are targeted with such product;
- the safety of such product seen in a broader patient group, including its use outside the approved indications;
- the cost of treatment in relation to alternative treatments;
- the availability of adequate reimbursement and pricing by third-party payors and government authorities;
- relative convenience and ease of administration;
- the prevalence and severity of adverse side effects; and
- the effectiveness of sales and marketing efforts.

If CEL-SCI's product candidates are approved, but fail to achieve an adequate level of acceptance by physicians, healthcare payors and patients, CEL-SCI will not be able to generate significant revenues, and CEL-SCI may not become or remain profitable.

CEL-SCI's ability to utilize its net operating loss carryforwards and certain other tax attributes may be limited.

Under Section 382 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change" (generally defined as a greater than 50% change (by value) in CEL-SCI's equity ownership over a three-year period), the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income may be limited. As a result of public offerings and other transactions, CEL-SCI may experience ownership changes in the future based on subsequent shifts in its stock ownership, some of which are outside its control. As a result, the ability to use the pre-change net operating loss carryforwards and other pre-change tax attributes to offset U.S. federal taxable income may be subject to limitations, which could result in increased tax liability to CEL-SCI.

Under CEL-SCI's amended bylaws, stockholders that initiate certain proceedings may be obligated to reimburse CEL-SCI and its officers and directors for all fees, costs and expenses incurred in connection with such proceedings if the claim proves unsuccessful.

On February 18, 2015, CEL-SCI adopted new bylaws which include a fee-shifting provision in Article X for stockholder claims. Article X provides that in the event any stockholder initiates or asserts a claim against CEL-SCI, or any of its officers or directors, including any derivative claim or claim purportedly filed on CEL-SCI's behalf, and the stockholder does not obtain a judgment on the merits that substantially achieves, in substance and amount, the full remedy sought, then the stockholder will be obligated to reimburse CEL-SCI and any of its officers or directors named in the action, for all fees, costs and expenses of every kind and description that CEL-SCI or its officers or directors may incur in connection with the claim. In adopting Article X, it is the intent that:

- all actions, including federal securities law claims, would be subject to Article X;
- the phrase "a judgment on the merits" means the determination by a court of competent jurisdiction on the matters submitted to the court;
- the phrase "substantially achieves, in both substance and amount" means the plaintiffs in the action would be awarded at least 90% of the relief sought;
- only persons who were stockholders at the time an action was brought would be subject to Article X; and
- only the directors or officers named in the action would be allowed to recover.

The fee-shifting provision contained in Article X of the bylaws is not limited to specific types of actions, but is rather potentially applicable to the fullest extent permitted by law. Fee-shifting bylaws are relatively new and untested. The case law and potential legislative action on fee-shifting bylaws are evolving and there exists considerable uncertainty regarding the validity of, and potential judicial and legislative responses to, such bylaws. For example, it is unclear whether the ability to invoke the fee-shifting bylaw in connection with claims under the federal securities laws would be pre-empted by federal law. Similarly, it is unclear how courts might apply the standard that a claiming stockholder must obtain a judgment that substantially achieves, in substance and amount, the full remedy sought. The application of the fee-shifting bylaw in connection with such claims, if any, will depend in part on future developments of the law. CEL-SCI cannot assure its shareholders that CEL-SCI will or will not invoke the fee-shifting bylaw in any particular dispute. In addition, given the unsettled state of the law related to fee-shifting bylaws, such as CEL-SCI's, CEL-SCI may incur significant additional costs associated with resolving disputes with respect to such bylaw, which could adversely affect CEL-SCI's business and financial condition.

If a stockholder that brings any such claim, suit, action or proceeding is unable to obtain the required judgment, the attorneys' fees and other litigation expenses that might be shifted to a claiming stockholder are potentially significant. This fee-shifting bylaw may therefore dissuade or discourage stockholders and their attorneys from initiating lawsuits or claims against CEL-SCI or its directors and officers. In addition, it may impact the fees, contingency or otherwise, required by potential plaintiffs' attorneys to represent the stockholders or otherwise discourage plaintiffs' attorneys from representing the stockholders at all. As a result, this bylaw may limit the ability of stockholders to affect CEL-SCI's management and direction, particularly through litigation or the threat of litigation.

The provision of the amended bylaws requiring exclusive venue in the U.S. District Court for Delaware for certain types of lawsuits may have the effect of discouraging lawsuits against CEL-SCI and its directors and officers.

Article X of CEL-SCI's amended bylaws provides that stockholder claims brought against CEL-SCI, or its officers or directors, including any derivative claim or claim purportedly filed on its behalf, must be brought in the U.S. District Court for the district of Delaware and that with respect to any such claim, the laws of Delaware will apply.

The exclusive forum provision may limit a stockholder's ability to bring a claim in a judicial forum the stockholder finds favorable for disputes with CEL-SCI or its directors or officers, and may have the effect of discouraging lawsuits with respect to claims that may benefit CEL-SCI or its stockholders.

Risks Related to Clinical Development, Government Approvals and the Marketing of Biopharmaceutical Products

CEL-SCI depends heavily on the success of Multikine, which is in Phase 3 clinical development, while our other candidates are still in preclinical phases. CEL-SCI's product candidates must undergo rigorous preclinical and clinical testing and regulatory approvals, which could be costly and time-consuming and subject CEL-SCI to unanticipated delays or prevent CEL-SCI from marketing any products. If CEL-SCI is unable to advance its product candidates in clinical development, obtain regulatory approval and ultimately commercialize its product candidates, or experience significant delays in doing so, CEL-SCI's business will be materially harmed.

CEL-SCI currently has no products approved for sale and CEL-SCI cannot guarantee that it will ever have marketable products. CEL-SCI's product candidates are subject to premarket approval from the FDA in the United States, the EMA in the European Union, and by comparable agencies in most foreign countries before they can be sold. Before obtaining marketing approval, these product candidates must undergo costly and time consuming preclinical and clinical testing which could subject CEL-SCI to unanticipated delays and may prevent CEL-SCI from marketing the product candidates in the future. There can be no assurance that such approvals will be granted on a timely basis, if at all.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of the product candidates may not be predictive of the results of later-stage clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. CEL-SCI's current and future clinical trials may not be successful.

Although CEL-SCI is no longer treating patients and simply following the patients per the protocol of the Phase 3 clinical trial for its lead investigational product Multikine, CEL-SCI may experience delays in completion of this clinical trial and CEL-SCI does not know whether the clinical trial will need to be redesigned. In addition, CEL-SCI is in the early development stages for the candidates designed using its LEAPS technology and have not yet initiated any clinical studies for any of those product candidates. Clinical trials can be delayed for a variety of reasons, including delays related to:

- the availability of financial resources needed to commence and complete the planned trials;
- obtaining regulatory approval to commence a trial;
- reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining Institutional Review Board, or IRB, approval at each clinical trial site;
- recruiting suitable patients to participate in a trial;
- having patients complete a trial or return for post-treatment follow-up;
- clinical trial sites deviating from trial protocol or dropping out of a trial;
- adding new clinical trial sites; or
- manufacturing sufficient quantities of the product candidate for use in clinical trials.

Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors including the competence of the CRO running the study, size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications CEL-SCI is investigating. Furthermore, CEL-SCI relies on CROs and clinical trial sites to ensure the proper and timely conduct of the clinical trials and while CEL-SCI has agreements governing their committed activities, CEL-SCI has limited influence over their actual performance.

CEL-SCI could also encounter significant delays and/or need to terminate a development program for a product candidate if physicians encounter unresolved ethical issues associated with enrolling patients in clinical trials of the product candidates while existing treatments have established safety and efficacy profiles. Further, a clinical trial may be suspended or terminated by CEL-SCI, one or more of the IRBs for the institutions in which such trials are being conducted, by CEL-SCI upon a final recommendation by the Independent Data Monitoring Committee, or IDMC, with which CEL-SCI agrees for such trial, or by FDA or other regulatory authorities due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or the clinical protocols, as a result of inspection of the clinical trial operations or trial site(s) by FDA or other regulatory authorities, the imposition of a clinical hold or partial clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. The occurrence of any one or more of these events would have significant and severe material consequences for CEL-SCI and could impact CEL-SCI's ability to continue as a going concern.

If CEL-SCI experiences termination of, or delays in the completion of, any clinical trial of its product candidates, the commercial prospects for the product candidates will be harmed, and the ability to generate product revenues will be delayed. In addition, any delays in completing the clinical trials will increase the costs, slow the product development and approval process and jeopardize the ability to commence product sales and generate revenues. Any of these occurrences may harm CEL-SCI's business, prospects, financial condition and results of operations significantly. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to a delay or the denial of regulatory approval for the product candidates.

CEL-SCI cannot be certain when or under what conditions it will undertake future clinical trials. A variety of issues may delay the ongoing Phase 3 clinical trial for Multikine for advanced head and neck cancer. Early trials for the other product candidates, or the plans for later trials, may not satisfy the requirements of regulatory authorities, such as the FDA. CEL-SCI may fail to find subjects willing to enroll in the trials. Accordingly, the clinical trials relating to the product candidates may not be completed on schedule, the FDA or foreign regulatory agencies may order CEL-SCI to stop or modify research, or these agencies may not ultimately approve any of the product candidates for commercial sale. Varying interpretations of the data obtained from pre-clinical and clinical testing could delay, limit or prevent regulatory approval of the product candidates. The data collected from the clinical trials may not be sufficient to support regulatory approval of the various product candidates, including Multikine. The failure to adequately demonstrate the safety and efficacy of any of the product candidates would delay or prevent regulatory approval of the product candidates in the United States, which could prevent CEL-SCI from achieving profitability. Although CEL-SCI had positive results in the Phase 2 trials for Multikine, those results were for a very small sample set, and CEL-SCI will not know how Multikine will perform in a larger set of subjects until CEL-SCI completes the Phase 3 clinical trial.

The development and testing of product candidates and the process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant to administrative or judicial sanctions. FDA sanctions could include, among other actions, refusal to approve pending applications, withdrawal of an approval, a clinical hold, termination of the Phase 3 study, warning letters, product recalls or withdrawals from the market, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on CEL-SCI.

The requirements governing the conduct of clinical trials, manufacturing and marketing of the product candidates, including Multikine, outside the United States vary from country to country. Foreign approvals may take longer to obtain than FDA approvals and can require, among other things, additional testing and different trial designs. Foreign regulatory approval processes include all of the risks associated with the FDA approval process. Some of those agencies also must approve prices for products approved for marketing. Approval of a product by the FDA or the EMA does not ensure approval of the same product by the health authorities of other countries. In addition, changes in regulatory requirements for product approval in any country during the clinical trial process and regulatory agency review of each submitted new application may cause delays or rejections.

CEL-SCI has only limited experience in filing and pursuing applications necessary to gain regulatory approvals. The lack of experience may impede its ability to obtain timely approvals from regulatory agencies, if at all. CEL-SCI will not be able to commercialize Multikine and other product candidates until CEL-SCI has obtained regulatory approval. In addition, regulatory authorities may also limit the types of patients to which CEL-SCI or its third-party partners may market Multikine (if approved) or the other product candidates. Any failure to obtain or any delay in obtaining required regulatory approvals may adversely affect CEL-SCI's or its third-party partners' ability to successfully market the product candidates after they are approved.

Even if CEL-SCI obtains regulatory approval for its investigational products, CEL-SCI will be subject to stringent, ongoing government regulation.

If CEL-SCI's investigational products receive regulatory approval, either in the United States or internationally, those products will be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, and may contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance of the safety and efficacy of the investigational products. CEL-SCI will continue to be subject to extensive regulatory requirements. These regulations are wide-ranging and govern, among other things:

- product design, development and manufacture;
- product application and use
- adverse drug experience monitoring reporting;
- product advertising and promotion;
- product manufacturing, including compliance with good manufacturing practices
- record keeping requirements;
- registration and listing of the establishments and products with the FDA, EMA and other state and national agencies;
- product storage and shipping;
- drug sampling and distribution requirements;
- electronic record and signature requirements; and
- labeling changes or modifications.

CEL-SCI and any of its third-party manufacturers or suppliers must continually adhere to federal regulations setting forth human drug and biologic manufacturing requirements, known as current Good Manufacturing Practices, or cGMPs, and their foreign equivalents, which are enforced by the FDA, the EMA and other national regulatory bodies through their facilities inspection programs. If the facilities, or the facilities of the contract manufacturers or suppliers, cannot pass a pre-approval inspection by regulators or fail such inspections in the future, the FDA, EMA or other national regulators will not approve the marketing applications for the product candidates, or may withdraw any prior approval. In complying with cGMP and foreign regulatory requirements, CEL-SCI and any of its potential third-party manufacturers or suppliers will be obligated to expend time, money and effort in production, record-keeping and quality control to ensure that the product candidates meet applicable specifications and other requirements.

If CEL-SCI does not comply with regulatory requirements at any stage, whether before or after marketing approval is obtained, CEL-SCI may be subject to, among other things, license suspension or revocation, criminal prosecution, seizure, injunction, fines, be forced to remove a product from the market or experience other adverse consequences, including restrictions or delays in obtaining regulatory marketing approval for such products or for other product candidates for which CEL-SCI seeks approval. This could materially harm CEL-SCI's financial results, reputation and stock price. Additionally, CEL-SCI may not be able to obtain the labeling claims necessary or desirable for product promotion. If CEL-SCI or other parties identify adverse effects after any of the products are on the market, or if manufacturing problems occur, regulatory approval may be suspended or withdrawn. CEL-SCI may be required to reformulate products, conduct additional clinical trials, make changes in product labeling or indications of use, or submit additional marketing applications to support any changes. If CEL-SCI encounters any of the foregoing problems, its business and results of operations will be harmed and the market price of its common stock may decline.

The FDA and other governmental authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of CEL-SCI's product candidates. If CEL-SCI is slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if CEL-SCI is not able to maintain regulatory compliance, CEL-SCI may lose any marketing approval that it may have obtained, which would adversely affect its business, prospects and ability to achieve or sustain profitability. CEL-SCI cannot predict the extent of adverse government regulations which might arise from future legislative or administrative action. Without government approval, CEL-SCI will be unable to sell any of its product candidates.

CEL-SCI's product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial utility of an approved prescribing label, or result in significant negative consequences following marketing approval, if any.

Undesirable side effects caused by its product candidates could cause CEL-SCI or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign authorities. Results of the clinical trials could reveal a high and unacceptable severity and/or prevalence of these or other side effects. In such an event, the trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order CEL-SCI to cease further development of, or deny approval of, the product candidates for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm CEL-SCI's business, financial condition and prospects significantly.

Additionally, if one or more of the product candidates receives marketing approval, and CEL-SCI or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including but not limited to the following:

- regulatory authorities may withdraw approvals of such product or require product recalls;
- regulatory authorities may require additional warnings on the label or impose restrictions on product distribution or use;
- regulatory authorities may require CEL-SCI to conduct new post-marketing studies or clinical trials;
- CEL-SCI could receive warning or untitled letters from the FDA or comparable notice of violations from foreign regulatory authorities;
- CEL-SCI may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- CEL-SCI could be sued and held liable for harm caused to patients; and
- CEL-SCI's reputation may suffer.

Any of these events could prevent CEL-SCI from achieving or maintaining market acceptance of a particular product candidate, if approved, and could significantly harm its business, results of operations and prospects.

CEL-SCI relies on third parties to conduct its preclinical and clinical trials. If these third parties do not successfully carry out their contractual duties and meet regulatory requirements, or meet expected deadlines, CEL-SCI may not be able to obtain regulatory approval for or commercialize the product candidates and its business could be substantially harmed.

CEL-SCI does not have the ability to independently conduct clinical trials. CEL-SCI has relied upon and plans to continue to rely upon third-party CROs to prepare for, conduct, monitor and manage data for its ongoing preclinical and clinical programs, including the global Phase 3 trial for Multikine. CEL-SCI relies on these parties for all aspects of the execution of its preclinical studies and clinical trials, and although CEL-SCI diligently oversees and carefully manages the CROs, CEL-SCI directly controls only certain aspects of their activities and relies upon them to provide timely, complete, and accurate reports on the conduct of the studies. Although such third parties provide support and represent CEL-SCI for regulatory purposes in the context of the clinical trials, ultimately CEL-SCI is responsible for ensuring that each of the studies is conducted in accordance with the applicable protocol, legal, regulatory, and scientific standards, and the reliance on the CROs does not relieve CEL-SCI of its regulatory responsibilities. CEL-SCI and the CROs acting on CEL-SCI's behalf, as well as principal investigators and trial sites, are required to comply with Good Clinical Practice, or GCP, and other applicable requirements, which are implemented through regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area, or EEA, and comparable foreign regulatory authorities for all of the products in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators, and trial sites. If CEL-SCI or any of the CROs fail to comply with applicable GCPs or other applicable regulations, the clinical data generated in the clinical trials may be determined to be unreliable and CEL-SCI may therefore need to enroll additional subjects in the clinical trials, or the FDA, EMA or comparable foreign regulatory authorities may require CEL-SCI to perform an additional clinical trial or trials before approving the marketing applications. Moreover, if CEL-SCI or any of the CROs, principal investigators, or trial sites, fail to comply with applicable regulatory and GCP requirements, CEL-SCI, the CROs, principal investigators, or trial sites may be subject to enforcement actions, such as fines, warning letters, untitled letters, clinical holds, civil or criminal penalties, and/or injunctions. CEL-SCI cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of the clinical trials comply with cGCP regulations. In addition, the clinical trials must be conducted with product produced under cGMP regulations. The failure to comply with these regulations may require CEL-SCI to delay or repeat clinical trials, which would delay the regulatory approval process.

If any of the relationships with the third-party CROs terminate, CEL-SCI may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. In addition, the CROs are not CEL-SCI's employees, and except for remedies available to CEL-SCI under the agreements with such CROs, CEL-SCI cannot control whether or not they devote sufficient time and resources to the on-going clinical, nonclinical and preclinical programs. If CROs do not successfully fulfill their regulatory obligations, carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to the clinical protocols, regulatory requirements or for other reasons, the clinical trials may be extended, delayed or terminated, and CEL-SCI may not be able to obtain regulatory approval for, or successfully commercialize, the product candidates. As a result, CEL-SCI's results of operations and the commercial prospects for the product candidates would be harmed, the costs could increase and the ability to generate revenues could be delayed.

Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays may occur, which can materially impact CEL-SCI's ability to meet the desired clinical development timelines. Though CEL-SCI diligently oversees and carefully manages its relationships with the CROs, there can be no assurance that CEL-SCI will not encounter similar challenges or delays in clinical development in the future or that these delays or challenges will not have a material adverse impact on CEL-SCI's business, financial condition and prospects.

CEL-SCI has obtained orphan drug designation from the FDA for Multikine for neoadjuvant, or primary, therapy in patients with squamous cell carcinoma of the head and neck, but CEL-SCI may be unable to maintain the benefits associated with orphan drug designation, including the potential for market exclusivity.

Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug or biologic intended to treat a rare disease or condition, which is defined as one occurring in a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug or biologic will be recovered from sales in the United States. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. In addition, if a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications, including a full BLA, to market the same biologic for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or where the manufacturer is unable to assure sufficient product quantity.

Even though CEL-SCI has received orphan drug designation for Multikine for the treatment of squamous cell carcinoma of the head and neck, CEL-SCI may not be the first to obtain marketing approval of a product for the orphan-designated indication due to the uncertainties associated with developing pharmaceutical products. In addition, exclusive marketing rights in the United States may be limited if CEL-SCI seeks approval for an indication broader than the orphan-designated indication, or may be lost if the FDA later determines that the request for designation was materially defective or if CEL-SCI is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Further, even if CEL-SCI obtains orphan drug exclusivity for a product candidate, that exclusivity may not effectively protect the product candidate from competition because different drugs with different active moieties can be approved for the same condition. Even after an orphan product is approved, the FDA can subsequently approve another drug with the same active moiety for the same condition if the FDA concludes that the later drug is safer, more effective, or makes a major contribution to patient care. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process.

Biologics carry unique risks and uncertainties, which could have a negative impact on future results of CEL-SCI's operations.

The successful discovery, development, manufacturing and sale of biological products like CEL-SCI's candidates is a long, expensive and uncertain process. There are unique risks and uncertainties with biologics. For example, access to and supply of necessary biological materials, such as cell lines, may be limited and governmental regulations restrict access to and regulate the transport and use of such materials. In addition, the development, manufacturing and sale of biologics is subject to regulations that are often more complex and extensive than the regulations applicable to other pharmaceutical products. Manufacturing biologics, especially in large quantities, is often complex and may require the use of innovative technologies. Such manufacturing also requires facilities specifically designed and validated for this purpose and sophisticated quality assurance and quality control procedures. Biologics are also frequently costly to manufacture because production inputs are derived from living animal or plant material, and some biologics cannot be made synthetically. Failure to successfully discover, develop, manufacture and sell its biological product candidates would adversely impact CEL-SCI's business and future results of operations.

CEL-SCI faces substantial competition, which may result in others discovering, developing or commercializing competing products before or more successfully than CEL-SCI.

