Annual Report

2022

CEL-SCI Corporation

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 a product candidate CEL-4000, under development for the potential treatment of rheumatoid arthritis.

MULTIKINE

CEL-SCI's lead investigational therapy Multikine® (Leukocyte Interleukin, Injection) comprised of a patented defined mixture of 14 human natural cytokines, completed a pivotal Phase 3 clinical trial for patients who are newly diagnosed with locally advanced (stage III and IV) primary (not yet treated) squamous cell carcinoma of the head and neck (SCCHN). Multikine has received Orphan Drug Status from the U.S. Food and Drug Administration (FDA) for this indication. The study is believed to be the biggest Phase 3 head and neck cancer study ever with 928 patients and lasted almost 10 years. This trial was under the management of two clinical research organizations (CROs): ICON plc. (ICON) and Ergomed Clinical Research Limited (Ergomed).

On June 28, 2021, the Company announced top line results from its pivotal Phase 3 study for Multikine. The Phase 3 results showed a long-term 5-year overall survival (OS) benefit in the treatment arm that received Multikine treatment followed by surgery and radiation (the lower risk to recurrence treatment arm). This survival benefit was robust and durable and added no toxicity to the overall treatment, something not commonly seen with cancer drugs. In fact, the survival benefit increased over time and at 5-years the overall survival benefit reached an absolute 14.1% advantage for the Multikine treated arm over control (n=380, total study patients treated with surgery plus radiation), control arm 48.6%, Multikine arm 62.7% survival.

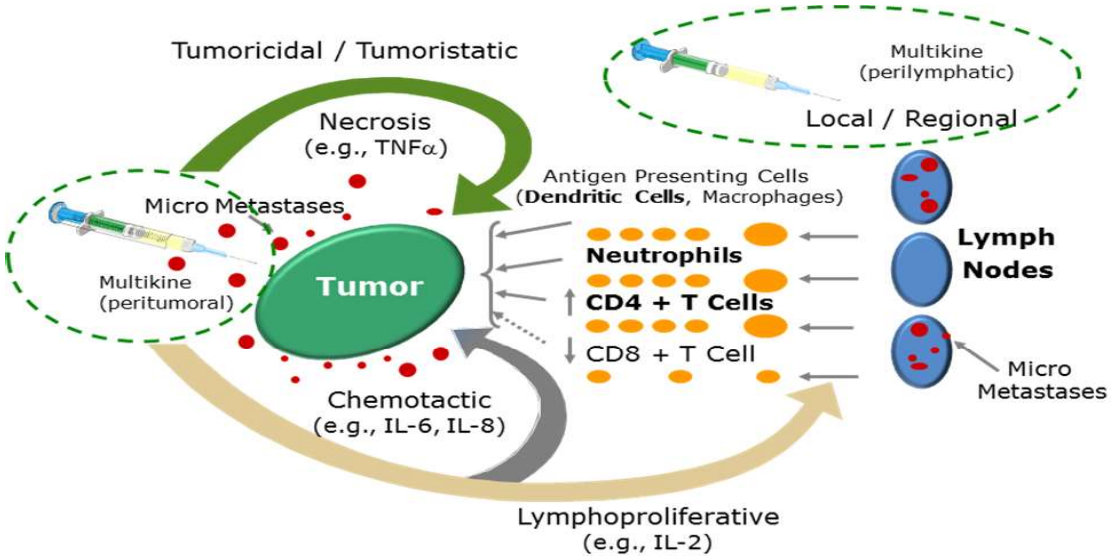
The study used the standard of care treatment for advanced primary head and neck cancer patients as a comparison. The patients received surgery followed by either radiation or chemoradiation (chemotherapy and radiation at the same time), as determined by the physician. This means that there were 2 treatment arms, 1) surgery plus radiation or 2) surgery plus chemoradiation. The arm that received Multikine treatment followed by surgery and radiation showed great survival benefit, but when chemotherapy was added in the second treatment arm, the immunological effect of Multikine was negated. Therefore, when the two treatment arms were combined the study did not achieve its primary endpoint of a 10% improvement in overall survival.

However, the analysis of the separate treatment arms was prespecified in the protocol and carried out prior to the Company becoming unblinded. The OS benefit of 14.1% at 5 years for this treatment arm exceeded the 10% OS benefit set out for the study population as a whole. The OS results for this treatment arm are significant (two-sided p=0.0236, HR=0.68) and the effect is robust, durable and increasing over time. In addition, the study had a significant number of patients who had partial and even complete tumor responses following the 3-week treatment with Multikine. Most of those were among the patients who did not receive chemotherapy. It was also discovered that patients who have tumor burden reductions (early tumor responders) have significantly improved survival. The results from the Phase 3 cancer study proved that Multikine met all of the protocol required benefits stated in the study protocol in patients in the treatment arm receiving surgery and radiation as their standard therapies. The Company will be filing for and seeking FDA approval for the use of Multikine in the treatment of advanced primary head and neck cancer in this patient population of about 210,000 patients annually worldwide.

Multikine is designed to be used in a different way than cancer immunotherapy is generally being used. Generally, cancer immunotherapy is given to patients who have already failed other treatments such as surgery, radiation and/or chemotherapy and most of the time it is administered systemically. Multikine on the other hand is administered locally to treat tumors and their microenvironment before any other therapy has been administered because it is believed that this is the time when the immune system would be strongest and most amenable to activation against the tumor. For example, in the Phase 3 clinical trial, Multikine was injected locally around the tumor and near the adjacent draining lymph nodes for three weeks, five days a week as a first treatment before surgery, radiation and/or chemotherapy. The goal is to help the intact immune system recognize and kill the tumor micro metastases that usually cause recurrence of the cancer. In short, CEL-SCI believes that the local administration of Multikine before weakening of the immune system by surgery, chemotherapy and radiation will result in better anti-tumor response than if Multikine were

administered after surgery and radiation. 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.

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 (EMA), and neither its safety nor its efficacy been established.



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).

On May 27, 2022, CEL-SCI announced the American Society of Clinical Oncology (ASCO) published two abstracts related to its pivotal Phase 3 Multikine head and neck cancer clinical trial. The poster was presented by CEL-SCI's Chief Scientific Officer, Eyal Talor, Ph.D. at the 2022 ASCO Annual Meeting on June 6, 2022 in Chicago, Illinois. The abstract titles and corresponding links are as follows:

- *"Leukocyte interleukin injection (LI) immunotherapy extends overall survival (OS) in treatment-naive low-risk (LR) locally advanced primary squamous cell carcinoma of the head and neck: The IT-MATTERS study."*
  - Link to abstract: https://meetings.asco.org/abstracts-presentations/207201
  - Link to poster: https://cel-sci.com/wp-content/uploads/2022/06/CEL-SCI-ASCO-2022-Poster-6032-June-6-Head-and-Neck-Cancer-1.pdf
- *"Novel algorithm for assigning risk/disease-directed treatment (DDT) choice in locally advanced primary squamous cell carcinoma of the head and neck (SCCHN): Using pretreatment data only."*
  - Link to abstract: https://meetings.asco.org/abstracts-presentations/207202/

At ASCO 2022, CEL-SCI presented data that showed the following:

- 14.1% absolute advantage in overall survival (OS) at 5-years in the lower-risk-for-recurrence treatment arm (62.7% vs 48.6%) of patients with previously untreated locally advanced primary squamous cell carcinoma of the head and neck (Multikine+CIZ) versus the standard of care (SOC) control patients. Patients in the "lower-risk-for-recurrence" treatment arm are those with no adverse features discovered during surgery and who are therefore supposed to receive radiotherapy only after surgery. However, "lower-risk" does not mean low risk, as this treatment arm without CEL-SCI's investigational Multikine still saw less than 50% survival 5-years post standard of care treatment alone (control group).
- Nearly 4-year increase in median survival in this treatment arm (101.7 months for Multikine+CIZ versus 55.2 months for the SOC alone).

- Objective response before surgery (partial and complete tumor responses):
  - In 8.5% (45/529) of Multikine-treated patients in the intent-to-treat (ITT) population (n=923) versus zero in the SOC alone (control).
  - In 16.0% (34/212) of Multikine-treated patients in this treatment arm (n=380) versus zero in the SOC alone (control).
- Complete tumor response before surgery in five of the early responders, all five of which were in the Multikine+CIZ treatment arm.
- Objective responses before surgery were prognostic for improved survival and significant for reduced death rate:
  - In the overall ITT population, 22.2% death rate (n=45) among objective responders before surgery versus 54.1% death rate for the Multikine non-responders (n=484).
  - In the Proposed Indication, 17.6% death rate (n=34) among objective responders before surgery versus 42.7% death rate for the Multikine non-responders (n=178).
- Histopathological analysis confirmed the effect of Multikine, as 61 markers, ratios, and combinations showed a statistically significant effect (two-sided $p<0.05$) favoring the Multikine+CIZ treatment arm versus the SOC alone (control) for OS, Progression Free Survival (PFS), and Locoregional Control (LRC) outcomes.
- Additional (confirmatory) progression-free survival (PFS) benefit in the Proposed Indication was observed for Multikine+CIZ versus the SOC alone.
- Pre-specified analysis of the Proposed Indication was noted and discussed in the original study protocol and pre-specified in the statistical analysis plan. The Proposed Indication comprised about 40% of all study participants.
- The overall incidence of adverse events and serious adverse events in the Multikine arms was not substantially different versus the SOC alone.

CEL-SCI also presented a selection process (algorithm) that allows physicians to select before surgery those patients who are intended to receive only radiotherapy after surgery.

On September 12, 2022, CEL-SCI announced two poster presentations were delivered at the European Society for Medical Oncology (EMSO) annual Congress. Data presented were from CEL-SCI's pivotal Phase 3 study and summarized below:

Poster Presentation: Early response to Neoadjuvant Leukocyte Interleukin Injection (LI) immunotherapy extends overall survival (OS) in locally advanced primary squamous cell carcinoma (SCC) of the head & neck (HN): the IT-MATTERS Study

- Early tumor response (early response) to neoadjuvant Multikine-Treatment is noted before surgery (occurring at median 5 weeks post-randomization) adding credibility to the isolated impact of early treatment
- Early response provides a positive signal to both patients and care providers (early in the treatment course)
- Early response was noted only in the Multikine* (Leukocyte Interleukin Injection) treatment groups and not in the control group
- Early response occurs in both the Lower Risk and Higher Risk groups for recurrence (Risk as defined per NCCN Guidelines)
- Early response is prognostic and predictive for overall survival in:
- The overall population; and
- The Lower Risk population
- Benefit was also seen in Multikine-treated Lower Risk non-responders
- Link to poster: https://cel-sci.com/wp-content/uploads/2022/09/CEL-SCI-ESMO-690P-Early-Responders-Poster-FINAL.pdf
- Link to video presentation: https://youtu.be/zMoFtweVGzs

Poster Presentation: Histopathology (HP) biomarkers confirm Leukocyte Interleukin Injection (LI) treatment (Tx) outcome in naïve locally advanced primary head & neck squamous cell carcinoma (SCCHN) the IT-MATTERS Study

- Pre-defined markers, ratios, and combinations derived from Multikine treated tumor samples at surgery contribute to Multikine efficacy for all three efficacy endpoints (OS), progression free survival (PFS), and local regional control (LRC)
- Broad representation of markers, ratios, and combinations overall and for Lower Risk (LR) for the OS, PFS, LRC efficacy study endpoints
- There were 61 (21.9%) favorable overall and 54 (19.4%) favorable Lower Risk treatment group outcomes (much beyond 2.5% chance) and only a total of five instances (1.9%) [all High Risk] having unfavorable treatment group outcome (within the realm of chance)