The development and commercialization of new drug and biological products is highly competitive. CEL-SCI faces competition with respect to its current product candidates and expects to face competition with respect to any product candidates that CEL-SCI may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

Many of the companies against which CEL-SCI is competing or against which CEL-SCI may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, nonclinical studies, conducting clinical trials, obtaining marketing approvals and marketing approved products than CEL-SCI. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of CEL-SCI's competitors. Smaller and early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with CEL-SCI in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, CEL-SCI's programs.

CEL-SCI may be unable to successfully scale-up manufacturing of its lead product candidate Multikine in sufficient quality and quantity, which would delay or prevent CEL-SCI from commercializing this product, if approved for marketing by the FDA or other regulatory agencies.

In order to commercialize its product candidates, CEL-SCI will need to manufacture them in large quantities. At the present time, CEL-SCI is not manufacturing Multikine while CEL-SCI completes the follow-up phase of its Phase 3 clinical trial. CEL-SCI is planning to increase the capacity of its proprietary facility to produce commercial quantities of Multikine, if approved, and is currently exploring options for implementing scale-up activities in anticipation of study completion and submitting applications for marketing approval, if supported by the Phase 3 data. CEL-SCI may be unable to successfully increase the manufacturing capacity for its lead product candidate Multikine in a timely or cost-effective manner, or at all. In addition, quality issues may arise during scale-up activities.

Further, in order to release product and demonstrate stability of product candidates for future commercial use, CEL-SCI's analytical methods must be validated in accordance with regulatory guidelines. CEL-SCI may not be able to successfully validate, or maintain validation of, its analytical methods during scale-up or demonstrate adequate purity, stability or comparability of the biological product candidates in a timely or cost-effective manner, or at all. Even if CEL-SCI believes its manufacturing processes meets all of the regulatory manufacturing requirements, the FDA will review those processes and the manufacturing facility as part of the review of the future BLA for Multikine, if submitted after completion the ongoing Phase 3 trial in advanced head and neck cancer. If CEL-SCI is unable to successfully scale up the manufacture of Multikine in sufficient quality and quantity, or if CEL-SCI encounters validation issues, the development, testing, and clinical trials of future product candidates, may be delayed or infeasible, and regulatory approval or commercial launch of any resulting product, including Multikine, may be delayed or may not be successfully achieved.

The current and future relationships with healthcare professionals, principal investigators, consultants, potential customers and third-party payors in the United States and elsewhere may be subject, directly or indirectly, to applicable healthcare laws and regulations.

Although CEL-SCI does not currently have any products on the market, once CEL-SCI begins commercializing its product candidates, CEL-SCI will be subject to additional healthcare statutory and regulatory requirements and oversight by federal and state governments as well as foreign governments in the jurisdictions in which CEL-SCI conducts its business. Healthcare providers, physicians and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any drug candidates for which CEL-SCI obtains marketing approval. The current and future arrangements with healthcare professionals, principal investigators, consultants, potential customers and third-party payors may expose CEL-SCI to broadly applicable healthcare laws, including, without limitation:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation. In addition, the Affordable Care Act provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;

- federal civil and criminal false claims laws, including the federal False Claims Act, which impose criminal and civil penalties, including civil whistleblower actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private), knowingly and willfully embezzling or stealing from a health care benefit program, willfully obstructing a criminal investigation of a healthcare offense and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;

- HIPAA, which also imposes obligations on covered entities, including healthcare providers, health plans, and healthcare clearinghouses, as well as their respective business associates that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- the U.S. federal physicians payment transparency requirements, sometimes called the “Sunshine Act” and its implementing regulations, which requires certain manufacturers of drugs, devices, biologicals and medical supplies that are reimbursable under Medicare, Medicaid, or the Children’s Health Insurance Program to report to the Centers for Medicare & Medicaid Services, or CMS, information related to physician payments and “other transfers of value” to physicians and teaching hospitals (and, beginning in 2021, for transfers of value to other healthcare providers), as well as the ownership and investment interests held by physicians and their immediate family members;

- analogous state and foreign laws, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts;

- the U.S. federal laws that require pharmaceutical manufacturers to report certain calculated product prices to the government or provide certain discounts or rebates to government authorities or private entities, often as a condition of reimbursement under federal healthcare programs; and

- state and foreign laws that govern the privacy and security of health information in certain circumstances, including state security breach notification laws, state health information privacy laws and federal and state consumer protection laws, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that the future business arrangements with third parties will comply with applicable healthcare laws and regulations may involve substantial costs. It is possible that governmental authorities will conclude that the business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws. If CEL-SCI's operations are found to be in violation of any of these laws or any other governmental regulations, CEL-SCI may be subject to significant civil, criminal and administrative penalties, including, without limitation, damages, fines, imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of the operations, all of which could significantly harm CEL-SCI's business. If any of the physicians or other healthcare providers or entities with whom CEL-SCI expects to do business, including current and future collaborators, are found not to be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from participation in government healthcare programs, which could also adversely affect CEL-SCI's business.

Failure to obtain or maintain adequate coverage and reimbursement for the product candidates, if approved, couldlimit the ability to market those products and decrease CEL-SCI's ability to generate revenue.

Sales of CEL-SCI's product candidates will depend substantially, both domestically and abroad, on the extent to which the costs of the approved products will be paid by health maintenance, managed care, pharmacy benefit, and similar healthcare management organizations, or reimbursed by government authorities, private health insurers and other third-party payors. CEL-SCI anticipates that government authorities and other third-party payors will continue efforts to contain healthcare costs by limiting the coverage and reimbursement levels for new drugs and biologics. If coverage and reimbursement are not available, or are available only to limited levels, CEL-SCI may not be able to successfully commercialize its product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow CEL-SCI to establish or maintain pricing sufficient to realize a return on its investment. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for CEL-SCI's product candidates.

Moreover, in some countries, particularly the countries of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, CEL-SCI may be required to conduct a clinical trial that compares the cost-effectiveness of its product candidate to other available therapies. If reimbursement of its products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, CEL-SCI's business could be harmed, possibly materially.

Even if any of CEL-SCI's product candidates receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

If any of CEL-SCI's product candidates receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. If CEL-SCI's product candidates do not achieve an adequate level of acceptance, CEL-SCI may not generate significant product revenues and CEL-SCI may not become profitable. The degree of market acceptance of its product candidates, including Multikine if approved for commercial sale, will depend on a number of factors, including:

- the timing of CEL-SCI's receipt of any marketing approvals;
- the terms of any approvals and the countries in which approvals are obtained;
- the efficacy and safety and potential advantages and disadvantages compared to alternative treatments, including future alternative treatments;
- the prevalence and severity of any side effects associated with CEL-SCI's product candidates;
- the indications for which its products are approved and the scope of risk information required to be included in the product labeling;
- adverse publicity about it's products or favorable publicity about competing products;
- the approval of other products for the same indications as CEL-SCI's products;
- CEL-SCI's ability to offer CEL-SCI's products for sale at competitive prices;
- the convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the success of CEL-SCI's physician education programs;
- the strength of CEL-SCI's marketing and distribution support; and
- the availability of third-party coverage and adequate reimbursement.

If any product candidate CEL-SCI commercializes fails to achieve market acceptance, it could have a material and adverse effect on CEL-SCI's business, financial condition, results of operation and prospects.

CEL-SCI currently has no marketing and sales force. If CEL-SCI is unable to establish effective sales or marketing capabilities or enter into agreements with third parties to sell or market its product candidates, CEL-SCI may not be able to effectively sell or market its product candidates, if approved, or generate product revenues.

CEL-SCI currently has a no sales and marketing infrastructure due to the fact that all of its product candidates are still in clinical development. To achieve commercial success for any approved product candidate for which CEL-SCI retains sales and marketing responsibilities, CEL-SCI must build its sales, marketing, managerial, and other non-technical capabilities or make arrangements with third parties to perform these services. For example, CEL-SCI has entered into agreements with certain foreign distributors to commercialize Multikine, if approved, within their respective territories. However, CEL-SCI may determine that there is a need to building its own sales force in the United States for the future marketing of Multikine, if approved, rather than seeking a U.S. co-marketing partner or relying on a contracted sales force. There are risks involved with either establishing its own sales and marketing capabilities or entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which CEL-SCI recruits a sales force and establishes marketing capabilities is delayed or does not occur for any reason, CEL-SCI would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and its investment would be lost if CEL-SCI cannot retain or reposition its sales and marketing personnel.

Factors that may inhibit CEL-SCI's efforts to commercialize its product candidates on its own include:

- CEL-SCI's inability to recruit, hire, retain and incentivize adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to use and administer CEL-SCI's future products;
- the lack of complementary products to be offered by sales personnel, which may put CEL-SCI at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with establishing an independent sales and marketing organization.

If CEL-SCI does not establish sales and marketing capabilities successfully, either on its own or in collaboration with third parties, CEL-SCI will not be successful in commercializing Multikine, if approved, or any of its other product candidates that receive marketing approval or any such commercialization may experience delays or limitations.

CEL-SCI's business activities may be subject to the Foreign Corrupt Practices Act and similar anti-bribery and anti-corruption laws of other countries in which CEL-SCI operates or will operate in the future.

CEL-SCI has conducted and has ongoing studies in international locations, and may in the future initiate additional studies in countries other than the United States. Moreover, CEL-SCI has entered into agreements with foreign distributors to commercialize Multikine, if approved, in various territories outside of the United States. As a result, CEL-SCI's business activities may be subject to the Foreign Corrupt Practices Act, or FCPA, and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which CEL-SCI operates. The FCPA generally prohibits offering, promising, giving or authorizing others to give anything of value, either directly or indirectly, to a non-U.S. government official in order to influence official action or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls.

CEL-SCI's business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many other countries, the healthcare providers who prescribe biopharmaceuticals are employed by their government, and the purchasers of biopharmaceuticals are government entities; therefore, CEL-SCI's dealings with these prescribers and purchasers are subject to regulation under the FCPA. Recently the SEC and Department of Justice have increased their FCPA enforcement activities with respect to biotechnology and pharmaceutical companies. There is no certainty that all of CEL-SCI's employees, agents or contractors conducting business abroad will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against CEL-SCI, its officers or employees, the closing of CEL-SCI's facilities, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs and prohibitions on the conduct of CEL-SCI's business. Any such violations could include prohibitions on CEL-SCI's ability to offer its product candidates, if approved, in one or more countries and could materially damage its reputation, its brand, its future international marketing efforts, its ability to attract and retain employees and its business, prospects, operating results and financial condition.

Healthcare legislative reform measures may have a material adverse effect on CEL-SCI's business and results of operations.

Existing regulatory policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of CEL-SCI's product candidates. CEL-SCI cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If CEL-SCI is slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if CEL-SCI is not able to maintain regulatory compliance, CEL-SCI may lose any marketing approval that it may have obtained and it may not achieve or sustain profitability.

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs that may result in more limited coverage or downward pressure on the price CEL-SCI may otherwise receive for its product candidates. For example, in March 2010, Congress passed the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the Affordable Care Act, which expanded healthcare coverage through Medicaid expansion and the implementation of the individual mandate for health insurance coverage and which included changes to the coverage and reimbursement of drug products under federal healthcare programs. The ACA contains a number of provisions that affect coverage and reimbursement of drug and biological products and/or that could potentially reduce the demand for pharmaceutical products such as increasing drug rebates under state Medicaid programs for brand name prescription drugs and extending those rebates to Medicaid managed care and assessing a fee on manufacturers and importers of brand name prescription drugs reimbursed under certain government programs, including Medicare and Medicaid. Under the Trump administration, there have been ongoing efforts to modify or repeal all or certain provisions of the ACA. For example, tax reform legislation was enacted at the end of 2017 that eliminates the tax penalty established under the ACA for individuals who do not maintain mandated health insurance coverage beginning in 2019. In a May 2018 report, the Congressional Budget Office estimated that, compared to 2018, the number of uninsured will increase by 3 million in 2019 and 6 million in 2028, in part due to the elimination of the individual mandate. The ACA has also been subject to judicial challenge. In December 2018, a federal district court, in a challenge brought by a number of state attorneys general, found the ACA unconstitutional in its entirety because, once Congress repealed the individual mandate provision, there was no longer a basis to rely on Congressional taxing authority to support enactment of the law. Pending appeals, which could take some time, the ACA is still operational in all respects.

CEL-SCI's industry continues to face potential changes in the legal and regulatory landscape on the federal, state and international levels. Additional legislative actions to control U.S. healthcare or other costs have passed. The Budget Control Act, as amended, resulted in the imposition of 2% reductions in Medicare (but not Medicaid) payments to providers in 2013 and will remain in effect through 2027 unless additional Congressional action is taken. There has also been increasing and considerable public and government interest in the United States with respect to specialty drug pricing practices, including proposed federal and state legislation designed to bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, put in place limits and caps on pharmaceutical prices, request rebates for certain pharmaceutical products, and reform government program reimbursement methodologies for drugs. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what biopharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. In markets outside of the United States, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and control the prices of medicinal products for human use.

CEL-SCI expects that current or future healthcare reform measures may result in more rigorous coverage criteria and in additional downward pressure on the price that it receives for any approved product, including Multikine if it is approved for commercialization. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent CEL-SCI from being able to generate revenue, attain profitability or commercialize its product candidates.

Legislative and regulatory proposals also have been made to expand post-approval requirements and restrict sales and promotional activities for biotechnology products. CEL-SCI cannot be sure whether additional legislative changes will be enacted, or whether FDA regulations, guidance or interpretations for biological products will be changed, or what the impact of such changes on the marketing approvals of its product candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval and decision-making processes may significantly delay or prevent marketing approval, as well as subject CEL-SCI to more stringent product labeling and post-marketing testing and other requirements.

Foreign governments often impose strict price controls, which may adversely affect CEL-SCI's future profitability.

CEL-SCI intends to seek approval to market its lead investigational product, Multikine, in both the United States and foreign jurisdictions. If CEL-SCI obtains approval in one or more foreign jurisdictions, CEL-SCI will be subject to rules and regulations in those jurisdictions relating to Multikine. In some foreign countries, particularly in the European Union, prescription drug pricing is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a drug candidate. Coverage and reimbursement decisions in one foreign jurisdiction may impact decisions in other countries. To obtain reimbursement or pricing approval in some countries, CEL-SCI may be required to conduct clinical trials that demonstrate the product candidate is more effective than current treatments and that compare the cost-effectiveness of Multikine to other available therapies. If reimbursement of Multikine is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, CEL-SCI may be unable to achieve or sustain profitability.

If CEL-SCI fails to comply with environmental, health and safety laws and regulations, CEL-SCI could become subject to fines or penalties or incur costs that could harm its business.

CEL-SCI is subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes generated in its biologic manufacturing facility. CEL-SCI cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from its use of hazardous materials, including radioactive materials used in its research laboratory, CEL-SCI could be held liable for any resulting damages, and the amount of the liability could exceed its resources. CEL-SCI also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

Risks Related to Intellectual Property

CEL-SCI may not be able to achieve or maintain a competitive position, and other technological developments may result in its proprietary technologies becoming uneconomical or obsolete.

CEL-SCI is involved in a biomedical field that is undergoing rapid and significant technological change. The pace of change continues to accelerate. The successful development of product candidates from the compounds, compositions and processes, through research financed by CEL-SCI, or as a result of possible third-party licensing arrangements with pharmaceutical or other companies, is not assured. CEL-SCI may fail to apply for patents on important technologies or product candidates in a timely fashion, or at all.

Many companies are working on drugs designed to cure or treat cancer or cure and treat viruses, such as HPV or H1N1. Many of these companies have financial, research and development, and marketing resources, which are much greater than CEL-SCI's, and are capable of providing significant long-term competition either by establishing in-house research groups or by forming collaborative ventures with other entities. In addition, smaller companies and non-profit institutions are active in research relating to cancer and infectious diseases. The future market share of Multikine or the other product candidates, if approved, will be reduced or eliminated if the competitors develop and obtain approval for products that are safer or more effective than CEL-SCI'S product candidates. Moreover, the patent positions of pharmaceutical companies are highly uncertain and involve complex legal and factual questions for which important legal principles are often evolving and remain unresolved. As a result, the validity and enforceability of patents cannot be predicted with certainty. In addition, CEL-SCI does not know whether:

- CEL-SCI was the first to make the inventions covered by each of its issued patents and pending patent applications;
- CEL-SCI was the first to file patent applications for these inventions;
- others will independently develop similar or alternative technologies or duplicate any of CEL-SCI's technologies;
- any of the pending patent applications will result in issued patents;
- any of the patents will be valid or enforceable;
- any patents issued to CEL-SCI or its collaboration partners will provide CEL-SCI with any competitive advantages, or will be challenged by third parties;
- CEL-SCI will be able to develop additional proprietary technologies that are patentable;
- the U.S. government will exercise any of its statutory rights to CEL-SCI's intellectual property that was developed with government funding; or
- its business may infringe the patents or other proprietary rights of others.

CEL-SCI's patents might not protect its technology from competitors, in which case CEL-SCI may not have any advantage over competitors in selling any products that CEL-SCI may develop.

CEL-SCI's commercial success will depend in part on its ability to obtain additional patents and protect its existing patent position, as well as its ability to maintain adequate intellectual property protection for the technologies, product candidates, and any future products in the United States and other countries. If CEL-SCI does not adequately protect its technology, product candidates and future products, competitors may be able to use or practice them and erode or negate any competitive advantage CEL-SCI may have, which could harm CEL-SCI's business and its ability to achieve profitability. The laws of some foreign countries do not protect the proprietary rights to the same extent or in the same manner as U.S. laws, and CEL-SCI may encounter significant problems in protecting and defending its proprietary rights in these countries. CEL-SCI will be able to protect its proprietary rights from unauthorized use by third parties only to the extent that its proprietary technologies, product candidates and any future products are covered by valid and enforceable patents or are effectively maintained as trade secrets.

Certain aspects of CEL-SCI's technologies are covered by U.S. and foreign patents. In addition, CEL-SCI has a number of new patent applications pending. There is no assurance that the applications still pending or which may be filed in the future will result in the issuance of any patents. Furthermore, there is no assurance as to the breadth and degree of protection any issued patents might afford CEL-SCI. Disputes may arise between CEL-SCI and others as to the scope and validity of these or other patents. Any defense of the patents could prove costly and time consuming and there can be no assurance that CEL-SCI will be in a position, or will deem it advisable, to carry on such a defense. A suit for patent infringement could result in increasing costs, delaying or halting development, or even forcing CEL-SCI to abandon a product candidate. Other private and public concerns, including universities, may have filed applications for, may have been issued, or may obtain additional patents and other proprietary rights to technology potentially useful or necessary to CEL-SCI. CEL-SCI is not currently aware of any such patents, but the scope and validity of such patents, if any, and the cost and availability of such rights are impossible to predict.

Much of CEL-SCI's intellectual property is protected as trade secrets or confidential know-how, not as a patent.

CEL-SCI considers proprietary trade secrets and/or confidential and unpatented know-how to be important to its business. Much of the intellectual property pertains to CEL-SCI'S manufacturing system, certain aspects of which may not be suitable for patent filings and must be protected as trade secrets and/or confidential know-how. This type of information must be protected diligently by CEL-SCI to protect its disclosure to competitors, since legal protections after disclosure may be minimal or non-existent. Accordingly, much of the value of this intellectual property is dependent upon the ability of CEL-SCI to keep its trade secrets and know-how confidential.

To protect this type of information against disclosure or appropriation by competitors, CEL-SCI's policy is to require its employees, consultants, contractors and advisors to enter into confidentiality agreements with CEL-SCI. However, current or former employees, consultants, contractors and advisers may unintentionally or willfully disclose the confidential information to competitors, and confidentiality agreements may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. Enforcing a claim that a third party obtained illegally, and is using, trade secrets and/or confidential know-how is expensive, time consuming and unpredictable. The enforceability of confidentiality agreements may vary from jurisdiction to jurisdiction.

In addition, in some cases a regulator considering the application for product candidate approval may require the disclosure of some or all of the proprietary information. In such a case, CEL-SCI must decide whether to disclose the information or forego approval in a particular country. If CEL-SCI is unable to market its product candidates in key countries, CEL-SCI's opportunities and value may suffer.

Failure to obtain or maintain trade secrets and/or confidential know-how trade protection could adversely affect CEL-SCI'S competitive position. Moreover, competitors may independently develop substantially equivalent proprietary information and may even apply for patent protection in respect of the same. If successful in obtaining such patent protection, competitors could limit the use of such trade secrets and/or confidential know-how.

CEL-SCI may be subject to claims challenging the inventorship or ownership of its patents and other intellectual property.

CEL-SCI may also be subject to claims that former employees, collaborators or other third parties have an ownership interest in its patents or other intellectual property. CEL-SCI may be subject to ownership disputes in the future arising, for example, from conflicting obligations of consultants or others who are involved in developing the product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If CEL-SCI fails in defending any such claims, in addition to paying monetary damages, CEL-SCI may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on its business. Even if CEL-SCI is successful in defending against such claims, litigation could result in substantial costs and be a distraction to CEL-SCI's management and employees.

Risks Related to CEL-SCI's common stock

You may experience future dilution as a result of future equity offerings or other equity issuances.

CEL-SCI expects that significant additional capital will be needed in the future to continue its planned operations. To raise additional capital, CEL-SCI may in the future offer additional shares of its common stock or other securities convertible into or exchangeable for its common stock. To the extent CEL-SCI raises additional capital by issuing equity securities, CEL-SCI's stockholders may experience substantial dilution. These sales may result in material dilution to CEL-SCI's existing stockholders and new investors could gain rights superior to existing stockholders.

CEL-SCI's outstanding options and warrants may adversely affect the trading price of its common stock.

As of September 30, 2019, there were outstanding warrants which allow the holders to purchase 5,772,303 shares of common stock, with a weighted average exercise price of $7.70 per share, and outstanding options which allow the holders to purchase up to 6,218,216 shares of common stock, with a weighted average exercise price of $5.54 per share. The outstanding options and warrants could adversely affect the ability of CEL-SCI to obtain future financing or engage in certain mergers or other transactions, since the holders of options and warrants can be expected to exercise them at a time when CEL-SCI may be able to obtain additional capital through a new offering of securities on terms more favorable to CEL-SCI than the terms of the outstanding options and warrants. For the life of the options and warrants, the holders have the opportunity to profit from a rise in the market price of its common stock without assuming the risk of ownership. The issuance of shares upon the exercise or conversion of outstanding options and warrants will also dilute the ownership interests of CEL-SCI's existing stockholders.

Since CEL-SCI does not intend to pay dividends on its common stock, any potential return to investors will result only from any increases in the price of its common stock.

At the present time, CEL-SCI intends to use available funds to finance its operations. Accordingly, while payment of dividends rests within the discretion of its board of directors, no common stock dividends have been declared or paid by CEL-SCI and CEL-SCI has no intention of paying any common stock dividends in the foreseeable future. Additionally, any future debt financing arrangement may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on CEL-SCI's common stock. Any return to CEL-SCI's shareholders will therefore be limited to appreciation in the price of its common stock, which may never occur. If CEL-SCI's stock price does not increase, CEL-SCI'S shareholders are unlikely to receive any return on their investments in CEL-SCI's common stock.

The price of CEL-SCI's common stock has been volatile and is likely to continue to be volatile, which could result in substantial losses for CEL-SCI's shareholders.

CEL-SCI's stock price has been, and is likely to continue to be, volatile. As a result of this volatility, CEL-SCI's shareholders may not be able to sell their shares at or above its current market price. The market price for CEL-SCI's common stock may be influenced by many factors, including:

- actual or anticipated fluctuations in CEL-SCI's financial condition and operating results;
- actual or anticipated changes in CEL-SCI's growth rate relative to competitors;
- competition from existing products or new products or product candidates that may emerge;
- development of new technologies that may make CEL-SCI's technology less attractive;
- changes in physician, hospital or healthcare provider practices that may make CEL-SCI's product candidates less useful;
- announcements by CEL-SCI, its partners or competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- failure to meet or exceed financial estimates and projections of the investment community or that CEL-SCI provides to the public;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in its financial results or those of companies that are perceived to be similar to CEL-SCI;
- changes to coverage and reimbursement levels by commercial third-party payors and government payors, including Medicare, and any announcements relating to reimbursement levels;
- general economic, industry and market conditions; and
- the other factors described in this "Risk Factors" section.

ITEM 1B. UNRESOLVED SEC COMMENTS

None

ITEM 2. PROPERTIES

CEL-SCI leases office space at 8229 Boone Blvd., Suite 802, Vienna, Virginia at a monthly rental of approximately $8,000. The lease on the office space expires on June 30, 2020. CEL-SCI believes this arrangement is adequate for the conduct of its present business.

CEL-SCI has a 17,900 square foot laboratory located in Baltimore, Maryland. The laboratory is leased by CEL-SCI at a cost of approximately $13,000 per month. The laboratory lease expires on February 28, 2022.

In August 2007, CEL-SCI leased a building near Baltimore, Maryland (the San Tomas lease). 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 3 clinical trial and sales of the drug if approved by the FDA. The lease expires on October 31, 2028 and required annual base rent payments of approximately $1.8 million during the twelve months ended September 30, 2019. The annual base rent escalates each year at 3% beginning on November 1st. CEL-SCI is also required to pay all real and personal property taxes, insurance premiums, maintenance expenses, repair costs and utilities, which were approximately $43,000 per month as of September 30, 2019. The lease allows CEL-SCI, 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. CEL-SCI is not the legal owner of the manufacturing building, but is deemed to be the owner for accounting purposes based on the accounting guidance for build-to-suit leases under ASC 840-40-55. The lease required CEL-SCI to pay $3,150,000 towards the remodeling costs, which is being recouped by reductions in the annual base rent of $303,228 beginning in fiscal year 2014. In August 2011, CEL-SCI was required to deposit $1,670,917, the equivalent of one year of base rent. The $1,670,917 was required to be deposited when the amount of CEL-SCI's cash had dropped below the amount stipulated in the lease and is included in non-current assets at September 30, 2019.

ITEM 3. LEGAL PROCEEDINGS

Not applicable.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. MARKET FOR CEL-SCI'S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS.

As of September 30, 2019, there were approximately 700 record holders of CEL-SCI's common stock. CEL-SCI's common stock is traded on the NYSE American under the symbol "CVM".

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

Quarter Ending	High	Low
12/31/2017	$ 2.14	$ 1.60
3/31/2018	$ 2.50	$ 1.30
6/30/2018	$ 3.66	$ 0.83
9/30/2018	$ 4.44	$ 0.82
12/31/2018	$ 4.39	$ 2.60
3/31/2019	$ 3.55	$ 2.37
6/30/2019	$ 8.99	$ 3.77
9/30/2019	$ 9.93	$ 5.80

Holders of common stock are entitled to receive dividends as may be declared by CEL-SCI's Board of Directors out of legally available funds and, in the event of liquidation, to share pro rata in any distribution of CEL-SCI's assets after payment of liabilities. CEL-SCI's Board of Directors is not obligated to declare a dividend. CEL-SCI has not paid any dividends on its common stock and CEL-SCI does not have any current plans to pay any common stock dividends.

The provisions in CEL-SCI's Articles of Incorporation relating to CEL-SCI's preferred stock allow CEL-SCI's directors to issue preferred stock with rights to multiple votes per share and dividend rights which would have priority over any dividends paid with respect to CEL-SCI's common stock. The issuance of preferred stock with such rights may make more difficult the removal of management even if such removal would be considered beneficial to shareholders generally, and will have the effect of limiting shareholder participation in certain transactions such as mergers or tender offers if such transactions are not favored by incumbent management.

The market price of CEL-SCI's common stock, as well as the securities of other biopharmaceutical and biotechnology companies, have historically been highly volatile, and the market has from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. Factors such as fluctuations in CEL-SCI's operating results, announcements of technological innovations or new therapeutic products by CEL-SCI or its competitors, governmental regulation, developments in patent or other proprietary rights, public concern as to the safety of products which may be developed by CEL-SCI or other biotechnology and pharmaceutical companies, and general market conditions may have a significant effect on the market price of CEL-SCI's common stock.

ITEM 6. SELECTED FINANCIAL DATA

CEL-SCI is a smaller reporting company as defined by Rule 12b-2 of the Securities and Exchange Commission and is not required to provide the information required under this item.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion should be read in conjunction with the financial statements and the related notes thereto appearing elsewhere in this report.

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

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

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

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

Results of Operations

During the year ended September 30, 2019, grant income decreased by approximately $14,000 compared to the year ended September 30, 2018. The income relates to a Phase 2 Small Business Innovation Research (SBIR) grant in the amount of $1.5 million received in September 2017 from the National Institute of Arthritis Muscoskeletal and Skin Diseases, which is part of the National Institutes of Health (NIH). This grant will provide funding to allow CEL-SCI to advance its first LEAPS product candidate, CEL-4000, towards an Investigational New Drug (IND) application, by funding IND enabling studies, and additional mechanism of action studies, among other preclinical development activities.

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

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

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

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

Research and Development Expenses

CEL-SCI's research and development efforts involved Multikine and LEAPS. The table below shows the research and development expenses associated with each project during the reporting periods.

	Year ended September 30,	
	2019	2018
Multikine	$ 11,623,050	$ 10,082,972
LEAPS	1,036,237	831,559
Total research and development	$ 12,659,287	$ 10,914,531

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

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

As explained in Item 1 of this report, CEL-SCI is involved in pre-clinical studies with respect to its LEAPS technology. As with Multikine, CEL-SCI does not know what obstacles it will encounter in future pre-clinical and clinical studies involving its LEAPS technology. Consequently, CEL-SCI cannot predict with any certainty the funds required for future research and clinical trials and the timing of future research and development projects.

Liquidity and Capital Resources

CEL-SCI has had only limited revenues from operations since its inception in March 1983. CEL-SCI has relied upon capital generated from the public and private offerings of its common stock and convertible notes. In addition, CEL-SCI has utilized short-term loans to meet its capital requirements. Capital raised by CEL-SCI has been used to acquire an exclusive worldwide license to use, and later purchase, certain patented and unpatented proprietary technology and know-how relating to the human immunological defense system and for clinical trials. Capital has also been used for patent applications, debt repayment, research and development, administrative costs, and for CEL-SCI's laboratory and manufacturing facilities. CEL-SCI does not anticipate realizing significant revenues until it enters into licensing arrangements regarding its technology and know-how or until it receives regulatory approval to sell its products (which could take a number of years). As a result, CEL-SCI has been dependent upon the proceeds from the sale of its securities to meet all of its liquidity and capital requirements and anticipates having to do so in the future. During fiscal year 2019 and 2018, CEL-SCI raised net proceeds of approximately $14.8 million and $21.4 million, respectively, through a combination of the sale of common stock and the exercise of warrants and options.

In August 2007, CEL-SCI leased a building near Baltimore, Maryland. The building, which consists of approximately 73,000 square feet, has been remodeled in accordance with CEL-SCI's specifications so that it can be used by CEL-SCI to manufacture Multikine for CEL-SCI's Phase III clinical trials and sales of the drug if approved by the FDA. The lease expires on October 31, 2028, and required annual base rent payments of approximately $1.8 million during the twelve months ended September 30, 2019. See Item 2 of this report for more information concerning the terms of this lease.

During the year ended September 30, 2018, note holders converted all outstanding Series MM and Series NN Notes (the Notes) in the principal amount of $2,294,300, into 1,166,105 shares of common stock. During the year ended September 30, 2017, note holders converted Notes in the principal amount of $450,700 into 266,686 shares of common stock. The unamortized debt discount relating to the converted notes was charged to interest expense. These Notes were issued during the year ended September 30, 2017, bore interest at 4% and were originally due on December 22, 2017.

On October 30, 2017, the Company extended the due dates of the Notes from December 22, 2017 to September 21, 20l8, and issued the note holders 583,057 of Series RR Warrants. The Series RR warrants expire on October 30, 2022 and are exercisable at a price of $1.65 per share. As of September 30, 2019, 125,941 Series RR warrants had been exercised for total proceeds of approximately $208,000.

On June 11, 2018, as an inducement to convert the Notes, the Company issued the then outstanding note holders 187,562 Series UU warrants The Series UU warrants are exercisable at a fixed price of $2.80 per share, are exercisable on December 11, 2018 and expire on June 11, 2020. As of September 30, 2019, 32,752 Series UU warrants had been exercised for total proceeds of approximately $92,000.

On December 19, 2017 the Company sold 1,289,478 shares of its common stock at a price of $1.90 per share for total proceeds of approximately $2.45 million. The purchasers of the common stock also received Series SS warrants which allow the purchasers to acquire up to 1,289,478 shares of the Company's common stock. The warrants are exercisable at a fixed price of $2.09 per share, and will expire on December 18, 2022. As of September 30, 2019, 806,834 Series SS warrants had been exercised for total proceeds of approximately $1.7 million.

On February 5, 2018, the Company sold 2,501,145 shares of its common stock at a price of $1.87 per share for total proceeds of approximately $4.7 million. The purchasers of the common stock also received Series TT warrants which allow the purchasers to acquire up to 1,875,860 shares of the Company's common stock. The warrants are exercisable at a fixed price of $2.24 per share, were exercisable on August 6, 2018 and expire on February 5, 2023. As of September 30, 2019, 1,316,171 Series TT Warrants had been exercised for total proceeds of approximately $2.9 million.

On July 2, 2018 the Company issued 3,900,000 registered shares of common stock at a purchase price of $1.30 per share in a registered direct offering. For each share of common stock purchased, the investors received an unregistered Series VV warrant to purchase one share of common stock. The Series VV warrants have an exercise price of $1.75 per share, were exercisable on January 2, 2019 and expire on January 2, 2024. As part of this transaction, the Company also issued 195,000 Series WW warrants to the placement agent. These Series WW warrants have an exercise price of $1.63 per share, were exercisable on January 2, 2019 and expire on July 2, 2023. As of September 30, 2019, 3,817,500 Series VV Warrants had been exercised for total proceeds of approximately $6.7 million and 195,000 Series WW Warrants had been exercised for total proceeds of approximately $317,000.

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

Fiscal Year 2019

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
	6,677,519		$ 14,517,260

Fiscal Year 2018

	Warrants Exercised	Exercise Price	Proceeds
Series S	709,391	$ 1.75	$ 1,241,434
Series GG	200,000	$ 3.00	600,000
Series II	383,500	$ 3.00	1,150,500
Series KK	182,100	$ 3.04	522,674
Series PP	1,577,500	$ 2.30	3,628,250
Series QQ	84,000	$ 2.50	210,000
Series RR	27,687	$ 1.65	45,684
Series SS	328,948	$ 2.09	687,500
Series TT	578,983	$ 2.24	1,296,922
	4,072,109		$ 9,412,964

During the years ended September 30, 2019 and 2018, CEL-SCI entered into Securities Purchase Agreements with Ergomed plc, one of CEL-SCI's Clinical Research Organizations responsible for managing CEL-SCI's Phase 3 clinical trial, to facilitate a partial payment of the amounts due Ergomed. Under the Agreements, CEL-SCI issued Ergomed shares of common stock in payment of amounts CEL-SCI owed Ergomed for providing these services. Upon issuance, CEL-SCI expenses the full value of the shares and subsequently offsets the expense as amounts are realized through the resale by Ergomed and reduces accounts payable to Ergomed. During the year ended September 30, 2019 and 2018, CEL-SCI issued Ergomed 750,000 and 2,260,000 shares, respectively. On December 31, 2018, the expiration date of the prior agreement, Ergomed returned 564,905 unsold shares for cancellation in accordance with the terms of the previous agreement. The following table summarizes the Other Non-Operating Gains (Loss) for the years ended September 30 relating to these agreements:

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

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

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

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

Future Capital Requirements

CEL-SCI's material capital commitments include funding operating losses, funding its research and development program, making required lease payments and repaying convertible notes. For information on employment contracts, see Item 11 of this report.

Further, CEL-SCI has contingent obligations with vendors for work that will be completed in relation to the Phase 3 trial. The timing of these obligations cannot be determined at this time. CEL-SCI estimates it will incur additional expenses of approximately $4.5 million for the remainder of the Phase 3 clinical trial. It should be noted that this estimate is based only on the information currently available in CEL-SCI's contracts with the CROs responsible for managing the Phase 3 clinical trial and does not include other related costs, e.g., the manufacturing of the drug.

CEL-SCI may or may not need to raise additional funds to reach the final read-out of the Phase 3 trial the timing of which depends on when 298 events is reached in the study. However, CEL-SCI will need to raise additional funds, either through the exercise of outstanding warrants/options, through a debt or equity financing or a partnering arrangement, to bring Multikine to market. The ability of CEL-SCI to complete the necessary clinical trials and obtain FDA approval for the sale of products to be developed on a commercial basis is uncertain. However, it is possible that CEL-SCI will not be able to generate enough cash to continue operations at its current level. CEL-SCI's registered independent public accounting firm has issued an audit opinion that includes an explanatory paragraph that expresses substantial doubt about CEL-SCI's ability to continue as a going concern mainly due to continued losses from operations and future liquidity needs of CEL-SCI. CEL-SCI's management has engaged in fundraising for over 20 years and believes that the manner in which it is proceeding will produce the best possible outcome for the shareholders. There can be no assurances that CEL-SCI will be successful in raising additional funds.

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

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

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

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

Critical Accounting Policies

CEL-SCI's significant accounting policies are more fully described in Note 4 to the financial statements included as part of this report. However, certain accounting policies are particularly important to the portrayal of CEL-SCI's financial position and results of operations and require the application of significant judgments by management. As a result, the financial statements are subject to an inherent degree of uncertainty. In applying those policies, management uses its judgment to determine the appropriate assumptions to be used in the determination of certain estimates. These estimates are based on CEL-SCI's historical experience, terms of existing contracts, observance of trends in the industry and information available from outside sources, as appropriate.

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

Share-based Compensation—Share-based compensation cost to employees is measured at fair value as of the grant date in accordance with the provisions of ASC 718. The fair value of the stock options is calculated using the Black-Scholes option pricing model. The Black-Scholes model requires various judgmental assumptions including volatility and expected option life. The compensation cost is recognized as expense over the requisite service or vesting period.

Options to non-employees are accounted for in accordance with ASC 505-50, " *Equity-Based Payments to Non-Employees*." Accordingly, compensation cost is recognized when services are received and is measured using the Black-Scholes valuation model. The Black-Scholes model requires CEL-SCI's management to make assumptions regarding the fair value of the options at the date of grant and the expected life of the options.

Derivative Instruments—CEL-SCI enters into financing arrangements that consist of freestanding derivative instruments or hybrid instruments that contain embedded derivative features. CEL-SCI accounts for these arrangements in accordance with ASC 815, "*Accounting for Derivative Instruments and Hedging Activities*, as well as related interpretations of these standards. In accordance with accounting principles generally accepted in the United States ("GAAP"), derivative instruments and hybrid instruments are recognized as either assets or liabilities in the statement of financial position and are measured at fair value with gains or losses recognized in earnings or other comprehensive income depending on the nature of the derivative or hybrid instruments. Embedded derivatives that are not clearly and closely related to the host contract are bifurcated and recognized at fair value with changes in fair value recognized as either a gain or loss in earnings if they can be reliably measured. When the fair value of embedded derivative features cannot be reliably measured, CEL-SCI measures and reports the entire hybrid instrument at fair value with changes in fair value recognized as either a gain or loss in earnings. CEL-SCI determines the fair value of derivative instruments and hybrid instruments based on available market data using appropriate valuation models, giving consideration to all of the rights and obligations of each instrument and precluding the use of "blockage" discounts or premiums in determining the fair value of a large block of financial instruments. Fair value under these conditions does not necessarily represent fair value determined using valuation standards that give consideration to blockage discounts and other factors that may be considered by market participants in establishing fair value.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISKS

Not applicable.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

See the financial statements included with this report.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

Not applicable

ITEM 9A. CONTROLS AND PROCEDURES

Under the direction and with the participation of CEL-SCI's management, including CEL-SCI's Chief Executive Officer and Chief Financial Officer, CEL-SCI carried out an evaluation of the effectiveness of the design and operation of its disclosure controls and procedures as of September 30, 2019. CEL-SCI maintains disclosure controls and procedures that are designed to ensure that information required to be disclosed in its periodic reports with the Securities and Exchange Commission is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and regulations, and that such information is accumulated and communicated to CEL-SCI's management, including its principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure. CEL-SCI's disclosure controls and procedures are designed to provide a reasonable level of assurance of reaching its desired disclosure control objectives.

Based on this evaluation, CEL-SCI's Chief Executive and Principal Financial Officer has concluded that CEL-SCI's disclosure controls were effective as of September 30, 2019.

Management's Report on Internal Control over Financial Reporting

CEL-SCI's management is responsible for establishing and maintaining adequate internal control over financial reporting and for the assessment of the effectiveness of internal control over financial reporting. As defined by the Securities and Exchange Commission, internal control over financial reporting is a process designed by, or under the supervision of CEL-SCI's principal executive officer and principal financial officer and implemented by CEL-SCI's Board of Directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of CEL-SCI's financial statements in accordance with U.S. generally accepted accounting principles.

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

Geert Kersten, CEL-SCI's Chief Executive and Principal Financial Officer, evaluated the effectiveness of CEL-SCI's internal control over financial reporting as of September 30, 2019 based on criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission, or the COSO Framework. Management's assessment included an evaluation of the design of CEL-SCI's internal control over financial reporting and testing of the operational effectiveness of those controls. Based on the evaluation of our controls and procedures as of September 30, 2019, our Chief Executive Officer and Chief Financial Officer concluded that as of such date, our disclosure controls and procedures were effective. The effectiveness of our internal control over financial reporting as of September 30, 2019 has been audited by BDO USA, LLP, an independent registered public accounting firm, as stated in its report which appears in this Annual Report on Form 10-K.

There was no change in CEL-SCI's internal control over financial reporting that occurred during the fiscal year ended September 30, 2019 that has materially affected, or is reasonably likely to materially affect, CEL-SCI's internal control over financial reporting except as disclosed above.

ITEM 9B. OTHER INFORMATION

None.

ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

Officers and Directors

Name	Age	Position
Geert R. Kersten, Esq.	61	Director, Chief Executive Officer and Treasurer
Patricia B. Prichep	68	Senior Vice President of Operations and Corporate Secretary
Dr. Eyal Talor	63	Chief Scientific Officer
Dr. Daniel H. Zimmerman	78	Senior Vice President of Research, Cellular Immunology
John Cipriano	77	Senior Vice President of Regulatory Affairs
Dr. Peter R. Young	74	Director
Bruno Baillavoine	67	Director
Robert Watson	62	Director

The directors of CEL-SCI serve in such capacity until the next annual meeting of CEL-SCI's shareholders or until their successors have been duly elected and qualified. The officers of CEL-SCI serve at the discretion of CEL-SCI's directors.

All of CEL-SCI's directors have served as directors for a significant period of time. Consequently, their long-standing experience with CEL-SCI benefits both CEL-SCI and its shareholders.

The principal occupations of CEL-SCI's officers and directors, during the past several years, are as follows:

Geert Kersten has served in his current leadership role at CEL-SCI since 1995. Mr. Kersten has been with CEL-SCI since 1987. He has been involved in the pioneering field of cancer immunotherapy for over two decades and has successfully steered CEL-SCI through many challenging cycles in the biotechnology industry. Mr. Kersten also provides CEL-SCI with significant expertise in the fields of finance and law and has a unique vision of how CEL-SCI's Multikine product could potentially change the way cancer is treated. Prior to joining CEL-SCI, Mr. Kersten worked at the law firm of Finley & Kumble and worked at Source Capital, an investment banking firm located in McLean, VA. He is a native of Germany, graduated from high school in England, and completed his studies in the US. Mr. Kersten received his Undergraduate Degree in Accounting and an M.B.A. from George Washington University, and a law degree (J.D.) from American University in Washington, DC.

Patricia B. Prichep joined CEL-SCI in 1992 and has been CEL-SCI's Senior Vice President of Operations since March 1994. Between December 1992 and March 1994, Ms. Prichep was CEL-SCI's Director of Operations. Ms. Prichep became CEL-SCI's Corporate Secretary in May 2000. She is responsible for all day-to-day operations of CEL-SCI, including human resources and is the liaison with CEL-SCI's independent registered public accounting firm for financial reporting. From June 1990 to December 1992, Ms. Prichep was the Manager of Quality and Productivity for the NASD's Management, Systems and Support Department and was responsible for the internal auditing and work flow analysis of operations. Between 1982 and 1990, Ms. Prichep was Vice President and Operations Manager for Source Capital, Ltd. She handled all operations and compliance for Source Capital and was licensed as a securities broker. Ms. Prichep received her B.A. from the University of Bridgeport in Connecticut.

Eyal Talor, Ph.D. joined CEL-SCI in October 1993. In October 2009, Dr. Talor was promoted to Chief Scientific Officer. Prior to this promotion, Dr. Talor was the Senior Vice President of Research and Manufacturing. He is a clinical immunologist with over 25 years of hands-on management of clinical research and drug development for immunotherapy application; pre-clinical to Phase III, in the biopharmaceutical industry. His expertise includes; biopharmaceutical R&D and Biologics product development, GMP (Good Manufacturing Practices) manufacture, Quality Control testing, and the design and building of GMP manufacturing and testing facilities. He served as Director of Clinical Laboratories (certified by the State of Maryland) and has experience in the design of pre-clinical and clinical trials (Phase I – III) and GCP (Good Clinical Practices) requirements. He also has broad experience in the different aspects of biological assay development, analytical methods validation, raw material specifications, and QC (Quality Control) tests development under FDA/GMP, USP, and ICH guidelines. He has extensive experience in the preparation of documentation for IND and other regulatory submissions. His scientific area of expertise encompasses immune response assessment. He is the author of over 25 publications and has published a number of reviews on immune regulations in relation to clinical immunology. Before coming to CEL-SCI, he was Director of R&D and Clinical Development at CBL, Inc., Principal Scientist - Project Director, and Clinical Laboratory Director at SRA Technologies, Inc. Prior to that he was a full time faculty member at The Johns Hopkins University, Medical Institutions; School of Public Health. He has invented technologies which are covered by ten issued patents on Multikine's composition of matter and method of use in cancer and two platform Peptide technologies, Antigen Directed Apoptosis of T-cells ('Adapt') and LEAPS, for the treatment of autoimmune diseases, asthma, allergy, transplantation rejection and infectious diseases. He also is responsible for numerous product and process inventions as well as a number of pending US and PCT patent applications. He received his Ph.D. in Microbiology and Immunology from the University of Ottawa, Ottawa, Ontario, Canada, and had post-doctoral training in clinical and cellular immunology at The Johns Hopkins University, Baltimore, Maryland, USA. He holds an Associate teaching position at the Johns Hopkins University Medical Institutions.

Daniel H. Zimmerman, Ph.D., was CEL-SCI's Senior Vice President of Cellular Immunology between 1996 and December 2008 and again since November 2009. He joined CEL-SCI in January 1996 as the Vice President of Research, Cellular Immunology. Dr. Zimmerman founded CELL-MED, Inc. and was its president from 1987-1995. From 1973-1987, Dr. Zimmerman served in various positions at Electronucleonics, Inc. His positions included: Scientist, Senior Scientist, Technical Director and Program Manager. Dr. Zimmerman held various teaching positions at Montgomery College between 1987 and 1995. Dr. Zimmerman has invented technologies which are covered by over a dozen US patents as well as many foreign equivalent patents. He is the author of over 40 scientific publications in the area of immunology and infectious diseases. He has been awarded numerous grants from NIH and DOD. From 1969-1973, Dr. Zimmerman was a Senior Staff Fellow at NIH. For the following 25 years, he continued on at NIH as a guest worker. Dr. Zimmerman received a Ph.D. in Biochemistry in 1969, and a Masters in Zoology in 1966 from the University of Florida as well as a B.S. in Biology from Emory and Henry College in 1963.

John Cipriano, was CEL-SCI's Senior Vice President of Regulatory Affairs between March 2004 and December 2008 and again since October 2009. Mr. Cipriano brings to CEL-SCI over 30 years of experience with both biotech and pharmaceutical companies. In addition, he held positions at the United States Food and Drug Administration (FDA) as Deputy Director, Division of Biologics Investigational New Drugs, Office of Biologics Research and Review and was the Deputy Director, IND Branch, Division of Biologics Evaluation, Office of Biologics. Mr. Cipriano completed his B.S. in Pharmacy from the Massachusetts College of Pharmacy in Boston, Massachusetts and his M.S. in Pharmaceutical Chemistry from Purdue University in West Lafayette, Indiana.

Peter R. Young, Ph.D. has been a Director of CEL-SCI since August 2002. Dr. Young has been a senior executive within the pharmaceutical industry in the United States and Canada for most of his career, originally in organizations that are now part of Sanofi S.A. Over the last 20 years he has primarily held positions of Chief Executive Officer or Chief Financial Officer and has extensive experience with acquisitions and equity financing. Since November 2001, Dr. Young has been the President of Agnus Dei, LLC, which has acted as a partner in an organization managing immune system clinics which treats patients with diseases such as cancer, multiple sclerosis and hepatitis. Dr. Young was also the President and Chief Executive Officer of SRL Technology, Inc., a company involved in the development of pharmaceutical drug delivery systems. Between 1998 and 2001, Dr. Young was the Chief Financial Officer of Adams Laboratories, Inc., the developer of Mucinex®. Dr. Young received his Ph.D. in Organic Chemistry from the University of Bristol, England after obtaining his Bachelor's degree in Honors Chemistry, Mathematics and Economics. Subsequently, he qualified as a Fellow of the Chartered Institute of Management Accountants.

Bruno Baillavoine joined CEL-SCI's board of directors in June 2015. Since 2017 Mr. Baillavoine has been the Director, Head of Pericles Group UK the subsidiary of the Paris based leading French consulting firm, Pericles Consulting Holdings SAS. Pericles is an expert in the field of Banking, Finance, Asset Management and Insurance with over 350 institutional clients. He has also been an advisor to the Board of CSL Inc, Combatives Sports League a US Mix Martial Arts company since 2017 and was appointed to the board in 2019. Between 2010-2016, Mr. Baillavoine was a partner of Globomass Holdings Limited, a London, England based developer of renewable energy projects from concept through final operations. From 2012-2016 Mr. Baillavoine was the Executive Chairman of Globomass Holdings. Globomass was acquired by CleanBay Inc. in 2016. Mr. Baillavoine remains a significant shareholder in CleanBay Inc. Between 1978 and 1982 he was the marketing manager of Ravenhead Ltd., a manufacturer of glass tableware, and part of United Distillers Group (later acquired by Grand Metropolitan). During this time Mr. Baillavoine became the UK Business Manager where he restored market share and profit for United Distillers. From 1982 to 1986 Mr. Baillavoine was Group Corporate Planning and Group Marketing Director for Prontaprint where he expanded the number of shops to 500 locations in four years. Mr. Baillavoine joined Grand Metropolitan Plc between 1986-1988 (now Diageo Plc), an FTSE 100 beverage, food, hotel and leisure company, as director in the Special Operations division. In this capacity, he developed plans for Grand Met's trouble-shooting division for over 20,000 Grand Met retail outlets. From 1988-1991 he was the Managing Director of Nutri Systems (UK) Ltd., a subsidiary of the US based provider of professionally supervised weight loss programs. Between 1991 and 1995, Mr. Baillavoine was Director of BET Group plc, a multinational business support services group, and in 1992, was promoted to the Managing Director for the manufacturing businesses. The £2.3 billion turnaround of BET during his tenure is one of the most successful turnarounds of a top 100 FTSE company. Since 1995, Mr. Baillavoine has held a number of CEO positions across a wide range of industries and geographical locations. Mr. Baillavoine has European and American educations (US high school and University of Wisconsin Eau Claire 1972-1976).

Robert Watson has been a director of CEL-SCI since December 2017. Mr. Watson is the President and CEO of Juvare, LLC (formerly Intermedix, Inc.) since July 2017 . Immediately prior to joining Intermedix, now Juvare, he was the President and Chief Growth Officer of NantHealth, Inc. (Nasdaq: NH) from January 2015 to May 2017. Prior to NantHealth, he was President and CEO of Streamline Health, Inc. (Nasdaq: STRM) from January 2011 to January 2015. Mr. Watson has over 35 years of experience in the healthcare information technology industry as a CEO, board member and advisor to multiple healthcare information technology companies. He has participated in over 75 acquisitions, raised nearly $750 million in capital, completed three public offerings and successfully sold four companies. Mr. Watson holds a MBA from the Wharton School of Business at the University of Pennsylvania and a BA degree from Syracuse University.

All of CEL-SCI's officers devote substantially all of their time to CEL-SCI's business.

CEL-SCI's Board of Directors does not have a "leadership structure", as such, since each director is entitled to introduce resolutions to be considered by the Board and each director is entitled to one vote on any resolution considered by the Board. CEL-SCI's Chief Executive Officer is not the Chairman of CEL-SCI's Board of Directors.

CEL-SCI's Board of Directors has the ultimate responsibility to evaluate and respond to risks facing CEL-SCI. CEL-SCI's Board of Directors fulfills its obligations in this regard by meeting on a regular basis and communicating, when necessary, with CEL-SCI's officers.

Dr. Peter R. Young, Bruno Baillavoine and Robert Watson are independent directors as that term is defined in section 803 of the listing standards of the NYSE American.

CEL-SCI has adopted a Code of Ethics which is applicable to CEL-SCI'S principal executive, financial, and accounting officers and persons performing similar functions. The Code of Ethics is available on CEL-SCI's website, located at *www.cel-sci.com.*

If a violation of this code of ethics act is discovered or suspected, any person (anonymously, if desired) may send a detailed note, with relevant documents, to CEL-SCI's Audit Committee, c/o Dr. Peter Young, 208 Hewitt Drive, Suite 103-143, Waco, TX 76712**.**

For purposes of electing directors at its annual meeting, CEL-SCI has a nominating committee that is made up of CEL-SCI's independent directors. The nominating committee selects the nominees to the Board of Directors and they are approved by CEL-SCI's shareholders.

CEL-SCI does not have any policy regarding the consideration of director candidates recommended by shareholders and under Colorado law, any shareholder can nominate a person for election as a director at the annual shareholders' meeting. However, CEL-SCI's Board of Directors will consider candidates recommended by shareholders. To submit a candidate for the Board of Directors the shareholder should send the name, address and telephone number of the candidate, together with any relevant background or biographical information, to CEL-SCI's Chief Executive Officer, at the address shown on the cover page of this report. The Board has not established any specific qualifications or skills a nominee must meet to serve as a director. Although the Board does not have any process for identifying and evaluating director nominees, the Board does not believe there would be any differences in the manner in which the Board evaluates nominees submitted by shareholders as opposed to nominees submitted by any other person.

CEL-SCI does not have a policy with regard to Board member's attendance at annual meetings. All Board members attended the last annual shareholder's meeting held on May 20, 2019.

Holders of CEL-SCI's common stock can send written communications to CEL-SCI's entire Board of Directors, or to one or more Board members, by addressing the communication to "the Board of Directors" or to one or more directors, specifying the director or directors by name, and sending the communication to CEL-SCI's offices in Vienna, Virginia. Communications addressed to the Board of Directors as whole will be delivered to each Board member. Communications addressed to a specific director (or directors) will be delivered to the director (or directors) specified.

A security holder communication not sent to the Board of Directors as a whole are not relayed to Board members which did not receive the communication.

ITEM 11.EXECUTIVE COMPENSATION

Components of Compensation — Executive Officers

CEL-SCI's executive officers are compensated through the following three components:

- Base Salary
- Long-Term Incentives ("LTIs") (stock options and/or grants of stock)
- Benefits

These components provide a balanced mix of base compensation and compensation that is contingent upon each executive officer's individual performance. A goal of the compensation program is to provide executive officers with a reasonable level of security through base salary and benefits. CEL-SCI wants to ensure that the compensation programs are appropriately designed to encourage executive officer retention and motivation to create shareholder value. The Compensation Committee believes that CEL-SCI's stockholders are best served when CEL-SCI can attract and retain talented executives by providing compensation packages that are competitive but fair.

Base Salaries

Base salaries generally have been targeted to be competitive when compared to the salary levels of persons holding similar positions in other pharmaceutical companies and other publicly traded companies of comparable size. Each executive officer's respective responsibilities, experience, expertise and individual performance are considered.

A further consideration in establishing compensation for the senior employees is their long term history with CEL-SCI. Taken into consideration are factors that have helped CEL-SCI survive in times when it was financially weak, such as: willingness to accept salary cuts, willingness not to be paid at all for extended time periods, and in general an attitude that helped CEL-SCI survive during financially difficult times.

Long-Term Incentives

Stock grants and option grants help to align the interests of CEL-SCI's employees with those of its shareholders. Options and stock grants are made under CEL-SCI's Stock Option, Incentive Stock Bonus, Stock Bonus and Stock Compensation Plans. Options are granted with exercise prices equal to the closing price of CEL-SCI's common stock on the day immediately preceding the date of grant, with pro rata vesting at the end of each of the following three years.

CEL-SCI believes that grants of equity-based compensation:

- Enhance the link between the creation of shareholder value and long-term executive incentive compensation;
- Provide focus, motivation and retention incentive; and
- Provide competitive levels of total compensation.

Benefits

In addition to cash and equity compensation programs, executive officers participate in the health and welfare benefit programs available to other employees. In a few limited circumstances, CEL-SCI provides other benefits to certain executive officers, such as car allowances.

All executive officers are eligible to participate in CEL-SCI's 401(k) plan on the same basis as its other employees. CEL-SCI matches 100% of each employee's contribution up to 6% of his or her salary.

The following table sets forth in summary form the compensation received by (i) the Chief Executive and Financial Officer of CEL-SCI and (ii) by each other executive officer of CEL-SCI who received in excess of $100,000 during the two fiscal years ended September 30, 2019.

Name and Principal Position	Fiscal Year	Salary (1)	Bonus (2)	Stock Awards (3)	Option Awards (4)	All Other Compensation (5)	Total
		$	$	$	$	$	$
Geert R. Kersten,	2019	511,387	--	16,500	3,922,841	55,631	4,506,359
Chief Executive	2018	557,756	--	16,350	1,011,048	55,631	1,640,784
Officer and Treasurer							
Patricia B. Prichep,	2019	285,964	--	14,679	1,956,794	9,031	2,266,467
Senior Vice President	2018	162,374	--	14,679	424,557	9,031	610,641
of Operations and Secretary							
Eyal Talor, Ph.D.,	2019	370,355	--	9,600	1,846,231	6,031	2,232,217
Chief Scientific Officer	2018	264,927	--	9,600	681,389	6,031	961,946
Daniel Zimmerman, Ph.D.,	2019	243,551	--	13,666	1,020,094	6,031	1,283,341
Senior Vice President of	2018	276,159	--	13,666	240,677	6,031	536,534
Research, Cellular Immunology							
John Cipriano,	2019	202,651	--	--	998,005	31	1,200,686
Senior Vice President of	2018	234,207	--	--	282,928	31	517,166
Regulatory Affairs							

(1) The dollar value of base salary (cash and non-cash) earned. Each of these officers have accepted to take less than their actual salary for the stated years above. As of September 30, 2019, CEL-SCI owed back salaries to the following employees:

Name	Salary
Geert Kersten	$ 196,546
Patricia Prichep	114,918
Eyal Talor, Ph.D.	4,796
Daniel Zimmerman, Ph.D.	5,194
John Cipriano	17,811

(2) The dollar value of bonus (cash and non-cash) earned.

(3) For all persons listed in the table, the shares were issued as CEL-SCI's contribution on behalf of the named officer who participates in CEL-SCI's 401(k) retirement plan. The value of all stock awarded during the periods covered by the table is calculated according to ASC 718-10-30-3 which represented the grant date fair value.

(4) The fair value of all stock options granted during the periods covered by the table are calculated on the grant date in accordance with ASC 718-10-30-3 which represented the grant date fair value.

(5) All other compensation received that CEL-SCI could not properly report in any other column of the table including the dollar value of any insurance premiums paid by, or on behalf of, CEL-SCI with respect to term life insurance for the benefit of the named executive officer and car allowances paid by CEL-SCI. Includes board of directors fees for Mr. Kersten.

Employee Pension, Profit Sharing or Other Retirement Plans

CEL-SCI has a defined contribution retirement plan, qualifying under Section 401(k) of the Internal Revenue Code and covering substantially all CEL-SCI's employees. CEL-SCI's contribution to the plan is made in shares of CEL-SCI's common stock. Each participant's contribution is matched by CEL-SCI with shares of common stock which have a value equal to 100% of the participant's contribution, not to exceed the lesser of $1,000 or 6% of the participant's total compensation. CEL-SCI's contribution of common stock is valued each quarter based upon the closing price of its common stock. The fiscal 2019 expenses for this plan were approximately $148,000 Other than the 401(k) Plan, CEL-SCI does not have a defined benefit, pension plan, profit sharing or other retirement plan.

Compensation of Directors During Year Ended September 30, 2019

Name	Fees	Stock Awards (1)	Option Awards (2)	Total
Geert Kersten	$ 40,000	-	3,922,841	$ 3,962,841
Peter R. Young	50,000	-	771,852	821,852
Bruno Baillavoine	45,000	-	771,852	816,852
Robert Watson	45,000	-	771,852	816,852

(1) The fair value of stock issued for services.

(2) The fair value of options granted computed in accordance with ASC 718-10-30-3 on the date of grant which represents their grant date fair value.

Directors' fees paid to Geert Kersten are included in the Executive Compensation table.

Employment Contracts

Geert Kersten

On August 31, 2019, CEL-SCI entered into a four-year employment agreement with Geert Kersten, CEL-SCI's Chief Executive Officer. The employment agreement with Mr. Kersten, which is essentially the same as Mr. Kersten's prior employment agreement, as amended on August 30, 2016, provided that, during the term of the agreement, CEL-SCI would pay Mr. Kersten an annual salary of $559,052, plus any increases in proportion to salary increases granted to other senior executive officers of CEL-SCI, as well any increases approved by the Board of Directors during the term of the employment agreement.

During the employment term, Mr. Kersten will be entitled to receive any other benefits which are provided to CEL-SCI's executive officers or other full time employees in accordance with CEL-SCI's policies and practices and subject to Mr. Kersten's satisfaction of any applicable conditions of eligibility.

If Mr. Kersten resigns within ninety (90) days of the occurrence of any of the following events: (i) a reduction in Mr. Kersten's salary (ii) a relocation (or demand for relocation) of Mr. Kersten's place of employment to a location more than ten (10) miles from his current place of employment, (iii) a significant and material reduction in Mr. Kersten's authority, job duties or level of responsibility or the imposition of significant and material limitations on the Mr. Kersten's autonomy in his position, or (iv) a Change in Control, then the employment agreement will be terminated and Mr. Kersten will be entitled to receive a lump-sum payment from CEL-SCI equal to 24 months of salary ($1,118,104) and the unvested portion of any stock options would vest immediately. For purposes of the employment agreement a change in the control of CEL-SCI means: (1) the merger of CEL-SCI with another entity if after such merger the shareholders of CEL-SCI do not own at least 50% of voting capital stock of the surviving corporation; (2) the sale of substantially all of the assets of CEL-SCI; (3) the acquisition by any person of more than 50% of CEL-SCI's common stock; or (4) a change in a majority of CEL-SCI's directors which has not been approved by the incumbent directors.