- These biomarkers were prognostic for superior efficacy of the post-surgery adjuvant radiotherapy as compared to adjuvant chemoradiotherapy
- The results support the Lower Risk treatment advantage (0.68 HR, Wald p<0.05) significantly favoring Multikine+CIZ+ SOC vs SOC alone
- Link to poster: https://cel-sci.com/wp-content/uploads/2022/09/CEL-SCI-ESMO-128P-HP-Poster-FINAL.pdf

The study used the standard of care treatment for advanced primary head and neck cancer patients as a comparison. The patients received surgery followed by either radiation or chemoradiation (chemotherapy and radiation at the same time), as determined by the physician based on pathology from surgery. This means that there were 2 distinctly different treatment arms, 1) surgery plus radiation or 2) surgery plus chemoradiation. The arm that received Multikine treatment followed by surgery and radiation showed great survival benefit, but when chemotherapy was added in the second treatment arm, the immunological effect of Multikine was negated. Therefore, when the two treatment arms were combined the study did not achieve its primary endpoint of a 10% improvement in overall survival.

However, the analysis of the separate treatment arms was prespecified in the protocol and carried out prior to the Company becoming unblinded. The OS benefit of 14.1% at 5 years for this treatment arm exceeded the 10% OS benefit set out for the study population as a whole. The OS results for this treatment arm are significant (two-sided p=0.0236, HR=0.68) and the effect is robust, durable and increasing over time. The results from the Phase 3 cancer study proved that Multikine met all of the protocol required benefits stated in the study protocol in patients in the treatment arm receiving surgery and radiation as their standard therapies.

CEL-SCI also presented data at the ESMO cancer meeting in September 2022. Particularly important is the early tumor response (ER) seen as a direct result of the 3-week Multikine treatment. LR means lower risk for recurrence which is scheduled to be treated with surgery and radiotherapy, HR means higher risk for recurrence which is scheduled to be treated with surgery followed by radiotherapy and concurrent chemotherapy. MK means Multikine. OS means Overall Survival.

There were 45 objective Early Tumor Responses (5 complete and 40 partial responders) and 462 deaths (50.1%); the 5 complete responders [CRs] were all confirmed by pathology. ERs were only observed in the two Multikine-treated groups (8.5% combined MK; 16% LR combined MK vs 3.7% HR MK; 15.2% LR MK+CIZ+SOC). ERs were more commonly seen in the LR group (16.0%) vs the HR group (3.7%). No responders were seen in the SOC patients. In the MK-treated groups, death rates fell significantly for ERs vs non-responders (54.1% vs 22.2% combined MK; 42.5% vs 17.6% LR combined MK groups; 40.7% vs 12.5% LR (MK+CIZ+SOC); the corresponding hazard ratios (HZR) were 0.301 (Wald p<0.0001) overall, 0.348 (p=0.0067) for LR MK, and 0.246 (p=0.01) for LR MK=CIZ=SO in support of ER being supportive.

Assuming no OS prolongation for the remaining 84.8%, this equates to a 46.5% OS gain corresponding to the observed 0.68 HZR (1/1.465) for the ITT Lower Risk LI (MK)+CIZ+SOC group; this was consistent with the observed 46.5-month median OS advantage for LR LI+CIZ+SOC (101.7 months) vs LR SOC (55.2 months). ER was also predictive; among the 45 responders; there were only 10 deaths (22.2%) in contrast to 452 (51.5%) for the overall ITT population. Thus, ER was predictive from both a modeling and outcome perspective. The conclusions were as follows: Objective ER was only observed for the MK treatments. Multiple ERs were observed across LR (n=34), HR (n=10), and UC (n=1). ER from MK treatment is not only prognostic but also predicts a most favorable OS outcome.

Since CEL-SCI launched its Phase 3 clinical trial for Multikine, CEL-SCI has incurred expenses of approximately $64.1 million as of September 30, 2022 on direct costs for the Phase 3 clinical trial. CEL-SCI estimates it will incur additional expenses of approximately $0.6 million for the remainder of the Phase 3 clinical trial and the filing of the clinical study report to the FDA. It should be noted that this estimate is based only on the information currently available from the CROs responsible for managing the Phase 3 clinical trial and does not include other related costs, e.g., preparations for the potential commercial manufacture of the drug.

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 section of 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. However, CEL-SCI does not believe that this would be ethical or supported by the survival data for this unmet medical need.

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.

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.

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 the 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 (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 the bankruptcy or uncured material breach by either party. 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 equally between CEL-SCI and Byron.

MANUFACTURING

If commercial approval is obtained, CEL-SCI intends to manufacture Multikine in a proprietary manner in CEL-SCI's manufacturing facility near Baltimore, Maryland, USA. CEL-SCI spent over 10 years and more than $100 million developing and validating the manufacturing process for Multikine. Multikine is a defined mixture of cytokines (small proteins released by cells that have a specific effect on the interactions between cells). The cytokine mixture includes interleukins, interferons, chemokines, and colony stimulating factors; all of which are molecules which stimulate the body's healthy immune response.

LEAPS

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

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

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

On September 19, 2017, CEL-SCI announced that it had been awarded a Phase 2 Small Business Innovation Research (SBIR) grant in the amount of $1.5 million from the National Institute of Arthritis and Musculoskeletal and Skin Diseases(NIAMS), which is part of the U.S. National Institutes of Health (NIH). This grant provided 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 was 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. This grant has been fully expended.

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

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

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

Prior to the SBIR Phase 2 grant in 2014, CEL-SCI was awarded a Phase 1 SBIR grant in the amount of $225,000 from NIAMS. This grant funded the development of CEL-SCI's LEAPS technology as a potential treatment for rheumatoid arthritis, an autoimmune disease of the joints. The work was conducted at Rush University Medical Center in Chicago, Illinois in the laboratories of Tibor Glant, MD, Ph.D., Katalin Mikecz, MD, Ph.D., and Allison Finnegan, Ph.D. Professor of Medicine.