The employment agreement will also terminate upon the death of Mr. Kersten or Mr. Kersten's physical or mental disability. If the employment agreement is terminated for any of these reasons, Mr. Kersten, or his legal representatives, as the case may be, will be paid the salary provided by the employment agreement through the date of termination, any options or bonus shares of CEL-SCI then held by Mr. Kersten will become fully vested and the expiration date of any options which would expire during the four year period following his termination of employment will be extended to the date which is four years after his termination of employment. The employment agreement will also terminate upon the willful misconduct, an act of fraud against CEL-SCI, or a breach of the employment agreement by Mr. Kersten, in which case Mr. Kersten will be paid the salary provided by the employment agreement through the date of termination.

Patricia B. Prichep / Eyal Talor, Ph.D.

On August 31, 2019, CEL-SCI entered into a three-year employment agreement with Patricia B. Prichep, CEL-SCI's Senior Vice President of Operations. The employment agreement with Ms. Prichep, which is essentially the same as Ms. Prichep's prior employment agreement entered into on August 30, 2016 provided that, during the term of the agreement, CEL-SCI would pay Ms. Prichep an annual salary of $245,804 plus any increases approved by the Board of Directors during the period of the employment agreement.

On August 31, 2019, CEL-SCI entered into a three-year employment agreement with Eyal Talor, Ph.D., CEL-SCI's Chief Scientific Officer. The employment agreement with Dr. Talor, which is essentially the same as Dr. Talor's prior employment agreement entered into on August 30, 2016, provided that, during the term of the agreement, CEL-SCI would pay Dr. Talor an annual salary of $303,453 plus any increases approved by the Board of Directors during the period of the employment agreement.

If Ms. Prichep or Dr. Talor resigns within ninety (90) days of the occurrence of any of the following events: (i) a relocation (or demand for relocation) of employee's place of employment to a location more than ten (10) miles from the employee's current place of employment, (ii) a significant and material reduction in the employee's authority, job duties or level of responsibility or (iii) the imposition of significant and material limitations on the employee's autonomy in her or his position, the employment agreement will be terminated and the employee will be paid the salary provided by the employment agreement through the date of termination and the unvested portion of any stock options held by the employee will vest immediately.

In the event there is a change in the control of CEL-SCI, the employment agreements with Ms. Prichep and Dr. Talor allow Ms. Prichep and/or Dr. Talor (as the case may be) to resign from her or his position at CEL-SCI and receive a lump-sum payment from CEL-SCI equal to 18 months of salary ($368,706 and $455,180 respectively). In addition, the unvested portion of any stock options held by the employee will vest immediately. For purposes of the employment agreements, a change in the control of CEL-SCI means: (1) the merger of CEL-SCI with another entity if after such merger the shareholders of CEL-SCI do not own at least 50% of voting capital stock of the surviving corporation; (2) the sale of substantially all of the assets of CEL-SCI; (3) the acquisition by any person of more than 50% of CEL-SCI's common stock; or (4) a change in a majority of CEL-SCI's directors which has not been approved by the incumbent directors.

The employment agreements with Ms. Prichep and Dr. Talor will also terminate upon the death of the employee, the employee's physical or mental disability, willful misconduct, an act of fraud against CEL-SCI, or a breach of the employment agreement by the employee. If the employment agreement is terminated for any of these reasons the employee, or her or his legal representatives, as the case may be, will be paid the salary provided by the employment agreement through the date of termination.

Compensation Committee Interlocks and Insider Participation

CEL-SCI has a compensation committee comprised of Mr. Bruno Baillavoine, Dr. Peter Young and Mr. Robert Watson, all of whom are independent directors.

During the year ended September 30, 2019, no director of CEL-SCI was also an executive officer of another entity, which had an executive officer of CEL-SCI serving as a director of such entity or as a member of the compensation committee of such entity.

Stock Option, Bonus and Compensation Plans

CEL-SCI has Incentive Stock Option Plans, Non-Qualified Stock Option Plans, Stock Bonus Plans, Stock Compensation Plans and an Incentive Stock Bonus Plan. All Stock Option, Bonus and Compensation Plans have been approved by the stockholders. A summary description of these Plans follows. In some cases these Plans are collectively referred to as the "Plans".

Incentive Stock Option Plan. The Incentive Stock Option Plans authorize the issuance of shares of CEL-SCI's common stock to persons who exercise options granted pursuant to the Plans. Only CEL-SCI's employees may be granted options pursuant to the Incentive Stock Option Plans.

Options may not be exercised until one year following the date of grant. Options granted to an employee then owning more than 10% of the common stock of CEL-SCI may not be exercisable by its terms after five years from the date of grant. Any other option granted pursuant to the Plans may not be exercisable by its terms after ten years from the date of grant.

The purchase price per share of common stock purchasable under an option is determined by the CEL-SCI's Compensation Committee but cannot be less than the fair market value of the common stock on the date of the grant of the option (or 110% of the fair market value in the case of a person owning more than 10% of CEL-SCI's outstanding shares).

Non-Qualified Stock Option Plans. The Non-Qualified Stock Option Plans authorize the issuance of shares of CEL-SCI's common stock to persons that exercise options granted pursuant to the Plans. CEL-SCI's employees, directors, officers, consultants and advisors are eligible to be granted options pursuant to the Plans, provided however that bona fide services must be rendered by such consultants or advisors and such services must not be in connection with a capital-raising transaction or promoting CEL-SCI's common stock. The option exercise price is determined by CEL-SCI's Compensation Committee.

Stock Bonus Plan. Under the Stock Bonus Plans shares of CEL-SCI's common stock may be issued to CEL-SCI's employees, directors, officers, consultants and advisors, provided however that bona fide services must be rendered by consultants or advisors and such services must not be in connection with a capital-raising transaction or promoting CEL-SCI's common stock.

Stock Compensation Plan. Under the Stock Compensation Plan, shares of CEL-SCI's common stock may be issued to CEL-SCI's employees, directors, officers, consultants and advisors in payment of salaries, fees and other compensation owed to these persons. However, bona fide services must be rendered by consultants or advisors and such services must not be in connection with a capital-raising transaction or promoting CEL-SCI's common stock.

Incentive Stock Bonus Plan. Under the 2014 Incentive Stock Bonus Plan, shares of CEL-SCI's common stock may be issued to executive officers and other employees who contribute significantly to the success of CEL-SCI, to participate in its future prosperity and growth and aligns their interests with those of CEL-SCI's shareholders. The purpose of the Plan is to provide long term incentive for outstanding service to CEL-SCI and its shareholders and to assist in recruiting and retaining people of outstanding ability and initiative in executive and management positions.

Other Information Regarding the Plans. The Plans are administered by CEL-SCI's Compensation Committee ("the Committee"), each member of which is a director of CEL-SCI. The members of the Committee were selected by CEL-SCI's Board of Directors and serve for a one-year tenure and until their successors are elected. A member of the Committee may be removed at any time by action of the Board of Directors. Any vacancies which may occur on the Committee will be filled by the Board of Directors. The Committee is vested with the authority to interpret the provisions of the Plans and supervise the administration of the Plans. In addition, the Committee is empowered to select those persons to whom shares or options are to be granted, to determine the number of shares subject to each grant of a stock bonus or an option and to determine when, and upon what conditions, shares or options granted under the Plans will vest or otherwise be subject to forfeiture and cancellation.

In the discretion of the Committee, any option granted pursuant to the Plans may include installment exercise terms such that the option becomes fully exercisable in a series of cumulating portions. The Committee may also accelerate the date upon which any option (or any part of any options) is first exercisable. Any shares issued pursuant to the Stock Bonus Plans or Stock Compensation Plan and any options granted pursuant to the Incentive Stock Option Plans or the Non-Qualified Stock Option Plans will be forfeited if the "vesting" schedule established by the Committee administering the Plans at the time of the grant is not met. For this purpose, vesting means the period during which the employee must remain an employee of CEL-SCI or the period of time a non-employee must provide services to CEL-SCI. At the time an employee ceases working for CEL-SCI (or at the time a non-employee ceases to perform services for CEL-SCI), any shares or options not fully vested will be forfeited and cancelled. At the discretion of the Committee payment for the shares of common stock underlying options may be paid through the delivery of shares of CEL-SCI's common stock having an aggregate fair market value equal to the option price, provided such shares have been owned by the option holder for at least one year prior to such exercise. A combination of cash and shares of common stock may also be permitted at the discretion of the Committee.

Options are generally non-transferable except upon death of the option holder. Shares issued pursuant to the Stock Bonus Plans will generally not be transferable until the person receiving the shares satisfies the vesting requirements imposed by the Committee when the shares were issued.

The Board of Directors of CEL-SCI may at any time, and from time to time, amend, terminate, or suspend one or more of the Plans in any manner it deems appropriate, provided that such amendment, termination or suspension will not adversely affect rights or obligations with respect to shares or options previously granted.

Stock Options

The following table show information concerning the options granted during the fiscal year ended September 30, 2019, to the persons named below:

Options Granted

Name	Grant Date	Options Granted	Price Per Share	Expiration Date
Geert Kersten	4/11/2019	813,180	$ 5.65	4/10/2029
Patricia Prichep	4/11/2019	405,631	$ 5.65	4/10/2029
Eyal Talor	4/11/2019	382,712	$ 5.65	4/10/2029
John Cipriano	4/11/2019	206,880	$ 5.65	4/10/2029
Dan Zimmerman	4/11/2019	211,459	$ 5.65	4/10/2029
Bruno Baillavoine	4/11/2019	160,000	$ 5.65	4/10/2029
Peter Young	4/11/2019	160,000	$ 5.65	4/10/2029
Robert Watson	4/11/2019	160,000	$ 5.65	4/10/2029

The following table shows the outstanding options held by the persons named below on September 30, 2019:

Name	Shares underlying unexercised Option which are: Exercisable	Unexercisable	Exercise Price	Expiration Date
Geert R. Kersten	1,200		120.00	07/20/20
	1,200		172.50	04/14/21
	1,800		97.50	05/17/22
	15,752	4,248	70.00	12/17/22
	1,800		52.50	06/30/23
	3,600		27.25	02/25/24
	120,000	60,000	2.18	07/27/27
	176,708	353,413	2.45	04/30/28
		813,180	5.65	04/10/29
Patricia B. Prichep	600		120.00	07/20/20
	600		172.50	04/14/21
	1,200		97.50	05/17/22
	6,000		70.00	12/17/22
	1,200		52.50	06/30/23
	2,400		27.25	02/25/24
	80,000	40,000	2.18	07/27/27
	74,203	148,404	2.45	04/30/28
		405,631	5.65	04/10/29
Eyal Talor, Ph.D	600		120.00	07/20/20
	600		172.50	04/14/21
	1,200		97.50	05/17/22
	6,000		70.00	12/17/22
	1,200		52.50	06/30/23
	2,400		27.25	02/25/24
	80,000	40,000	2.18	07/27/27
	64,645	129,289	2.45	04/30/28
	33,334	66,666	3.55	09/20/28
		382,712	5.65	04/10/29
Daniel Zimmerman, Ph.D	600		120.00	07/20/20
	600		172.50	04/14/21
	900		97.50	05/17/22
	900		52.50	06/30/23
	1,800		27.25	02/25/24
	8,000		27.50	08/05/24
	4,000		15.50	06/25/25
	4,000		11.75	07/21/26
	4,000	2,000	1.87	06/28/27
	13,334	6,666	1.59	09/17/27
	42,066	84,128	2.45	04/30/28
		211,459	5.65	04/10/29
John Cipriano	600		120.00	07/20/20
	600		172.50	04/14/21
	900		97.50	05/17/22
	900		57.50	06/30/23
	1,800		27.25	02/25/24
	60,000	30,000	2.18	07/27/27
	49,449	98,898	2.45	04/30/28
		206,880	5.65	04/10/29

Summary. The following shows certain information as of September 30, 2019 concerning the stock options and stock bonuses granted by CEL-SCI. Each option represents the right to purchase one share of CEL-SCI's common stock.

Name of Plan	Total Shares Reserved Under Plans	Shares Reserved for Outstanding Options	Shares Issued	Remaining Options/Shares Under Plans
Incentive Stock Option Plans	138,400	89,895	N/A	213
Non-Qualified Stock Option Plans	6,387,200	6,128,321	N/A	112,166
Stock Bonus Plans	783,760	N/A	331,226	452,501
Stock Compensation Plan	634,000	N/A	130,183	485,407
Incentive Stock Bonus Plan	640,000	N/A	616,500	23,500

Of the shares issued pursuant to CEL-SCI's Stock Bonus Plans, 248,904 shares were issued as part of CEL-SCI's contribution to its 401(k) plan.

The following table shows the weighted average exercise price of the outstanding options granted pursuant to CEL-SCI's Incentive and Non-Qualified Stock Option Plans as of September 30, 2019, CEL-SCI's most recent fiscal year end. CEL-SCI's Incentive and Non-Qualified Stock Option Plans have been approved by CEL-SCI's shareholders.

Plan category	Number of Securities to be Issued Upon Exercise of Outstanding Options (a)	Weighted-Average Exercise Price of Outstanding Options	Number of Securities Remaining Available For Future Issuance Under Equity Compensation Plans, Excluding Securities Reflected in Column (a)
Incentive Stock Option Plans	89,895	$ 36.26	213
Non-Qualified Stock Option Plans	6,128,216	$ 5.09	112,166

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The following table shows, as of December 1, 2019, information with respect to the only persons owning beneficially 5% or more of CEL-SCI's outstanding common stock and the number and percentage of outstanding shares owned by each director and officer of CEL-SCI and by the officers and directors as a group. Unless otherwise indicated, each owner has sole voting and investment powers over his shares of common stock.

Name and Address	Number of Shares (1)	Percent of Class (2)
Geert R. Kersten 8229 Boone Blvd., Suite 802 Vienna, VA 22182	2,428,308 (3)	6.6%
Patricia B. Prichep 8229 Boone Blvd., Suite 802 Vienna, VA 22182	387,789	1.1%
Eyal Talor, Ph.D. 8229 Boone Blvd., Suite 802 Vienna, VA 22182	308,205	*
Daniel H. Zimmerman, Ph.D. 8229 Boone Blvd., Suite 802 Vienna, VA 22182	193,291	*
John Cipriano 8229 Boone Blvd., Suite 802 Vienna, VA 22182	197,357	*
Peter R. Young, Ph.D. 208 Hewitt Drive, Suite 103-143 Waco, TX 76712	86,892	*
Bruno Baillavoine 8229 Boone Blvd., Suite 802 Vienna, VA 22182	58,001	*
Robert Watson 245 N. Highland Ave. NE Suite 230-296 Atlanta, GA 30307	34,792	*
All Officers and Directors as a Group (8 persons)	3,694,635	9.88%

* Less than 1%

(1) Includes shares issuable prior to February 28, 2020 upon the exercise of options or warrants granted to the following persons:

Name	Options or Warrants Exercisable Prior to February 28, 2020
Geert R. Kersten, Esq.	1,320,884(3)
Patricia B. Prichep	184,762
Eyal Talor, Ph.D.	189,979
Daniel Zimmerman, Ph.D.	80,200
John Cipriano	114,249
Peter R. Young, Ph.D.	65,801
Bruno Baillavoine	55,001
Robert Watson	33,334

(2) Amount includes shares referred to in (1) above but excludes shares which may be issued upon the exercise of options and warrants previously issued by CEL-SCI.

(3) Amount includes shares held in trust for the benefit of Mr. Kersten's children and warrants held in the de Clara Trust, of which Mr. Kersten is a beneficiary.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

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

See Note 13 to the financial statements included as part of this report for additional information concerning related party transactions.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

BDO USA, LLP served as CEL-SCI's independent registered public accountant for the two years ended September 30, 2019. The following table shows the aggregate fees billed to CEL-SCI for these years by BDO USA, LLP:

	Year Ended September 30,	
	2019	2018
Audit Fees	$ 363,000	$ 445,000
Audit Related Fees	-	-
Tax Fees	-	-
All Other Fees	-	-

Audit fees represent amounts billed for professional services rendered for the audit of CEL-SCI's annual financial statements and the reviews of the financial statements included in CEL-SCI's 10-Q reports for the fiscal year and all regulatory filings.

Before BDO USA, LLP was engaged by CEL-SCI to render audit or non-audit services, the engagement was approved by CEL-SCI's audit committee. CEL-SCI's Board of Directors is of the opinion that the Audit Fees charged by BDO USA, LLP are consistent with BDO USA, LLP maintaining its independence from CEL-SCI.

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

See the Financial Statements attached to this Report.

Exhibits

3(a)	Articles of Incorporation	Incorporated by reference to Exhibit 3(a) of CEL-SCI's combined Registration Statement on Form S-1 and Post-Effective Amendment ("Registration Statement"), Registration Nos. 2-85547-D and 33-7531.
3(b)	Amended Articles	Incorporated by reference to Exhibit 3(a) of CEL-SCI's Registration Statement on Form S-1, Registration Nos. 2-85547-D and 33-7531.
3(c)	Amended Articles (Name change only)	Incorporated by reference to Exhibit 3(c) of CEL-SCI's report on Form 8-K dated October 15, 2019.
3(d)	Bylaws	Incorporated by reference to Exhibit 3(b) of CEL-SCI's Registration Statement on Form S-1, Registration Nos. 2-85547-D and 33-7531.
3(e)	Amended Bylaws	Incorporated by reference to Exhibit 3(d) of CEL-SCI's report on Form 8-K dated October 15, 2019.
4	Shareholders Rights Agreement, as Amended	Incorporated by reference to Exhibit 4 filed with CEL-SCI's 10-K report for the year ended September 30, 2015.
4(b)	Incentive Stock Option Plan	Incorporated by reference to Exhibit 4 (b) filed on September 25, 2012 with the Company's registration statement on Form S¬8 (File number 333-184092).
4(c)	Non-Qualified Stock Option Plan	Incorporated by reference to Exhibit 4 (b) filed on August 19, 2014 with the Company's registration statement on Form S¬8 (File number 333-198244).
4(d)	Stock Bonus Plan	Incorporated by reference to Exhibit 4 (d) filed on September 25, 2012 with the Company's registration statement on Form S¬8 (File number 333-184092).
4(e)	Stock Compensation Plan	Incorporated by reference to Exhibit 4 (e) filed on September 25, 2012 with the Company's registration statement on Form S¬8 (File number 333-184092).
4(f)	2014 Incentive Stock Bonus Plan	Incorporated by reference to Exhibit 4 (c) filed with the Company's registration statement on Form S-8 (333-198244).
10(f)	Securities Purchase Agreement (together with schedule required by Instruction 2 to Item 601 of Regulation S-K) pertaining to Series K notes and warrants, together with the exhibits to the Securities Purchase Agreement	Incorporated by reference to Exhibit 10 to CEL-SCI's report on Form 8-K dated August 4, 2006.
10(g)	Subscription Agreement (together with Schedule required by Instruction 2 to Item 601 of Regulation S-K) pertaining to April 2007 sale of 800,000 shares of CEL-SCI's common stock, 400,000 Series L warrants and 400,000 Series M Warrants	Incorporated by reference to Exhibit 10 of CEL-SCI's report on Form 8-K dated April 18, 2007
10(h)	Warrant Adjustment Agreement with Laksya Ventures	Incorporated by reference to Exhibit 10(i) of CEL-SCI's report on Form 8-K dated August 3, 2010
10(l)	First Amendment to Development Supply and Distribution Agreement with Orient Europharma.	Incorporated by reference to Exhibit 10(m) filed with CEL-SCI's 10-K report for the year ended September 30, 2010.
10(m)	Exclusive License and Distribution Agreement with Teva Pharmaceutical Industries Ltd.	Incorporated by reference to Exhibit 10(n) filed with CEL-SCI's 10-K report for the year ended September 30, 2010.
10(n)	Lease Agreement	Incorporated by reference to Exhibit 10(o) filed with CEL-SCI's 10-K report for the year ended September 30, 2010.
10(o)	Promissory Note with Maximilian de Clara, together with Amendments 1 and 2	Incorporated by reference to Exhibit 10(p) filed with CEL-SCI's 10-K report for the year ended September 30, 2010

10(p)	Licensing Agreement with Byron Biopharma	Incorporated by reference to Exhibit 10(i) of CEL-SCI's report on Form 8-K dated March 27, 2009
10(z)	Development, Supply and Distribution Agreement with Orient Europharma	Incorporated by reference to Exhibit 10(z) filed with CEL-SCI's report on Form 10-K for the year ended September 30, 2003.
10(aa)	Securities Purchase Agreement and form of the Series F warrants, which is and exhibit to the Securities Purchase Agreement	Incorporated by reference to Exhibit 10(aa) of CEL-SCI's report on Form 8-K dated October 3, 2011.
10(bb)	Placement Agent Agreement	Incorporated by reference to Exhibit 10(bb) of CEL-SCI's report on Form 8-K dated October 3, 2011.
10(cc)	Securities Purchase Agreement, together with the form of the Series H warrant, which is an exhibit to the securities Purchase Agreement	Incorporated by reference to Exhibit 10(cc) of CEL-SCI's report on Form 8-K dated January 25, 2012.
10(dd)	Placement Agent Agreement	Incorporated by reference to Exhibit 10(dd) of CEL-SCI's report on Form 8-K dated January 25, 2012.
10(ee)	Warrant Amendment Agreement, together with the form of the Series P warrant, which is an exhibit to the Warrant Amendment Agreement	Incorporated by reference to Exhibit 10(ee) of CEL-SCI's report on Form 8-K dated February 10, 2012.
10(ff)	Placement Agent Agreement	Incorporated by reference to Exhibit 10(ff) of CEL-SCI's report on Form 8-K dated February 10, 2012.
10(gg)	Securities Purchase Agreement and the form of the Series Q warrant, which is an exhibit to the Securities Purchase Agreement	Incorporated by reference to Exhibit 10(gg) of CEL-SCI's report on Form 8-K dated June 18, 2012.
10(hh)	Placement Agent Agreement	
10(ii)	Securities Purchase Agreement and the form of the Series R warrant, which is an exhibit to the Securities Purchase Agreement	Incorporated by reference to Exhibit 10(ii) of CEL-SCI's report on Form 8-K dated December 5, 2012.
10(jj)	Placement Agent Agreement	Incorporated by reference to Exhibit 10(jj) of CEL-SCI's report on Form 8-K dated December 5, 2012.
10(nn)	Underwriting Agreement, together with the form of Series S warrant which is an exhibit to the underwriting agreement	Incorporated by reference to Exhibit 1.1 of CEL-SCI's report on Form 8-K dated October 8, 2013.
10(oo)	Underwriting Agreement, together with the form of Series S warrant which is an exhibit to the Underwriting Agreement.	Incorporated by reference to Exhibit 1.1 of CEL-SCI's report on Form 8-K dated December 19, 2013.
10(pp)	Underwriting Agreement, together with the form of Series T warrant which is an exhibit to the warrant agent agreement	Incorporated by reference to Exhibit 1.1 of CEL-SCI's report on Form 8-K dated April 15, 2014.
10(qq)	Underwriting Agreement, together with the form of Series S warrant which is an exhibit to the warrant agent agreement	Incorporated by reference to Exhibit 1.1 of CEL-SCI's report on Form 8-K dated October 23, 2014.
10(rr)	Assignment and Assumption Agreement with Teva Pharmaceutical Industries, Ltd. and GCP Clinical Studies, Ltd.	Incorporated by reference to Exhibit 10(rr) of CEL-SCI's report on Form 10-K/A report for the year ended September 30, 2014 dated April 17, 2015.
10(ss)	Service Agreement with GCP Clinical Studies, Ltd., together with Amendment 1 thereto*	Incorporated by reference to Exhibit 10(ss) of CEL-SCI's first amendment to its Form 10-K report for the year ended September 30, 2014 dated April 17, 2015.
10 (tt)	Joinder Agreement with PLIVA Hrvatska d.o.o.	Incorporated by reference to Exhibit 10(tt) of CEL-SCI's first amendment to its Form 10-K report for the year ended September 30, 2014 dated April 17, 2015.
10 (uu)	Master Service Agreement with Ergomed Clinical Research, Ltd., and Clinical Trial Orders thereunder	Incorporated by reference to Exhibit 10(uu) of CEL-SCI's first amendment to its Form 10-K report for the year ended September 30, 2014 dated April 17, 2015.

10 (vv)	Co-Development and Revenue Sharing Agreement with Ergomed Clinical Research Ltd., dated April 19, 2013, as amended	Incorporated by reference to Exhibit 10(vv) of CEL-SCI's first amendment to its Form 10-K report for the year ended September 30, 2014 dated April 17, 2015.
10 (ww)	Co-Development and Revenue Sharing Agreement II: Cervical Intraepithelial Neoplasia in HIV/HPV co-infected women, with Ergomed Clinical Research Ltd., dated October 10, 2013, as amended	Incorporated by reference to Exhibit 10(ww) of CEL- first amendment to its Form 10-K report for the year ended September 30, 2014 dated April 17, 2015.
10 (xx)	Co-Development and Revenue Sharing Agreement III: Anal warts and anal intraepithelial neoplasia in HIV/HPV co-infected patients, with Ergomed Clinical Research Ltd., dated October 24, 2013	Incorporated by reference to Exhibit 10(xx) of CEL-SCI's first amendment to its Form 10-K report for the year ended September 30, 2014 dated April 17, 2015.
10 (yy)	Master Services Agreement with Aptiv Solutions, Inc.	Incorporated by reference to Exhibit 10(yy) of CEL-SCI's first amendment to its Form 10-K report for the year ended September 30, 2014 dated April 17, 2015.
10 (zz)	Project Agreement Number 1 with Aptiv Solutions, Inc. together with Amendments 1 and 2 thereto*	Incorporated by reference to Exhibit 10(zz) of CEL-SCI's first amendment to its Form 10-K report for the year ended September 30, 2014 dated April 17, 2015.
10 (aaa)	Second Amendment to Development Supply and Distribution Agreement with Orient Europharma	Incorporated by reference to Exhibit 10(aaa) of CEL-SCI's first amendment to its Form 10-K report for the year ended September 30, 2014 dated April 17, 2015.
10(bbb)	Amended and Restated Promissory Note with Maximilian de Clara	Incorporated by reference to Exhibit 10(bbb) of CEL-SCI's report on Form 10-K/A report for the year ended September 30, 2014 dated April 17, 2015.
10(ccc)	Placement Agent Agreement dated May 22, 2015 by and among CEL-SCI Corporation and Dawson James Securities, Inc.	Incorporated by reference to Exhibit 1.1 of CEL-SCI's report on Form 8-K filed on May 26, 2015.
10 (ddd)	Warrant Agent Agreement (as amended), Series V warrants	Incorporated by reference to Exhibit 10 (ccc) of CEL-SCI's report on Form 8-K filed on May 29, 2015.
10 (eee)	Assignment of Proceeds and Investment Agreement between CEL-SCI Corporation and Lake Whillans Vehicle 1.	Incorporated by reference to Exhibit 10 (ddd) of CEL-SCI's report on Form 8-K filed on October 16, 2015.
10(fff)	Placement Agent Agreement dated October 22, 2015 by and among CEL-SCI Corporation and Dawson James Securities, Inc.	Incorporated by reference to Exhibit 1.1 of CEL-SCI's report on Form 8-K filed on October 23, 2015.
10 (ggg)	Warrant Agent Agreement, Series W warrants	Incorporated by reference to Exhibit 10 (eee) of CEL-SCI's report on Form 8-K filed on October 23, 2015.
10(iii)	Amendment to Co-Development and Revenue Sharing Agreement with Ergomed Clinical Research, Ltd., dated September 15, 2015	Incorporated by reference to Exhibit 10 (iii) filed with CEL-SCI's 10-K report for the year ended September 30, 2015.
10 (jjj)	Securities Purchase Agreement	Incorporated by reference to Exhibit 10(jjj) of CEL-SCI's report on Form 8-K dated May 19, 2016.
10 (kkk)	Securities Purchase Agreement	Incorporated by reference to Exhibit 10(kkk) of CEL-SCI's report on Form 8-K dated August 24, 2016.
10 (lll)	Termination Agreement with Maximilian de Clara	Incorporated by reference to Exhibit 10(lll) of CEL-SCI's report on Form 8-K dated September 2, 2016.
10(mmm)	Employment Agreement with Geert Kersten (2016-2019)	Incorporated by reference to Exhibit 10(mmm) of CEL-SCI's report on Form 8-K dated September 2, 2016.
10 (nnn)	Employment Agreement with Patricia Prichep (2016-2019)	Incorporated by reference to Exhibit 10(nnn) of CEL-SCI's report on Form 8-K dated September 2, 2016.

10 (ooo)	Employment Agreement with Eyal Taylor (2016-2019)	Incorporated by reference to Exhibit 10(ooo) of CEL-SCI's report on Form 8-K dated September 2, 2016.
10 (ppp)	Securities Purchase Agreement	Incorporated by reference to Exhibit 10(ppp) of CEL-SCI's report on Form 8-K dated December 1, 2016.
10 (qqq)	Securities Purchase Agreement	Incorporated by reference to Exhibit 10(qqq) of CEL-SCI's report on Form 8-K dated February 16, 2017.
10 (rrr)	Securities Purchase Agreement	Incorporated by reference to Exhibit 10(rrr) of CEL-SCI's report on Form 8-K dated March 8, 2017.
10 (ttt)	Securities Purchase Agreement (sale of 100,000 shares to private investor, plus Series OO warrants).	Incorporated by reference to Exhibit 10(ttt) of CEL-SCI's report on Form 8-K dated July 27, 2017.
10 (uuu)	Securities Purchase Agreement with Ergomed	Incorporated by reference to Exhibit 10(uuu) of CEL-SCI's report on Form 8-K dated August 17, 2017.
10 (vvv)	Securities Purchase Agreement	Incorporated by reference to Exhibit 10(vvv) of CEL-SCI's report on Form 8-K dated August 22, 2017.
10 (www)	Amendment No. 1 to Assignment of Proceeds and Investment Agreement	Incorporated by reference to Exhibit 10(www) of CEL-SCI's report on Form 8-K dated November 2, 2017.
10 (xxx)	Amendment to Convertible Promissory Notes	Incorporated by reference to Exhibit 10(xxx) of CEL-SCI's registration statement on Form S-1 dated January 5, 2018.
10 (zzz)	Securities Purchase Agreement with Ergomed	Incorporated by reference to Exhibit 10(zzz) of CEL-SCI's report on Form 8-K dated January 1, 2018.
10.1	Securities Purchase Agreements (December 2017 Financing)	Incorporated by reference to Exhibit 10.1 of CEL-SCI's registration statement on Form S-1 dated January 5, 2018.
10.2	Securities Purchase Agreements (February 2018 Financing)	Incorporated by reference to Exhibit 10.1 of CEL-SCI's registration statement on Form S-1 dated February 14, 2018.
10.3	Securities Purchase Agreement with Ergomed	Incorporated by reference to Exhibit 10.3 of CEL-SCI's report on Form 8-K dated May 21, 2018.
10.4	Securities Purchase Agreement	Incorporated by reference to Exhibit 10.4 of CEL-SCI's report on Form 8-K dated June 29, 2018.
10.5	Securities Purchase Agreement	Incorporated by reference to Exhibit 10.5 of CEL-SCI's report on Form 8-K dated August 31, 2018.
10.6	Securities Purchase Agreement with Ergomed	Incorporated by reference to Exhibit 10.6 of CEL-SCI's report on Form 8-K dated August 16, 2019.
10.7	2019 Non-Qualified Stock Option Plan	Incorporated by reference to Exhibit 10.7 of CEL-SCI's report on Form 8-K dated October 15, 2019.
10.8	2019 Stock Compensation Plan	Incorporated by reference to Exhibit 10.8 of CEL-SCI's report on Form 8-K dated October 15, 2019.
23.1	Consent of BDO USA, LLP	
31	Rule 13a-14(a) Certifications	
32	Section 1350 Certifications	

* Portions of this exhibit have been omitted pursuant to a request for confidential treatment filed with the Commission under Rule 24b-2 of the Securities Exchange Act of 1934. The omitted confidential material has been filed separately with the Commission. The location of the omitted confidential information is indicated in the exhibit with asterisks (*)

CEL-SCI CORPORATION

Financial Statements for the Years

Ended September 30, 2019 and 2018, and

Report of Independent Registered Public Accounting Firm

CEL-SCI CORPORATION

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Report of Independent Registered Public Accounting Firm

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

Opinion on the Financial Statements

We have audited the accompanying balance sheets of CEL-SCI Corporation (the "Company") as of September 30, 2019 and 2018, the related statements of operations, stockholders' equity, and cash flows for the years then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company at September 30, 2019 and 2018, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

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

Going Concern Uncertainty

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

Basis for Opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud.

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

/s/ BDO USA, LLP

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

Potomac, Maryland

December 16, 2019

Report of Independent Registered Public Accounting Firm

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

Opinion on Internal Control over Financial Reporting

We have audited CEL-SCI Corporation's (the "Company's") internal control over financial reporting as of September 30, 2019, based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (the "COSO criteria"). In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of September 30, 2019, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the balance sheets of the Company as of September 31, 2019 and 2018, the related consolidated statements of operations, stockholders' equity, and cash flows for each of the years then ended, and the related notes (collectively referred to as "the financial statements") and our report dated December 16, 2019 expressed an unqualified opinion thereon.

Basis for Opinion

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

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

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

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

/s/ BDO USA, LLP

Potomac, Maryland

December 16, 2019

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

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

See notes to financial statements.

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

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

See notes to financial statements.

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

	Common Shares	Stock Amount	Additional Paid-In Capital	Accumulated Deficit	Total
BALANCE, OCTOBER 1, 2017	11,903,133	$ 119,031	$ 296,298,401	$ (299,754,409)	$ (3,336,977)
Sale of common stock	7,690,623	76,906	11,715,335	-	11,792,241
Warrant exercises	4,072,109	40,721	10,752,142	-	10,792,863
401(k) contributions paid in common stock	93,640	937	144,153	-	145,090
Stock issued to nonemployees for service	356,197	3,562	689,626	-	693,188
Equity based compensation - employees	-	-	2,743,267	-	2,743,267
Purchase of stock by officers and directors	463,855	4,639	380,361	-	385,000
Stock issuance costs	-	-	(206,583)	-	(206,583)
Warrants issued with notes payable	-	-	947,616	-	947,616
Conversion of notes payable and interest to common stock	1,194,930	11,950	2,363,066	-	2,375,016
Shares issued for settlement of clinical research costs	2,260,000	22,600	5,484,800	-	5,507,400
Net loss	-	-	-	(31,837,205)	(31,837,205)
BALANCE, SEPTEMBER 30, 2018	28,034,487	$ 280,346	$ 331,312,184	$ (331,591,614)	$ 916
Warrant exercises	6,677,519	66,775	18,039,842	-	18,106,617
401(k) contributions paid in common stock	30,996	310	143,568	-	143,878
Stock issued to nonemployees for service	199,977	1,999	876,589	-	878,588
Equity based compensation - employees	(7,500)	(75)	4,428,249	-	4,428,174
Option exercises	65,997	660	149,822	-	150,482
Purchase of stock by officers and directors	45,205	452	291,545	-	291,997
Stock issuance costs	-	-	(132,345)	-	(132,345)
Shares issued for settlement of clinical research costs	185,095	1,851	3,398,149	-	3,400,000
Net loss	-	-	-	(22,134,640)	(22,134,640)
BALANCE, SEPTEMBER 30, 2019	35,231,776	$ 352,318	$ 358,507,603	$ (353,726,254)	$ 5,133,667

See notes to financial statements.

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

SUPPLEMENTAL SCHEDULE OF NON-CASH INVESTING AND FINANCING ACTIVITIES:

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

See notes to financial statements.

1. ORGANIZATION

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

The Company is focused on finding the best way to activate the immune system to fight cancer and infectious diseases. Its lead investigational therapy, Multikine® (Leukocyte Interleukin, Injection), is currently in a pivotal Phase 3 clinical trial involving head and neck cancer, for which the Company has received Orphan Drug Status from the United States Food and Drug Administration (FDA). The study was fully enrolled with 928 patients in September 2016. Currently the Company is waiting for the occurrence of 298 events (deaths) in the two main groups to determine final results. If the primary endpoint of this global study is achieved, the Company expects to use the results to support applications to regulatory agencies around the world for worldwide commercial marketing approvals for Multikine for neoadjuvant therapy in patients with squamous cell carcinoma of the head and neck.

The Company's investigational immune therapy, Multikine, is being used in a different way than other immune therapy is usually used. It is given before any other therapy has been administered because that is when the immune system is thought to be strongest. It is also administered locally at the site of the tumors. For example, in the Phase 3 clinical trial, Multikine is given locally at the site of the tumor as a first line treatment before surgery, radiation and/or chemotherapy. The goal is to help the intact immune system kill the micro metastases that usually cause recurrence of the cancer. In short, CEL-SCI believes that local administration of this neoadjuvant therapy and administration before weakening of the immune system by surgery, chemotherapy and radiation will result in improved outcomes and better overall survival rates for patients suffering from head and neck cancer.

The Company is also investigating a different peptide-based immunotherapy as a vaccine for Rheumatoid Arthritis. The Company was awarded a Phase 2 Small Business Innovation Research (SBIR) grant in the amount of $1.5 million from the National Institutes of Health (NIH) in September 2017. This grant provides funding to allow the Company to advance its first LEAPS product candidate for Rheumatoid Arthritis towards an Investigational New Drug (IND) application, by funding GMP manufacturing, IND enabling studies, and additional mechanism of action studies.

2. OPERATIONS AND FINANCING

The Company has incurred significant costs since its inception in connection with the acquisition of certain patented and unpatented proprietary technology and know-how relating to the human immunological defense system, patent applications, research and development, administrative costs, construction of laboratory facilities, and clinical trials. The Company has funded such costs with proceeds from loans and the public and private sale of its securities. The Company will be required to raise additional capital or find additional long-term financing in order to continue with its research efforts. To date, the Company has not generated any revenue from product sales. As a result, the Company has been dependent upon the proceeds from the sale of its securities to meet all of its liquidity and capital requirements and anticipates having to do so in the future. During fiscal year 2019 and 2018, the Company received net proceeds of approximately $14.8 million and $21.4 million, respectively, through the sale of stock and the exercise of warrants and options. The ability of the Company to complete the necessary clinical trials and obtain FDA approval for the sale of products to be developed on a commercial basis is uncertain. Ultimately, the Company must complete the development of its products, obtain the appropriate regulatory approvals and obtain sufficient revenues to support its cost structure.

The Company is currently in the final stages of its large multi-national Phase 3 clinical trial for head and neck cancer with its partners TEVA Pharmaceuticals and Orient Europharma. To finance the study beyond the next twelve months, the Company plans to raise additional capital in the form of warrant exercises, corporate partnerships, debt and/or equity financings. The Company believes that it will be able to obtain additional financing because it has done so consistently in the past and because Multikine is a product in the Phase 3 clinical trial stage. However, there can be no assurance that the Company will be successful in raising additional funds on a timely basis or that the funds will be available to the Company on acceptable terms or at all. If the Company does not raise the necessary amounts of money, it may have to curtail its operations until such time as it is able to raise the required funding.

The financial statements have been prepared assuming that the Company will continue as a going concern, but due to the Company's recurring losses from operations and future liquidity needs, there is substantial doubt about the Company's ability to continue as a going concern. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Since the Company launched its Phase 3 clinical trial for Multikine, the Company has incurred expenses of approximately $55.8 million as of September 30, 2019 on direct costs for the Phase 3 clinical trial. The Company estimates it will incur additional expenses of approximately $4.5 million for the remainder of the Phase 3 clinical trial. It should be noted that this estimate is based only on the information currently available from the Clinical Research Organizations responsible for managing the Phase 3 clinical trial and does not include other related costs, e.g., the manufacturing of the drug. This number may be affected by the rate of death accumulation in the study, foreign currency exchange rates and many other factors, some of which cannot be foreseen today. It is therefore possible that the cost of the Phase 3 clinical trial will be higher than currently estimated.

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

On October 31, 2013, the Company commenced arbitration proceedings against inVentiv Health Clinical, LLC, or inVentiv, its former clinical research organization (CRO), and now part of Syneos Health. The arbitration claim, initiated under the Commercial Rules of the American Arbitration Association, alleged (i) breach of contract, (ii) fraud in the inducement, and (iii) common law fraud. On June 25, 2018, the arbitrator ruled that inVentiv materially breached its contract with the Company and denied inVentiv all but one of its counterclaims ($429,649 for certain unpaid invoices) against the Company. The arbitrator awarded the Company $2,917,834 in damages. This is a final and binding decision and to the Company's knowledge, marks the first ever decision in favor of a pharmaceutical/biomedical company against a CRO for breach of contract. However, pursuant to the terms of an agreement with an affiliate of Lake Whillans Litigation Finance, LLC, a firm that produced partial funding for the legal expenses incurred by the Company in the arbitration proceedings, all amounts received from inVentiv by virtue of the arbitration award were paid to Lake Whillans Litigation Finance. As a result of the arbitrator's ruling, during the year ended September 30, 2018, the Company wrote off approximately $471,000, which will no longer be realized.

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

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

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

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

4. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Cash and Cash Equivalents – For purposes of the statements of cash flows, cash and cash equivalents consist principally of unrestricted cash on deposit and short-term money market funds. The Company considers all highly liquid investments with a maturity when purchased of less than three months as cash and cash equivalents.

Prepaid Expenses – Prepaid expenses are payments for future services to be rendered and are expensed over the time period for which the service is rendered. Prepaid expenses may also include payment for goods to be received within one year of the payment date.