With the support of these SBIR grants, CEL-SCI is developing several new drug candidates, CEL-2000 and CEL-4000, as potential rheumatoid arthritis therapeutic treatments. The data from animal studies using the CEL-2000 treatment suggests that it could be used against rheumatoid arthritis with fewer administrations than those required by other anti-rheumatoid arthritis treatments currently on the market for arthritic conditions associated with the Th17 signature cytokine TNF-a. The preclinical data indicates these peptides could be used against rheumatoid arthritis where a Th1 signature cytokine (IFN-γ) is dominant. CEL-2000 and CEL-4000 each have the potential to become a personalized, disease-specific therapy that acts at an earlier step in the disease process than current therapies, and which may be useful in patients not responding to existing rheumatoid arthritis therapies. CEL-SCI believes this represents a large unmet medical need in the rheumatoid arthritis market.

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.

Accordingly, even though the various LEAPS candidates have not yet been given to humans, they have been tested in vitro with human cells. They have induced similar cytokine responses that were seen in these animal models, which may indicate that the LEAPS technology might translate to humans. The LEAPS candidates have demonstrated protection against lethal herpes simplex virus (HSV1) and H1N1 influenza infection as a prophylactic or therapeutic agent in animals. They have also shown some level of activity in animals in two autoimmune conditions, curtailing and sometimes preventing disease progression in arthritis and myocarditis animal models.

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

GENERAL

None of CEL-SCI's product candidates have been approved for sale, barter or exchange by the FDA or any other regulatory agency for any use to treat disease in humans nor has the safety or efficacy of these products been established for any use. There can be no assurance that obtaining marketing approval from the FDA in the United States and by comparable agencies in most foreign countries will be granted.

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. These filings are available on its website free of charge as soon as practicable after they are filed or furnished to the SEC.

MANUFACTURING FACILITY

Before starting the Phase 3 clinical trial, for reasons related to regulatory considerations, CEL-SCI built a dedicated manufacturing facility to produce its investigational biological product candidate Multikine. This facility produced multiple clinical lots for the Phase 3 clinical trial and has also passed quality systems review by a European Union Qualified Person on several occasions. CEL-SCI expanded the manufacturing facility so CEL-SCI will be able to meet the expected demand for Multikine, if FDA approval is granted. This expansion was completed at the end of 2021, allowing CEL-SCI employees to return to work inside the manufacturing facility. The facility is currently undergoing validation.

CEL-SCI's lease on the manufacturing facility expires on October 31, 2028. At that time CEL-SCI can either purchase the facility or extend its lease.

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

As of September 30, 2022, there were approximately 525 holders of record 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 by the NYSE American.

Quarter Ending	High	Low
12/31/2020	$16.70	$10.76
3/31/2021	$40.91	$11.88
6/30/2021	$27.86	$8.20
9/30/2021	$12.90	$7.08
12/31/2021	$12.82	$7.06
3/31/2022	$7.73	$3.80
6/30/2022	$6.14	$2.49
9/30/2022	$5.42	$3.09

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

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

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

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

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

Multikine (Leukocyte Interleukin, Injection) which, for simplicity, is referred to in this report as Multikine, is the trademark that the Company has registered for this investigational therapy, and this proprietary name is subject to FDA review under the Company's future anticipated regulatory submission for approval. Multikine has not been licensed or approved by the FDA or any other regulatory agency. Neither has its safety or efficacy been established for any use.

CEL-SCI also owns and is developing a pre-clinical technology called LEAPS (Ligand Epitope Antigen Presentation System). CEL-SCI is using its LEAPS technology platform to investigate its lead peptide-based immunotherapy (CEL-4000) as a vaccine treatment for rheumatoid arthritis.

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 will likely continue to generate net operating losses 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

The Company incurred a net operating loss of approximately $36.1 million for the twelve months ended September 30, 2022. This net operating loss consists of significant non-cash expenses accounting for approximately 42% of the operating loss. The non-cash operating expenses include approximately $11.4 million in stock-based employee compensation and approximately $3.8 million in depreciation and amortization expense.

During the year ended September 30, 2022, research and development expenses increased by approximately $2.2 million, or 10%, compared to the year ended September 30, 2021. Major components of this increase include approximately $0.5 million in employee stock compensation expense, approximately $1.6 million in depreciation, primarily related to leasehold improvements to the manufacturing facility that were placed in service in October 2021, an increase of approximately $1.2 million of costs incurred to prepare for the potential commercial sale of Multikine, and an increase of approximately $0.2 million in other miscellaneous research and development expenses. These increases were offset by a decrease of approximately $1.3 million in costs related to the Phase 3 clinical study.

During the year ended September 30, 2022, general and administrative expenses decreased by approximately $2.4 million, or 18%, compared to the year ended September 30, 2021. This decrease is primarily due to a decrease in employee stock compensation expense of approximately $2.8 million offset by a $0.4 million increase in other net general and administrative expenses.

During the years ended September 30, 2022 and 2021, CEL-SCI recorded a derivative gain of approximately $0.4 million and a loss of approximately $0.7 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.

During the year ended September 30, 2022, other non-operating gain decreased by approximately $1.7 million compared to the year ended September 30, 2021 resulting in a loss of approximately $31,000 for the year ended September 30, 2022. This gain for the year ended September 30, 2021 relates to the Securities Purchase Agreement (SPA) described in Note 12 to the financial statements included as part of this report. Under the SPA, the Company issued Ergomed shares of common stock and the net proceeds from the sales of those shares reduces outstanding amounts due Ergomed. Upon issuance, the Company expensed the full value of the shares as other non-operating gain/loss and subsequently offset the gain or loss as amounts were realized through the sale by Ergomed and reduced accounts payable to Ergomed. The amount of the gain or loss is a result of the timing of shares issued to Ergomed and the subsequent re-sale of those shares. There was no activity under the agreement during the year ended September 30, 2022. During the year ended September 30, 2021, the Company realized approximately $1.7 million in value upon the resale of shares. Ergomed resold the final balance of shares issued in the quarter ended September 30, 2021.