Inventory – Inventory consists of manufacturing production advances and bulk purchases of laboratory supplies to be consumed in the manufacturing of the Company's product for clinical studies. Inventories are stated at the lower of cost or market, where cost is determined using the first-in, first out method applied on a consistent basis.

Deposits – The deposits are required by the lease agreement for the manufacturing facility and by the clinical research organization (CRO) agreements.

Plant, property and equipment – The leased manufacturing facility is recorded at total project costs incurred and is depreciated over the 20-year useful life of the building. Research and office equipment is recorded at cost and depreciated using the straight-line method over estimated useful lives of five to seven years. Leasehold improvements are depreciated over the shorter of the estimated useful life of the asset or the term of the lease. Repairs and maintenance which do not extend the life of the asset are expensed when incurred. The plant, property and equipment are reviewed on a quarterly basis to assess impairment, if any.

Patents – Patent expenditures are capitalized and amortized using the straight-line method over the shorter of the expected useful life or the legal life of the patent (17 years). In the event changes in technology or other circumstances impair the value or life of the patent, appropriate adjustment to the asset value and period of amortization is made. An impairment loss is recognized when estimated future undiscounted cash flows expected to result from the use of the asset, and from disposition, are less than the carrying value of the asset. The amount of the impairment loss would be the difference between the estimated fair value of the asset and its carrying value.

Leases – Leases are categorized as either operating or capital leases at inception. Operating lease costs are recognized on a straight-line basis over the term of the lease. An asset and a corresponding liability for the capital lease obligation are established for the cost of capital leases. The capital lease obligation is amortized over the life of the lease. For build-to-suit leases, the Company establishes an asset and liability for the estimated construction costs incurred to the extent that it is involved in the construction of structural improvements or takes construction risk prior to the commencement of the lease. Upon occupancy of facilities under build-to-suit leases, the Company assesses whether these arrangements qualify for sales recognition under the sale-leaseback accounting guidance. If a lease does not meet the criteria to qualify for a sale-leaseback transaction, the established asset and liability remain on the Company's balance sheet. See Note 12.

Deferred Rent – Certain of the Company’s operating leases provide for minimum annual payments that adjust over the life of the lease. The aggregate minimum annual payments are expensed on a straight-line basis over the minimum lease term. The Company recognizes a deferred rent liability for rent escalations when the amount of straight-line rent exceeds the lease payments, and reduces the deferred rent liability when the lease payments exceed the straight-line rent expense. For tenant improvement allowances and rent holidays, the Company records a deferred rent liability and amortizes the deferred rent over the lease term as a reduction to rent expense.

Derivative Instruments - The Company has entered into financing arrangements that consist of freestanding derivative instruments that contain embedded derivative features, specifically, the settlement provisions in the warrant agreements preclude the warrants from being treated as equity. The Company accounts for these arrangements in accordance with Accounting Standards Codification (ASC) 815, “Accounting for Derivative Instruments and Hedging Activities”. In accordance with accounting principles generally accepted in the United States (U.S. GAAP), derivative instruments and hybrid instruments are recognized as either assets or liabilities on the balance sheet and are measured at fair value with gains or losses recognized in earnings or other comprehensive income depending on the nature of the derivative or hybrid instruments. The Company determines the fair value of derivative instruments and hybrid instruments based on available market data using appropriate valuation models, and considering all of the rights and obligations of each instrument. The derivative liabilities are remeasured at fair value at the end of each reporting period as long as they are outstanding.

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

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

Net Loss Per Common Share – The Company calculates net loss per common share in accordance with ASC 260 “Earnings Per Share” (ASC 260). Basic and diluted net loss per common share was determined by dividing net loss applicable to common shareholders by the weighted average number of common shares outstanding during the period. The Company’s potentially dilutive shares, which include outstanding common stock options, restricted stock from the Company’s 2014 Incentive Stock Bonus Plan, convertible preferred stock and common stock warrants, have not been included in the computation of diluted net loss per share for all periods as the result would be anti-dilutive.

Concentration of Credit Risk – Financial instruments, which potentially subject the Company to concentrations of credit risk, consist of cash and cash equivalents. The Company maintains its cash and cash equivalents with high quality financial institutions. At times, these accounts may exceed federally insured limits. The Company has not experienced any losses in such bank accounts. The Company believes it is not exposed to significant credit risk related to cash and cash equivalents. All non-interest bearing cash balances were fully insured up to $250,000 at September 30, 2019.

Income Taxes – The Company uses the asset and liability method of accounting for income taxes. Under the asset and liability method, deferred tax assets and liabilities are recognized for future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating and tax loss carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. The Company records a valuation allowance to reduce the deferred tax assets to the amount that is more likely than not to be recognized. A full valuation allowance was recorded against the deferred tax assets as of September 30, 2019 and 2018.

Use of Estimates – The preparation of financial statements in conformity U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and the accompanying disclosures. These estimates are based on management's best knowledge of current events and actions the Company may undertake in the future. Estimates are used in accounting for, among other items, inventory obsolescence, accruals, stock options, useful lives for depreciation and amortization of long-lived assets, deferred tax assets and the related valuation allowance, and the valuation of derivative liabilities. Actual results could differ from estimates, although management does not generally believe such differences would materially affect the financial statements in any given year. However, in regard to the valuation of derivative liabilities determined using various valuation techniques including the Black-Scholes and binomial pricing methodologies, significant fluctuations may materially affect the financial statements in a given year. The Company considers such valuations to be significant estimates.

Fair Value Measurements – The Company evaluates financial assets and liabilities subject to fair value measurements in accordance with a fair value hierarchy to prioritize the inputs used to measure fair value. A financial instrument's level within the fair value hierarchy is based on the lowest level of input significant to the fair value measurement, where Level 1 is the highest and Level 3 is the lowest. See Note 15 for the definition of levels and the classification of assets and liabilities in those levels.

Stock-Based Compensation – Compensation cost for all stock-based awards is measured at fair value as of the grant date in accordance with the provisions of ASC 718, "Compensation – Stock Compensation." The fair value of stock options is calculated using the Black-Scholes option pricing model. The Black-Scholes model requires various judgmental assumptions including volatility and expected option life. The stock-based compensation cost is recognized on the straight line allocation method as expense over the requisite service or vesting period.

Equity instruments issued to non-employees are accounted for in accordance with ASC 505-50, "Equity-Based Payments to Non-Employees." Accordingly, compensation is recognized when goods or services are received and may be measured using the Black-Scholes valuation model, based on the type of award. The Black-Scholes model requires various judgmental assumptions regarding the fair value of the equity instruments at the measurement date and the expected life of the options.

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

The Company's stock options are not transferable, and the actual value of the stock options that an employee may realize, if any, will depend on the excess of the market price on the date of exercise over the exercise price. The Company has based its assumption for stock price volatility on the variance of daily closing prices of the Company's stock. The risk-free interest rate assumption was based on the U.S. Treasury rate at date of the grant with term equal to the expected life of the option. Historical data was used to estimate option exercise and employee termination within the valuation model. The expected term of options represents the period over which options granted are expected to be outstanding and has been determined using an analysis of historical exercise behavior. Forfeitures of awards are recognized as they occur. If any of the assumptions used in the Black-Scholes model change significantly, stock-based compensation expense for new awards may differ materially in the future from that recorded in the current period.

Vesting of restricted stock granted under the Incentive Stock Bonus Plan is subject to service, performance or market conditions and meets the classification of equity awards. These awards were measured at fair market value on the grant-dates for issuances where the attainment of performance criteria is probable and at fair value on the grant-dates using a Monte Carlo simulation for issuances where the attainment of performance criteria is uncertain. The total compensation cost will be expensed over the estimated requisite service period.

Reclassifications-

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

Recent Accounting Pronouncements –

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

In February 2016, the FASB issued ASU 2016-02, Leases, which will require most leases (with the exception of leases with terms of less than one year) to be recognized on the balance sheet as a right-of-use asset and a lease liability. Leases will be classified as operating or financing. Operating leases are expensed using the straight-line method whereas financing leases will be treated similarly to a capital lease under the current standard. The new standard ASU 2016-02 is effective for fiscal years and interim periods, within those fiscal years, beginning after December 15, 2018, but early adoption is permitted. The Company is currently evaluating the effect of the new standard on its financial statements and related disclosures. In July 2018, the FASB issued ASU No. 2018-11, Leases (Topic 842): Targeted Improvements which allows entities to initially apply the new leases standard at the adoption date and recognize a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. ASU 2016-02 also requires expanded financial statement disclosures on leasing activities. These changes will become effective for the Company on October 1, 2019.

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

- The optional transition method set forth in ASU 2018-11 noted above – Upon adopting the standard effective October 1, 2019, the Company will recognize a cumulative-effect adjustment to the opening balance of retained earnings without recasting comparative periods.

- The election to apply a "package of practical expedients," which allows management to not reassess whether any expired or existing contracts are or contain leases under the new standard, or to reassess prior conclusions on lease identification, lease classification and the recording of initial direct costs. As required, these practical expedients must be elected as a package and must be applied to all leases.

- The option not to separate lease and non-lease components within the lease and account for all lease components as a single lease component.

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

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

5. WARRANTS AND NON-EMPLOYEE OPTIONS

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

Warrant	Issue Date	Shares Issuable upon Exercise of Warrants	Exercise Price	Expiration Date
Series N	8/18/2008	85,339	$ 3.00	2/18/2020
Series V	5/28/2015	810,127	$ 19.75	5/28/2020
Series UU	6/11/2018	154,810	$ 2.80	6/11/2020
Series W	10/28/2015	688,930	$ 16.75	10/28/2020
Series X	1/13/2016	120,000	$ 9.25	1/13/2021
Series Y	2/15/2016	26,000	$ 12.00	2/15/2021
Series ZZ	5/23/2016	20,000	$ 13.75	5/18/2021
Series BB	8/26/2016	16,000	$ 13.75	8/22/2021
Series Z	5/23/2016	264,000	$ 13.75	11/23/2021
Series FF	12/8/2016	68,048	$ 3.91	12/1/2021
Series CC	12/8/2016	277,463	$ 5.00	12/8/2021
Series HH	2/23/2017	6,500	$ 3.13	2/16/2022
Series AA	8/26/2016	200,000	$ 13.75	2/22/2022
Series JJ	3/14/2017	9,450	$ 3.13	3/8/2022
Series LL	4/30/2017	26,398	$ 3.59	4/30/2022
Series MM	6/22/2017	893,491	$ 1.86	6/22/2022
Series NN	7/24/2017	473,798	$ 2.52	7/24/2022
Series OO	7/31/2017	50,000	$ 2.52	7/31/2022
Series RR	10/30/2017	457,116	$ 1.65	10/30/2022
Series SS	12/19/2017	482,644	$ 2.09	12/18/2022
Series TT	2/5/2018	559,689	$ 2.24	2/5/2023
Series VV	7/2/2018	82,500	$ 1.75	1/2/2024
Consultants	7/28/17	10,000	$ 2.18	7/27/2027

The following warrants and non-employee options were outstanding at September 30, 2018:

Warrant	Issue Date	Shares Issuable upon Exercise of Warrants	Exercise Price	Expiration Date
Series S	10/11/13- 10/24/14	327,729	$ 31.25	10/11/2018
Series DD	12/8/2016	1,360,960	$ 4.50	12/10/2018
Series EE	12/8/2016	1,360,960	$ 4.50	12/10/2018
Series N	8/18/2008	85,339	$ 3.00	2/18/2020
Series V	5/28/2015	810,127	$ 19.75	5/28/2020
Series UU	6/11/2018	187,562	$ 2.80	6/11/2020
Series W	10/28/2015	688,930	$ 16.75	10/28/2020
Series X	1/13/2016	120,000	$ 9.25	1/13/2021
Series Y	2/15/2016	26,000	$ 12.00	2/15/2021
Series ZZ	5/23/2016	20,000	$ 13.75	5/18/2021
Series BB	8/26/2016	16,000	$ 13.75	8/22/2021
Series Z	5/23/2016	264,000	$ 13.75	11/23/2021
Series FF	12/8/2016	68,048	$ 3.91	12/1/2021
Series CC	12/8/2016	680,480	$ 5.00	12/8/2021
Series HH	2/23/2017	20,000	$ 3.13	2/16/2022
Series AA	8/26/2016	200,000	$ 13.75	2/22/2022
Series JJ	3/14/2017	30,000	$ 3.13	3/8/2022
Series LL	4/30/2017	26,398	$ 3.59	4/30/2022
Series MM	6/22/2017	893,491	$ 1.86	6/22/2022
Series NN	7/24/2017	539,300	$ 2.52	7/24/2022
Series OO	7/31/2017	60,000	$ 2.52	7/31/2022
Series QQ	8/22/2017	3,500	$ 2.50	8/22/2022
Series GG	2/23/2017	200,000	$ 3.00	8/23/2022
Series II	3/14/2017	216,500	$ 3.00	9/14/2022
Series RR	10/30/2017	555,370	$ 1.65	10/30/2022
Series KK	5/3/2017	213,870	$ 3.04	11/3/2022
Series SS	12/19/2017	960,530	$ 2.09	12/18/2022
Series TT	2/5/2018	1,296,877	$ 2.24	2/5/2023
Series PP	8/28/2017	172,500	$ 2.30	2/28/2023
Series WW	7/2/2018	195,000	$ 1.63	6/28/2023
Series VV	7/2/2018	3,900,000	$ 1.75	1/2/2024
Consultants	1/1/16 - 7/28/17	30,400	$ 2.18- $11.50	12/31/18- 7/27/27

1. Warrant Liabilities

Warrant liabilities outstanding at September 30 are as follows:

	2019	2018
Series S warrants	$ -	$ 33
Series V warrants	674,442	770,436
Series W warrants	1,193,507	999,081
Series Z warrants	1,109,545	487,767
Series ZZ warrants	77,638	34,215
Series AA warrants	916,908	380,474
Series BB warrants	63,966	28,456
Series CC warrants	1,710,898	1,779,724
Series DD warrants	-	1,249,287
Series EE warrants	-	1,249,287
Series FF warrants	446,185	188,921
Series GG warrants	-	607,228
Series HH warrants	45,657	58,816
Series II warrants	-	660,135
Series JJ warrants	66,599	88,642
Series KK warrants	-	656,930
Series LL warrants	182,965	77,632
Total warrant liabilities	$ 6,488,310	$ 9,317,064

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

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

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

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

Exercise of Warrant Liabilities

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

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
	1,067,437		$ 4,020,087

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

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

Expiration of Warrants

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

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

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

2. Equity Warrants

Series VV and Series WW Warrants

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

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

Series UU Warrants

On June 11, 2018, the Company issued 187,562 Series UU Warrants to holders of the outstanding Series MM and NN notes payable as an inducement to convert their notes into common stock (See Note 8). The Series UU warrants are exercisable at a fixed price of $2.80 per share and expire on June 11, 2020. The Company recognized an expense equal to the excess of the fair value of the consideration transferred in the transaction over the fair value of consideration issuable under the original conversion terms. This expense represents the fair value of the Series UU warrants, which was calculated to be approximately $291,000 and is included as interest expense on the statement of operations for the year ended September 30, 2018. The Series UU warrants qualify for equity treatment in accordance with ASC 815.

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

Series TT Warrants

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

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

Series SS Warrants

On December 19, 2017, the Company sold 1,289,478 shares of its common stock at a price of $1.90 per share for total proceeds of approximately $2.45 million. The purchasers of the common stock also received Series SS warrants which allow the purchasers to acquire up to 1,289,478 shares of the Company's common stock. The warrants are exercisable at a fixed price of $2.09 per share and will expire on December 18, 2022. The Company allocated the proceeds received to the shares and the Series SS warrants on a relative fair value basis. As a result of such allocation, the Company determined the relative fair value of the Series SS warrants to be approximately $1.0 million. The Series SS warrants qualify for equity treatment in accordance with ASC 815.

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

Series RR Warrants

On October 30, 2017, in consideration for an extension of the maturity date of the Series MM and Series NN convertible notes, the Company issued a total of 583,057 Series RR warrants to the note holders who agreed to the extension. Each Series RR warrant allows the holder to purchase one share of the Company's common stock at an exercise price of $1.65 per share through the expiration date of October 30, 2022. The Series RR warrants were classified as equity warrants and are recorded at approximately $0.7 million, the relative fair value on the date of issuance, as described in Note 8.

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

Series N Warrants

Series N warrants were previously issued in connection with a financing and were subsequently transferred to the de Clara Trust, of which the Company's CEO, Geert Kersten, is a beneficiary. On August 4, 2018 the expiration date of the Series N warrants was extended to February 18, 2020. The incremental cost of this extension was approximately $14,000, which was recorded as a deemed dividend in the financial statements for the year ended September 30, 2018.

Exercise of Equity Warrants

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

Warrants	Warrants Exercised	Exercise Price	Proceeds
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
	5,610,082		$ 10,497,173

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

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

3. Options and Shares Issued to Consultants

The Company typically enters into consulting arrangements in exchange for common stock or stock options. During the years ended September 30, 2019 and 2018 the Company issued 199,977 and 356,197 shares, respectively, of common stock to consultants of which 199,977 and 353,197 shares, respectively, were restricted shares. Under these arrangements, the common stock was issued with stock prices ranging between $0.85 and $8.76 per share. The weighted average grant price was $4.25 and $1.95, respectively, for stock issued during the years and September 30, 2019 and 2018.

During the years ended September 30, 2019 and 2018, the Company recorded total expense of approximately $856,000 and $531,000, respectively, relating to these consulting agreements. At September 30, 2019 and 2018, approximately $230,000 and $207,000, respectively, are included in prepaid expenses. During the year ended September 30, 2019, 10,000 options issued to consultants were exercised and 10,400 options expired. As of September 30, 2019, 10,000 options issued to consultants as payment for services remained outstanding, all of which were issued from the Non-Qualified Stock Option plans and are fully vested.

6. PLANT, PROPERTY AND EQUIPMENT

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

	2019	2018
Leased manufacturing facility	$ 21,183,756	$ 21,183,756
Research equipment	3,320,358	3,162,151
Furniture and equipment	125,872	124,369
Leasehold improvements	149,239	131,910
	24,779,225	24,602,186
Accumulated depreciation and amortization	(8,953,589)	(8,383,335)
Net plant, property and equipment	$ 15,825,636	$ 16,218,851

The Company is not the legal owner of the manufacturing building, but is deemed to be the owner for accounting purposes, based on the accounting guidance for build-to-suit leases. See Note 12, Commitments and Contingencies–Lease Obligations, for additional information. As of September 30, 2019 and 2018, accumulated depreciation on the manufacturing building is approximately $5.6 million and $5.1 million, respectively. Depreciation expense for the years ended September 30, 2019 and 2018 totaled approximately $588,000 and, $575,000, respectively. Depreciation expense includes depreciation on the leased manufacturing building of approximately $514,000, which is included in research and development costs on the Statements of Operations.

7. PATENTS

Patents consist of the following at September 30:

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

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

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

8. NOTES PAYABLE

During the year ended September 30, 2017, the Company issued two series of convertible notes to individual investors, Series MM and Series NN (the Notes) along with Series MM and Series NN warrants (See Note 5). The Notes had an aggregate principal amount of $1.5 million and $1.2 million, respectively, bore interest at 4% and were originally due on December 22, 2017. During the year ended September 30, 2018, note holders converted the remaining outstanding Notes with an aggregate principal amount of $2,294,300, into 1,166,105 shares of common stock. Upon issuance, the Company allocated proceeds received to the Notes and warrants on a relative fair value basis. As a result of such allocation, the Company determined the initial carrying value of the Notes to be approximately $1.6 million, the Series MM warrants to be approximately $0.6 million, the Series NN warrants to be approximately $0.5 million, and recorded a debt discount in the amount of approximately $1.1 million.

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

As an inducement to convert, on June 11, 2018, the Company issued the note holders 187,562 Series UU warrants The Series UU warrants are exercisable at a fixed price of $2.80 per share and expire on June 11, 2020. Shares issuable upon the exercise of the warrants are restricted securities unless registered. The Company recognized an expense equal to the excess of the fair value of the consideration transferred in the transaction over the fair value of consideration issuable under the original conversion terms. This expense represents the fair value of the Series UU warrants, which was calculated to be approximately $291,000 and is included as interest expense on the statement of operations for the year ended September 30, 2018.

On October 30, 2017, the Company extended the due dates of the Notes from December 22, 2017 to September 21, 20l8, and issued the note holders 583,057 Series RR Warrants. The Series RR warrants expire on October 30, 2022 and are exercisable at a price of $1.65 per share. These Series RR warrants are classified as equity warrants and are recorded at approximately $0.7 million, the fair value on the date of issuance.

Because the Company was experiencing financial difficulties at the time of the October 2017 modification and the creditors granted the Company a concession they would not have otherwise considered in the form of a lower effective interest rate, this modification was accounted for under ASC 470-60, "*Troubled Debt Restructuring*." The Company calculated the future cash flows of the restructured debt to be greater than the carrying value of the debt and accounted for the change in debt prospectively, using the effective interest rate that equated the carrying amount to the future cash flows. The carrying value of the debt on the date of restructuring was approximately $0.7 million, which was net of a discount of approximately $1.6 million. The discount is being amortized to interest expense over the life of the Notes using the effective interest method.