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,	
	2022	2021
Multikine	$ 24,251,629	$ 21,508,026
LEAPS	1,103,717	1,600,871
Total research and development	$ 25,355,346	$ 23,108,897

CEL-SCI's Phase 3 clinical trial began in December 2010 after the completion and validation of CEL-SCI's dedicated manufacturing facility. The Phase 3 clinical trial was fully enrolled in September 2016, reached its primary endpoint in April 2020 and achieved database lock in December 2020. The data was unblinded in June 2021, the primary endpoint results were announced in June 2021, additional data was presented at ASCO 2022 and ESMO 2022 in June 2022 and September 2022, respectively. CEL-SCI is currently preparing the BLA to submit to the FDA.

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 the Company's clinical trials and research programs are primarily based upon the amount of capital available to the Company and the extent to which the Company has received regulatory approvals for clinical trials. The inability of the Company to conduct clinical trials or research, whether due to a lack of capital or regulatory approval, will prevent the Company from completing the studies and research required to obtain regulatory approval for any products which the Company is developing. Without regulatory approval, the Company will be unable to sell any of its products. Since all of the Company's projects are under development, the Company cannot predict when it will be able to generate any revenue from the sale of any of its products.

Liquidity and Capital Resources

CEL-SCI has had only limited revenues from operations since its inception in March 1983. CEL-SCI has relied primarily upon capital generated from the public and private offerings of its common stock and convertible notes. In addition, CEL-SCI has utilized short-term loans to meet its capital requirements. Capital raised by CEL-SCI has been used to acquire an exclusive worldwide license to use, and later purchase, certain patented and unpatented proprietary technology and know-how relating to the human immunological defense system and for clinical trials. Capital has also been used for patent applications, debt repayment, research and development, administrative costs, and for CEL-SCI's laboratory and manufacturing facilities. CEL-SCI does not anticipate realizing significant revenues until it enters into licensing arrangements regarding its technology and know-how or until it receives regulatory approval to sell its products (which could take a number of years). As a result, CEL-SCI has been dependent primarily upon the proceeds from the sale of its securities to meet all of its liquidity and capital requirements and anticipates having to do so in the future. During fiscal years 2022 and 2021, CEL-SCI raised net proceeds of approximately $0.1 million and $54.0 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 $2.5 million during the twelve months ended September 30, 2022.

In June 2021, the Company sold 1,400,000 shares of common stock at a public offering price of $22.62 per share and received aggregate net proceeds of approximately $29.4 million. Under the terms of the Underwriting Agreement the Company granted the Underwriters a 30-day option to purchase up to an additional 210,000 shares of common stock solely to cover over-allotments. The underwriter fully exercised this option in June 2021 resulting in additional net proceeds to the Company of approximately $4.4 million.

In December 2020, the Company sold 1,000,000 shares of common stock at a public offering price of $14.65 per share and received aggregate net proceeds of approximately $13.6 million.

The following charts list the warrants that were exercised and the proceeds received during the years ended September 30, 2022 and 2021.

Fiscal Year 2022

Warrants	Warrants Exercised	Exercise Price	Proceeds
Series CC	15,205	$5.00	$ 76,025
Series NN	10,000	$2.52	25,200
	25,205		$ 101,225

Fiscal Year 2021

Warrants	Warrants Exercised	Exercise Price	Proceeds
Series Z	79,200	$13.75	$ 1,089,000
Series ZZ	20,000	$13.75	275,000
Series AA	100,000	$13.75	1,375,000
Series CC	132,798	$5.00	663,990
Series MM	464,201	$1.86	863,414
Series NN	138,755	$2.52	349,663
Series RR	165,888	$1.65	273,715
Series SS	126,064	$2.09	263,474
Series TT	370,964	$2.24	830,959
	1,597,870		$ 5,984,215

CEL-SCI entered into Securities Purchase Agreements (SPAs) with Ergomed plc, one of CEL-SCI's Clinical Research Organizations responsible for managing the Phase 3 clinical trial, to facilitate payment of amounts due Ergomed. Under the Agreements, CEL-SCI issued Ergomed shares of common stock and the net proceeds from the sales of those shares reduces outstanding amounts due Ergomed. Upon issuance, CEL-SCI expensed the full value of the shares as other non-operating gain/loss and subsequently offset the expense as amounts were realized through the sale by Ergomed and reduced accounts payable to Ergomed.

During the years ended September 30, 2022 and 2021, CEL-SCI did not issue Ergomed any shares of common stock. Additionally, no shares were sold during the year ended September 30, 2022. During the year ended September 30, 2021, the Company recorded other non-operating gains of approximately $1.7 million upon the resale of shares from the SPA.

As of September 30, 2022 and 2021, Ergomed had no shares remaining for resale.

During the year ended September 30, 2022, the Company used approximately $19.6 million, or approximately $1.6 million per month, in cash, after considering the maturity and transfer to cash of the remaining $6.2 million in U.S. Treasury bills (T-bills). Significant components of this decrease include cash used to fund the Company's regular operations of approximately $18.2 million, the purchase of property and equipment for approximately $0.6 million, approximately $0.2 million in share issuance costs and approximately $1.4 million in lease payments. These outflows are offset by approximately $0.8 million in lease incentives received from the landlord to partially offset costs of the manufacturing facility upgrade.

During the year ended September 30, 2022, 25,205 warrants were exercised at a weighted average exercise price of $4.02 for total proceeds of approximately $0.1 million.

Prepaid expenses decreased by approximately $0.2 million during the year ended September 30, 2022 as compared to September 30, 2021 primarily due to the timing of payments and recognition of related expenses relating to the Company's Phase 3 clinical trial status.

Supplies are purchased for use in the Company's manufacturing and R&D efforts. During the year ended September 30, 2022, the supplies increased by approximately $0.2 million in support of the work to validate and prepare the manufacturing facility to produce Multikine for commercial purposes and before the Company's Biologics License Application (BLA) can be submitted to the FDA.

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 this disclosure on numerous occasions in the preceding years.

Future Capital Requirements

CEL-SCI's material capital commitments include funding operating losses, funding its research and development program and making required lease payments. Additionally, the Company recently completed upgrading the manufacturing facility to prepare for the potential commercial production of Multikine. Total costs of this upgrade were approximately $11.1 million. The landlord of the property agreed to finance the final $2.4 million of costs and allow for the repayment through increased lease payments which began on March 1, 2021. As of September 30, 2022, the landlord had provided approximately all $2.4 million of the agreed funding. Because of the change in lease payments, the new financing arrangement was considered a lease modification.

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 $0.6 million for the filing of the clinical study report with the FDA. It should be noted that this estimate is based only on the information currently available from the CROs responsible for managing the Phase 3 clinical trial and does not include other related costs, e.g., the manufacturing of the drug.

CEL-SCI will need to raise additional funds, either through the exercise of outstanding warrants/options, through debt or equity financings 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 management has engaged in fundraising for over 25 years and believes that the manner in which it is proceeding will produce the best possible outcome for the shareholders. There can be no assurances that CEL-SCI will be successful in raising additional funds.

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

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

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

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

Critical Accounting Policies

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

Management believes that the following critical accounting policies require the most significant judgments and estimates with respect to the preparation of CEL-SCI's financial statements.

Lease Accounting – The measurement of the finance and operating lease right-of-use asset and lease liabilities requires the determination of an estimated lease term and an incremental borrowing rate, which involves complex judgment

by management. The determination of the incremental borrowing rates for new and modified lease contracts is a critical accounting policy. Significant judgment is required by management to develop inputs and assumptions used to determine the incremental borrowing rate for lease contracts.

Share-based Compensation – Share-based compensation cost to employees is measured at fair value as of the grant date in accordance with the provisions of ASC 718. The fair value of the stock options is calculated using the Black-Scholes option pricing model. The Black-Scholes model requires various judgmental assumptions including volatility and expected option life. The compensation cost is recognized as expense over the requisite service or vesting period. Performance-based options are valued using a Monte-Carlo simulation model, which requires inputs based on estimates, including the likelihood of the occurrence of performance and market conditions, volatility and expected option life.

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. Fair value is generally calculated using a Black-Scholes valuation model. 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 CORPORATION

Financial Statements for the Years
Ended September 30, 2022 and 2021, and
Report of Independent Registered Public Accounting Firm

CEL-SCI CORPORATION

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Report of Independent Registered Public Accounting Firm

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

Opinion on the Financial Statements

We have audited the accompanying balance sheets of CEL-SCI Corporation (the "Company") as of September 30, 2022 and 2021, the related 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"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company at September 30, 2022 and 2021, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Going Concern Uncertainty

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

Basis for Opinion

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

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

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

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Evaluation of Liquidity

As described in Note 2 to the financial statements, the Company has experienced recurring losses. The Company expects to continue incurring losses for the foreseeable future. Further, the Company has spent, and expects to continue to spend, a substantial amount of funds in connection with implementing its business strategy, including planned product development efforts, clinical trials and research and discovery efforts. The Company is dependent on its ability to raise additional funding from the capital markets in order to continue to fund its operations.

We identified management's evaluation of the Company's liquidity as a critical audit matter due to the significant judgments and assumptions used by management in (i) preparing its forecast of cash expenditures to support the Company's drug development and clinical trials, and (ii) providing complete and accurate disclosures related to the Company's liquidity. Auditing these judgments and assumptions involved especially challenging auditor judgment due to the nature and extent of audit effort required to address these matters.

The primary procedures we performed to address this critical audit matter included:

- Assessing the reasonableness of management's key assumptions in forecasting cash expenditures by comparing the key assumptions to (i) historical forecasts and (ii) the Company's ongoing drug development pipeline.

- Testing the completeness and accuracy of underlying data used in the forecasted cash expenditures by (i) inspecting contractual arrangements with third-party clinical research organizations and suppliers, and (ii) considering current and past expenditures in evaluating the forecasted fixed and variable costs.

- Evaluating the adequacy of management's disclosure in the financial statements regarding the Company's liquidity by comparing the disclosure to other audit evidence obtained to determine whether such evidence is consistent with or contradictory to the Company's liquidity disclosure.

/s/BDO USA, LLP

We have served as the Company's auditor since 2005.
Potomac, Maryland
December 27, 2022

CEL-SCI CORPORATION
BALANCE SHEETS
SEPTEMBER 30, 2022 AND 2021

	2022	2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 22,672,138	$ 36,060,148
U.S. Treasury Bills	-	6,151,385
Receivables	-	54,922
Prepaid expenses	762,063	998,482
Supplies used for R&D and manufacturing	2,001,715	2,006,584
Total current assets	25,435,916	45,271,521
Finance lease right of use assets	10,937,797	12,691,921
Operating lease right of use assets	1,884,464	2,056,178
Property and equipment, net	11,889,029	13,663,562
Patent costs, net	212,201	275,866
Deposits	-	1,910,917
Supplies used for R&D and manufacturing, net of current portion	164,299	-
Total assets	$ 50,523,706	$ 75,869,965
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 1,618,290	$ 1,675,813
Accrued expenses	842,492	859,216
Due to employees	471,488	265,993
Derivative instruments, current portion	-	437,380
Lease liabilities, current portion	1,731,481	698,665
Total current liabilities	4,663,751	3,937,067
Finance lease liabilities, net of current portion	11,721,368	13,252,364
Operating lease liabilities, net of current portion	1,850,380	2,021,308
Other liabilities	125,000	125,000
Total liabilities	18,360,499	19,335,739
Commitments and contingencies		
STOCKHOLDERS' EQUITY		
Common stock, $.01 par value – 600,000,000 shares authorized; 43,448,317 and 43,207,183 shares issued and outstanding at September 30, 2022 and 2021, respectively	434,484	432,072
Additional paid-in capital	486,625,816	474,298,566
Accumulated deficit	(454,897,093)	(418,196,412)
Total stockholders' equity	32,163,207	56,534,226
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 50,523,706	$ 75,869,965