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

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

9. INCOME TAXES

At September 30, 2019 and 2018, the Company had net deferred tax assets of $28.8million and $24.8 million, respectively. Due to uncertainties surrounding the Company's ability to generate future taxable income to realize these assets, a full valuation allowance has been established to offset the net deferred tax assets. In assessing the realization of deferred tax assets, management considered whether it was more likely than not that some, or all, of the deferred tax asset will be realized. The ultimate realization of the deferred tax assets is dependent upon the generation of future taxable income. Management has considered the history of the Company's operating losses and believes that the realization of the benefit of the deferred tax assets cannot be reasonably assured.

Pursuant to Section 382 of the Internal Revenue Code, or IRC, annual use of the Company's net operating loss (NOL) carryforwards may be limited in the event a cumulative change in ownership of more than 50% occurs within a three-year period. The Company determined that because of various stock issuances used to finance its operations, an ownership change as defined in the provisions of Section 382 of the IRC occurred on February 5, 2018. Such ownership change resulted in annual limitations on the utilization of tax attributes, including NOL carryforwards and tax credits. The Company estimates that $188.9 million of its NOL carryforwards were effectively eliminated under Section 382 for federal income tax purposes. A portion of the remaining NOL carryforwards limited by Section 382 will become available each year. No limitations on NOL carryforwards relating to change in ownership were imposed during the year ended September 30, 2019. The Company's Section 382 estimated analysis was completed through September 30, 2018. If additional changes in ownership occur after year end, additional NOL and tax credit carryforwards could be eliminated or restricted. If eliminated, the related asset would be removed from the deferred tax asset schedule with a corresponding reduction in the valuation allowance.

The Company had federal NOL carryforwards of approximately $36.7 million and $18.6 million at September 30, 2019 and 2018, respectively. The NOL carryforwards begin to expire during the year ended September 30, 2021 and become fully expired by the end of the fiscal year ended 2039. In addition, the Company has a general business credit as a result of the credit for increasing research activities ("R&D credit") of approximately $1.2 million at September 30, 2019 and 2018. The R&D credit begins to expire during the year ended September 30, 2020 and becomes fully expired during the fiscal year ended 2029.

Significant components of the Company's deferred tax assets as of September 30, 2019 and 2018 are listed below:

	2019	2018
NOL carryforwards	$ 9,698,000	$ 5,052,000
R&D credit	1,221,000	1,221,000
Stock-based compensation	3,165,000	3,097,000
Capitalized R&D	14,777,000	15,518,000
Vacation and other	544,000	544,000
Total deferred tax assets	29,405,000	25,432,000
Fixed assets and intangibles	(586,000)	(634,000)
Total deferred tax liability	(586,000)	(634,000)
Net deferred tax asset	28,819,000	24,798,000
Valuation allowance	(28,819,000)	(24,798,000)
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:

	2019	2018
Federal Rate	21.00%	24.28%
Federal rate change	(2.8)	(88.94)
State tax rate, net of federal benefit	5.31	4.47
Net operating loss – write-off	-	(161.21)
Other adjustments	(4.77)	(5.95)
Permanent differences	(0.57)	(5.79)
Change in valuation allowance	(18.17)	233.14
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 2017. These years remain open to examination by the major domestic taxing jurisdictions to which the Company is subject.

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

10. STOCK COMPENSATION

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

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

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

During the years ended September 30, 2019 and 2018 the fair value of each option grant was estimated on the date of grant using the Black-Scholes option-pricing model with the following assumptions.

	2019	2018
Expected stock price volatility	87.67 – 92.84%	89.90 – 94.32%
Risk-free interest rate	1.62 – 2.82%	2.30 – 3.04%
Expected life of options	9.67 – 9.68 Years	9.67 – 9.70 Years
Expected dividend yield	-	-

Non-Qualified Stock Option Plans – At September 30, 2019, the Company has collectively authorized the issuance of 6,387,200 shares of common stock under its Non-Qualified Stock Option Plans. Options typically vest over a three-year period and expire no later than ten years after the grant date. Terms of the options were determined by the Company's Compensation Committee which administers the plans. The Company's employees, directors, officers, and consultants or advisors are eligible to be granted options under the Non-Qualified Stock Option Plans.

Incentive Stock Option Plans – At September 30, 2019, the Company had collectively authorized the issuance of 138,400 shares of common stock under its Incentive Stock Option Plans. Options typically vest over a three-year period and expire no later than ten years after the grant date. Terms of the options were determined by the Company's Compensation Committee which administers the plans. Only the Company's employees are eligible to be granted options under the Incentive Stock Option Plans.

Activity in the Company's Non-Qualified and Incentive Stock Option Plans for the two years ended September 30, 2019 is summarized as follows:

Non-Qualified and Incentive Stock Option Plans

	Outstanding				Exercisable			
	Number of Shares	Weighted Average Exercise Price	Weighted Ave Remaining Contractual Term (Years)	Aggregate Intrinsic Value	Number of Shares	Weighted Average Exercise Price	Weighted Ave Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding at September 30, 2017	1,239,844	$ 16.44	8.50	$ 1,400	275,982	$ 53.53	4.91	$ 0
Vested					334,111	$ 7.63		
Granted	1,958,108	$ 2.50						
Exercised								
Forfeited	5,426	$ 3.79						
Expired	32,399	$ 67.73			32,399	$ 67.73		
Cancelled								
Outstanding at September 30, 2018	3,160,127	$ 7.30	8.88	$ 4,761,973	577,694	$ 26.18	6.74	$ 604,763
Vested					945,359	$ 2.56		
Granted	3,271,362	$ 5.40						
Exercised (a)	65,997	$ 2.28			65,997	$ 2.28		
Forfeited	82,461	$ 17.89						
Expired (b)	64,815	$ 71.86			64,815	$ 71.86		
Cancelled								
Outstanding at September 30, 2019	6,218,216	$ 5.54	8.88	$ 29,562,594	1,392,241	$ 9.15	7.68	$ 7,869,555

(a) Includes 10,000 stock options exercised by consultants
(b) Includes 10,400 stock options to consultants

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

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

Incentive Stock Bonus Plan – Up to 640,000 shares are authorized under the 2014 Incentive Stock Bonus Plan. The shares will only be earned upon the achievement of certain milestones leading to the commercialization of the Company's Multikine technology, or specified increases in the market price of the Company's stock. If the performance or market criteria are not met as specified in the Incentive Stock Bonus Plan, all or a portion of the awarded shares will be forfeited. The fair value of the shares on the grant date was calculated using the market value on the grant-date for issuances where the attainment of performance criteria is likely and using a Monte Carlo simulation for issuances where the attainment of performance criteria is uncertain. The grant date fair value of shares issued that remain outstanding as of September 30, 2019 was approximately $8.6 million. The total value of the shares, if earned, is being expensed over the requisite service periods for each milestone, provided the requisite service periods are rendered, regardless of whether the market conditions are met. No compensation cost is recognized for awards where the requisite service period is not rendered. During the years ended September 30, 2019 and 2018, the Company recorded expense relating to the issuance of restricted stock pursuant to the plan of approximately $0.3 million and $1.4 million, respectively. At September 30, 2019, the Company has unrecognized compensation expense of approximately $0.7 million which is expected to be recognized over a weighted average period of 2.3 years.

A summary of the status of the Company's restricted common stock issued from the Incentive Stock Bonus Plan for the two years ended September 30, 2019 is presented below:

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

Stock Bonus Plans – At September 30, 2019, the Company was authorized to issue up to 783,760 shares of common stock under its Stock Bonus Plans. All employees, directors, officers, consultants, and advisors are eligible to be granted shares. As of September 30, 2019, the Company has issued a total of 33,226 shares of common stock from the Stock Bonus Plans.

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

11. EMPLOYEE BENEFIT PLAN

The Company maintains a defined contribution retirement plan, qualifying under Section 401(k) of the Internal Revenue Code, subject to the Employee Retirement Income Security Act of 1974, as amended, and covering substantially all Company employees. Each participant's contribution is matched by the Company with shares of common stock that have a value equal to 100% of the participant's contribution, not to exceed the lesser of $10,000 or 6% of the participant's total compensation. The Company's contribution of common stock is valued each quarter based upon the closing bid price of the Company's common stock. During the year ended September 30, 2019, 30,996 shares were issued to the Company's 401(k) plan for a cost of approximately $144,000. During the year ended September 30, 2018, 93,640 shares were issued to the Company's 401(k) plan for a cost of approximately $145,000.

12. COMMITMENTS AND CONTINGENCIES

Clinical Research Agreements

In April 2013, the Company entered into a co-development and revenue sharing agreement with Ergomed. Under the agreement, Ergomed will contribute up to $10 million towards the Company's Phase III clinical study in the form of offering discounted clinical services in exchange for a single digit percentage of milestone and royalty payments, up to a specific maximum amount. In October 2015, the Company entered into a second co-development and revenue sharing agreement with Ergomed for an additional $2 million, for a total of $12 million. The Company accounted for the co-development and revenue sharing agreement in accordance with ASC 808 "Collaborative Arrangements". The Company determined the payments to Ergomed are within the scope of ASC 730 "Research and Development." Therefore, the Company records the discount on the clinical services as a credit to research and development expense on its Statements of Operations. Since the Company entered into the co-development and revenue sharing agreement with Ergomed, it has incurred research and development expenses of approximately $30.9 million related to Ergomed's services. This amount is net of Ergomed's discount of approximately $10.5 million. During the years ended September 30, 2019 and 2018, the Company recorded approximately $2.8 million and $3.1 million, respectively, as research and development expense related to Ergomed's services. These amounts were net of Ergomed's discount of approximately $1.0 million during the years ended September 30, 2019 and 2018.

In October 2013, the Company entered into two co-development and profit sharing agreements with Ergomed. One agreement supported the Phase 1 study conducted at UCSF for the development of Multikine as a potential treatment for peri-anal warts in HIV/HPV co-infected men and women. The other agreement focuses on the development of Multikine as a potential treatment for cervical dysplasia in HIV/HPV co-infected women. Ergomed will assume up to $3 million in clinical and regulatory costs for each study.

Lease Agreements

The Company leases a manufacturing facility near Baltimore, Maryland under an operating lease (the San Tomas lease). The building was remodeled in accordance with the Company's specifications so that it can be used by the Company to manufacture Multikine for the Company's Phase 3 clinical trial and sales of the drug if approved by the FDA. The lease is for a term of twenty years and requires annual base rent to escalate each year at 3%. The Company is required to pay all real estate and personal property taxes, insurance premiums, maintenance expenses, repair costs and utilities. The lease allows the Company, at its election, to extend the lease for two ten-year periods or to purchase the building at the end of the 20-year lease. The Company contributed approximately $9.3 million towards the tenant-directed improvements, of which $3.2 million is being refunded during years six through twenty through reduced rental payments. The landlord paid approximately $11.9 million towards the purchase of the building, land and the tenant-directed improvements. The building was placed in service in October 2008.

Because the terms of the original lease agreements required the Company to be responsible for cost overruns, if there had been any, but of which there were none, the Company was deemed to be the owner of the building for accounting purposes under the build-to-suit guidance in ASC 840-40-55. In addition to the tenant improvements the Company incurred and capitalized on its balance sheet, the Company recorded an asset for tenant-directed improvements and for the costs paid by the lessor to purchase the building and to perform improvements, as well as a corresponding liability for the landlord costs. Upon completion of the improvements, the Company did not meet the "sale-leaseback" criteria under ASC 840-40-25, *Accounting for Leases, Sale-Leaseback Transactions,* and therefore, treated the lease as a financing obligation. Therefore, the asset and corresponding liability were not derecognized.

As of September 30, 2019 and 2018, the leased building asset has a net book value of approximately $15.6 million and $16.1 million, respectively, and the landlord liability has a balance of $13.5 million and $13.4 million, respectively. The leased building is being depreciated using a straight line method of the 20 year lease term to a residual value. The landlord liability is being amortized over the 20 years using the effective interest method.

The Company was required to deposit the equivalent of one year of base rent in accordance with the San Tomas lease. When the Company meets the minimum cash balance required by the lease, the deposit will be returned to the Company. The approximate $1.7 million deposit is included in non-current assets on September 30, 2019 and 2018.

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

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

The Company subleases a portion of its rental space on a month to month term lease, which requires a 30 day notice for termination. The sublease rent for the years ended September 30, 2019 and 2018 was approximately $73,000 and $71,000, respectively.

The Company leases its research and development laboratory under a 60 month lease which expires February 28, 2022. The operating lease includes escalating rental payments. The Company is recognizing the related rent expense on a straight line basis over the full 60 month term of the lease at the rate of approximately $13,000 per month. As of September 30, 2019 and 2018, the Company has recorded a deferred rent liability of approximately $14,000 and $12,000, respectively.

The Company leases its office headquarters under a 60 month lease which expires June 30, 2020. The operating lease includes escalating rental payments. The Company is recognizing the related rent expense on a straight line basis over the full 60 month term of the lease at the rate approximately $8,000 per month. As of September 30, 2019 and 2018, the Company has recorded a deferred rent liability of approximately $7,000 and $14,000, respectively.

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

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

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

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

Vendor Obligations

Further, the Company has contingent obligations with vendors for work that will be completed in relation to the Phase 3 trial. The timing of these obligations cannot be determined at this time. CEL-SCI estimates it will incur additional expenses of approximately $4.5 million for the remainder of the Phase 3 clinical trial. It should be noted that this estimate is based only on the information currently available from the Clinical Research Organizations responsible for managing the Phase 3 clinical trial and does not include other related costs, e.g. the manufacturing of the drug.

13. RELATED PARTY TRANSACTIONS

On October 30, 2017, in consideration for an extension of the maturity date of the Series MM and Series NN convertible notes, which had been issued in the prior year, the Company issued a total of 583,057 Series RR warrants to the note holders who agreed to the extension. Geert Kersten, the Company's Chief Executive Officer, a trust in which Mr. Kersten holds a beneficial interest and Patricia B. Prichep, the Company's Senior Vice President of Operations received 73,965, 54,585 and 5,459 Series RR warrants, respectively. The Series RR warrants were classified as equity warrants in accordance with ASC 815 and the fair value of the portion attributable to Mr. Kersten, the trust and Ms. Prichep was calculated to be approximately $151,000 on the date of issuance. The terms of the related party notes and warrants were identical to the other participants.

On June 11, 2018, Mr. Kersten, the trust and Ms. Prichep converted the outstanding notes payable balances of $250,000, $250,000 and $25,000, respectively, into 147,929, 109,170 and 10,917 shares, respectively, of common stock in accordance with the original conversion terms, which were identical to those of the other participants. To induce conversion of the Series MM and NN Notes, all note holders, including Mr. Kersten, the trust and Ms. Prichep, were issued Series UU warrants in an amount equal to 20% of the shares into which the Notes were convertible. This resulted in the issuance of 29,586, 21,834 and 2,183 Series UU warrants to Mr. Kersten, the trust and Ms. Prichep, respectively. The Series UU warrants had an exercise price of $2.80 per share and expired on June 11, 2018. These terms are identical to the other recipients of the Series UU Warrants. The Company recognized an expense equal to the fair value of the consideration transferred in the transaction in excess of the fair value of consideration issuable under the original conversion terms. The portion of the expense attributed to the fair value of the Series UU warrants issued to Mr. Kersten, the trust and Ms. Prichep was approximately $83,000 and is included as interest expense on the statement of operations for the year ended September 30, 2018. The Series UU warrants qualified for equity treatment in accordance with ASC 815.

The Series MM and NN Notes accrued interest at 4%. Upon conversion, the officers elected to receive the accrued interest in shares of common stock instead of cash. On the conversion date in June 2018, the officers converted approximately $19,000 in accrued interest into 6,930 shares of common stock. No other interest payments were made to officers during the years ended September 30, 2019 and 2018.

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

14. STOCKHOLDERS' EQUITY

Exercise of Warrants

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

Sales of Securities

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

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

On December 19, 2017 the Company sold 1,289,478 shares of its common stock at a price of $1.90 per share for total proceeds of approximately $2.45 million. The purchasers of the common stock also received warrants which allow the purchasers to acquire up to 1,289,478 shares of the Company's common stock. The warrants are exercisable at a fixed price of $2.09 per share and expire on December 18, 2022. The Company allocated the proceeds received to the shares and the Series SS warrants on a relative fair value basis. As a result of such allocation, the Company determined the relative fair value of the Series SS warrants to be approximately $1.0 million. The Series SS warrants qualify for equity treatment in accordance with ASC 815.

Other Equity Transactions

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

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

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

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

15. FAIR VALUE MEASUREMENTS

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

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

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

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

The table below sets forth the liabilities measured at fair value on a recurring basis, by input level, on the balance sheet at September 30, 2019:

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

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

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

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

	2019	2018
Beginning balance	$ 9,317,031	$ 2,020,629
Issuances	-	-
Exercises	(3,589,357)	(595,780)
N Net realized and unrealized derivative loss (gain)	760,636	7,892,182
Ending balance	$ 6,488,310	$ 9,317,031

The fair values of the Company's derivative instruments disclosed above under Level 3 are primarily derived from valuation models where significant inputs such as historical price and volatility of the Company's stock as well as U.S. Treasury Bill rates are observable in active markets. At September 30, 2019, the Company's Level 3 derivative instruments have a weighted average fair value of $2.72 per share and a weighted average exercise price of $15.17 per share. Fair values were determined using a weighted average risk free interest rate of 1.85% and 103% volatility. The instruments have a weighted average time to maturity of 1.86 years. At September 30, 2018, the Company's Level 3 derivative instruments have a weighted average fair value of $1.50 per share and a weighted average exercise price of $8.50 per share. Fair values were determined using a weighted average risk free interest rate of 2.68% and 121% volatility. The instruments have a weighted average time to maturity of 2.3 years.

16. NET LOSS PER COMMON SHARE

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

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

	Year ended September 30,	
	2019	2018
Loss per share – basic and diluted		
Net loss available to common shareholders	$ (22,134,640)	$ (31,851,573)
Weighted average shares outstanding	31,174,394	17,004,722
Basic and diluted loss per common share	$ (0.71)	$ (1.87)

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:

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

17. SUBSEQUENT EVENTS

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

In accordance with Section 13 or 15(a) of the Securities Exchange Act of 1934, the Registrant has caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized on the 16th day of December 2019.

CEL-SCI CORPORATION

By: /s/ Geert Kersten

Geert Kersten, Chief Executive Officer

Pursuant to the requirements of the Securities Act of l934, this Report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Geert R. Kersten Geert Kersten	Chief Executive, Principal Accounting, Principal Financial Officer and a Director	December 16, 2019
/s/ Peter R. Young Dr. Peter R. Young	Director	December 16, 2019
/s/ Bruno Baillavoine Bruno Baillavoine	Director	December 16, 2019
/s/ Robert Watson Robert Watson	Director	December 16, 2019

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

CEL-SCI Corporation

Vienna, Virginia

We hereby consent to the incorporation by reference in the Registration Statements on Form S3 (File numbers 333-162039, 333-161504, 333-162792, 333-184094, 333-186103, 333-196243 and 333-205444 and 333-226558) and Form S-¬8 (File numbers 333-117088, 333-140792, 333-162265, 333-179477, 333-184092, 333-198244, 333-206538 and 333-214031, 333-222969 and 333-228252) of CEL-SCI Corporation of our reports dated December 16, 2019, relating to the financial statements, and the effectiveness of CEL-SCI Corporation's internal control over financial reporting, which appear in this form 10-K. Our report on the financial statements contains an explanatory paragraph regarding the Company's ability to continue as a going concern.

/s/ BDO USA, LLP

Potomac, Maryland
December 16, 2019

Exhibit 31

CERTIFICATIONS

I, Geert Kersten, of CEL-SCI Corporation, certify that:

1. I have reviewed this annual report on Form 10-K of CEL-SCI Corporation;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15 and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) designed such internal control over financial reporting, or cause such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of the internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and

b) any fraud, whether or not material, that involves management or other employees who have significant role in the registrant’s internal control over financial reporting.

December 16, 2019

By: /s/ Geert Kersten
Geert R. Kersten
Principal Executive Officer

CERTIFICATIONS

I, Geert Kersten, of CEL-SCI Corporation, certify that:

1. I have reviewed this annual report on Form 10-K of CEL-SCI Corporation;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15 and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) designed such internal control over financial reporting, or cause such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of the internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and

b) any fraud, whether or not material, that involves management or other employees who have significant role in the registrant’s internal control over financial reporting.

December 16, 2019

By: /s/ Geert Kersten
Geert R. Kersten
Principal Financial Officer

Exhibit 32

In connection with the Annual Report of CEL-SCI Corporation (the "Company") on Form 10-K for the period ending September 30, 2019 as filed with the Securities and Exchange Commission (the "Report"), Geert Kersten, the Chief Executive and Principal Financial Officer of the Company, certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects the financial condition and results of the Company.

December 16, 2019

By: /s/ Geert Kersten
Geert Kersten, Chief Executive and Principal Financial and Accounting Officer