CEL-SCI CORPORATION
STATEMENTS OF OPERATIONS
YEARS ENDED SEPTEMBER 30, 2022 AND 2021

	2022	2021
Operating expenses:		
Research and development	$ 25,355,346	$ 23,108,897
General & administrative	10,707,447	13,085,232
Total operating expenses	36,062,793	36,194,129
Operating loss	(36,062,793)	(36,194,129)
Other income (expense)	107,148	(8,213)
Gain (loss) on derivative instruments	366,791	(694,858)
Other non-operating (loss) gain	(30,793)	1,685,379
Interest expense, net	(1,081,034)	(1,149,288)
Net loss	$ (36,700,681)	$ (36,361,109)
Modification of warrants	(929,122)	(350,861)
Net loss available to common shareholders	$ (37,629,803)	$ (36,711,970)
Net loss per common share - basic	$(0.87)	$(0.90)
Weighted average common shares outstanding - basic	43,148,888	40,662,137
Net loss per common share - diluted	$(0.87)	$(0.93)
Weighted average common shares outstanding - diluted	43,148,888	40,694,248

CEL-SCI CORPORATION
STATEMENT OF STOCKHOLDERS' EQUITY
YEAR ENDED SEPTEMBER 30, 2022

	Common Shares	Stock Amount	Additional Paid-In Capital	Accumulated Deficit	Total
BALANCE, SEPTEMBER 30, 2020	38,730,150	$387,302	$401,174,675	$(381,835,303)	$19,726,674
Proceeds from the sale of common stock	2,610,000	26,100	47,337,326	-	47,363,426
Warrant exercises	1,597,870	15,978	9,991,328	-	10,007,306
Modification of warrants	-	-	24,387	-	24,387
401(k) contributions paid in common stock	17,990	180	200,919	-	201,099
Stock issued to nonemployees for service	75,885	759	1,194,945	-	1,195,704
Equity-based compensation - employees	(2,000)	(20)	13,685,066	-	13,685,046
Option exercises	149,788	1,498	744,730	-	746,228
Purchase of stock by officers and directors	27,500	275	219,725	-	220,000
Share issuance costs	-	-	(274,535)	-	(274,535)
Net loss	-	-	-	(36,361,109)	(36,361,109)
BALANCE, SEPTEMBER 30, 2021	43,207,183	$432,072	$474,298,566	$(418,196,412)	$56,534,226
Warrant exercises	25,205	252	171,562	-	171,814
401(k) contributions paid in common stock	52,882	528	222,515	-	223,043
Stock issued to nonemployees for service	156,547	1,567	691,926	-	693,493
Equity-based compensation - employees	-	-	11,389,932	-	11,389,932
Option exercises	6,500	65	29,770	-	29,835
Share issuance costs	-	-	(178,455)	-	(178,455)
Net loss	-	-	-	(36,700,681)	(36,700,681)
BALANCE, SEPTEMBER 30, 2022	43,448,317	$434,484	$486,625,816	$(454,897,093)	$32,163,207

CEL-SCI CORPORATION
STATEMENTS OF CASH FLOWS
YEARS ENDED SEPTEMBER 30, 2022 AND 2021

	2022	2021
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (36,700,681)	$ (36,361,109)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	3,828,917	2,231,108
Non-cash lease expense	54,469	31,441
Share-based payments for services	762,261	1,226,690
Equity-based compensation	11,389,932	13,685,046
Common stock contributed to 401(k) plan	223,043	201,099
Gain on short term investments	(615)	(5,621)
(Gain) loss on derivative instruments	(366,791)	694,858
Modification of warrants	-	24,387
Impairment loss on abandonment of patents	30,793	-
(Increase)/decrease in assets:		
Receivables	54,922	-
Prepaid expenses	167,651	283,964
Supplies used for R&D and manufacturing	(159,430)	(1,186,532)
Deposits	1,910,917	(240,000)
Increase/(decrease) in liabilities:		
Accounts payable	374,890	445,981
Accrued expenses	(16,724)	363,701
Due to employees	205,495	(182,029)
Net cash used in operating activities	(18,240,951)	(18,787,016)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Net sales (purchases) of U.S. Treasury Bills	6,152,000	(6,145,764)
Purchases of property and equipment	(637,892)	(9,016,329)
Expenditures for patent costs	(22,741)	(22,641)
Net cash provided by (used in) investing activities	5,491,367	(15,184,734)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock and warrants	-	47,363,426
Payments of share issuance costs	(169,445)	(325,034)
Proceeds from the exercise of warrants	101,225	5,984,215
Proceeds from the exercise of options	29,835	746,228
Proceeds from the purchase of stock by officers and directors	-	220,000
Proceeds from landlord funding of lease improvements	786,454	1,613,546
Payments of obligations under finance leases	(1,386,495)	(1,079,392)
Net cash (used in) provided by financing activities	(638,426)	54,522,989
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(13,388,010)	20,551,239
CASH AND CASH EQUIVALENTS, BEGINNING OF YEAR	36,060,148	15,508,909
CASH AND CASH EQUIVALENTS, END OF YEAR	$ 22,672,138	$ 36,060,148

CEL-SCI CORPORATION
STATEMENTS OF CASH FLOWS
YEARS ENDED SEPTEMBER 30, 2022 AND 2021

SUPPLEMENTAL SCHEDULE OF NON-CASH INVESTING AND FINANCING ACTIVITIES:

	2022	2021
Property and equipment included in accrued expenses and accounts payable	$ -	$ 435,412
Capitalizable patent costs included in accrued expenses and accounts payable	$ -	$ 6,510
Changes to right of use assets and liabilities	$ 16,268	$ 551,444
Finance lease obligation included in accounts payable	$ 1,354	$ 855
Prepaid consulting services paid with issuance of common stock	$ 295,143	$ 363,911
Fair value of warrant liabilities on date of exercise	$ 70,589	$ 4,023,091
Assets purchased under finance leases	$ 32,409	$ -
Financing costs included in current liabilities	$ 9,010	$ -
Accrued consulting services to be paid with common stock	$ 55,000	$ 55,000
Cash paid for interest	$ 1,156,778	$ 1,173,702

CEL-SCI CORPORATION
NOTES TO FINANCIAL STATEMENTS

1. ORGANIZATION

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

The Company is focused on finding the best way to activate the immune system to fight cancer and infectious diseases. The Company has announced results from its Phase 3 study for its lead investigational therapy, Multikine® (Leukocyte Interleukin, Injection), involving head and neck cancer, for which the Company has received Orphan Drug Status from the United States Food and Drug Administration (FDA). Unlike other immune therapies, Multikine is administered locally at the site of the tumor as a first line treatment right after diagnosis, before surgery and radiation. The goal is to help the intact immune system kill the micro metastases that usually cause recurrence of the cancer to improve outcomes and better overall survival rates for patients suffering from head and neck cancer.

CEL-SCI is also investigating a peptide-based immunotherapy (CEL-4000) as a vaccine for rheumatoid arthritis using its LEAPS technology platform. CEL-SCI is in the process of completing pre-IND studies for CEL-4000.

2. LIQUIDITY

The Company has incurred significant costs since its inception for the acquisition of certain proprietary technology and scientific knowledge relating to the human immunological defense system, patent applications, research and development, administrative costs, construction and expansion of manufacturing and laboratory facilities and participation in clinical trials. The Company has funded such costs primarily with proceeds from loans and the public and private sale of its securities. The Company will be required to raise additional capital or find additional long-term financing to continue with its efforts to bring Multikine to market. The ability to raise capital may be dependent upon market conditions that are outside the control of the Company. The ability of the Company to obtain approval from the U.S. Food and Drug Administration (FDA) for the sale of products to be developed on a commercial basis is uncertain. Ultimately, the Company must complete the development of its products, obtain the appropriate regulatory approvals and obtain sufficient revenues to support its cost structure. The Company believes there is a high likelihood that it will continue to receive funds from private and public offerings and warrant exercises similar to the way it has funded operations in the past. However, there can be no assurance that the Company will be able to raise sufficient capital to support its operations.

To finance the Company through marketing approval, the Company plans to raise additional capital in the form of warrant exercises, corporate partnerships, and debt and/or equity financings. The Company believes that it will be able to obtain additional financing because it has done so consistently in the past and because it showed great survival benefit in the Phase 3 study in one of the two treatment arms for advanced primary head and neck cancer. 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.

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.

Impact of the COVID-19 Pandemic

In response to the global outbreak of COVID-19 and the World Health Organization's classification of the outbreak as a pandemic, the Company continues to take the necessary precautions to ensure the safety of its employees and to minimize interruptions to its operations. Management follows the Centers for Disease Control and Prevention's ("CDC") guidance and the recommendations and restrictions provided by state and local authorities. The full impact of the COVID-19 outbreak continues to evolve as of the date of this report. As such, it is uncertain as to the full impact the pandemic will have on the Company's future financial condition, liquidity

and results of operations. Management is actively monitoring the risks to public health and the impact of overall global business activity on the Company's financial condition, liquidity, operations, suppliers, industry, and workforce.

3. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

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

U.S. Treasury Bills – U.S. Treasury Bills ("T-bills") are highly liquid short-term investments with maturity dates of greater than 3 months, but less than one year. These investments are recorded at fair value.

Supplies used for R&D and manufacturing – Supplies are consumable items kept on hand to support the Company's R&D and manufacturing operations. Supplies are recorded at cost and are charged to expense as they are used in operations.

Property and Equipment – Property and equipment are recorded at cost and depreciated using the straight-line method over estimated useful lives of five to seven years. Leasehold improvements are depreciated over the shorter of the estimated useful life of the asset or the term of the lease. Repairs and maintenance which do not extend the life of the asset are expensed when incurred. Property and equipment are reviewed on a quarterly basis to determine if any of the assets are impaired.

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

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

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

The Company adopted Accounting Standards Update (ASU) 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in an Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity* effective October 1, 2021. The amendments in this ASU simplify and clarify the guidance in Subtopic 815-40. There was no financial impact upon adoption.

The Company adopted ASU 2021-04, *Earnings Per Share (Topic 260), Debt—Modifications and Extinguishments (Subtopic 470-50), Compensation—Stock Compensation (Topic 718), and Derivatives and*

Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options. This standard was issued to clarify and reduce diversity in an issuer's accounting for modifications or exchanges of freestanding equity-classified written call options (for example, warrants) that remain equity classified after modification or exchange. ASU 2021-04 is effective for fiscal years beginning after December 15, 2021, however, as permitted, the Company has elected to prospectively adopt the standard effective as of October 1, 2021.

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 using the straight-line allocation method as expense over the requisite service or vesting period.

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

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

Restricted stock granted under the Incentive Stock Bonus Plan and options granted under the 2021 and 2020 Non-Qualified Stock Option Plans are subject to service, performance and market conditions and meet the classification of equity awards. These awards were measured at fair value on the grant dates using a Monte Carlo simulation for issuances where the attainment of performance criteria is uncertain. The total compensation cost will be expensed over the estimated requisite service period.

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

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

Concentration of Credit Risk – Financial instruments, which potentially subject the Company to concentrations of credit risk, consist of cash and cash equivalents. The Company maintains its cash and cash equivalents with high quality financial institutions. At times, these accounts may exceed federally insured limits. The Company has not experienced any losses in such bank accounts. The Company believes it is not exposed to significant credit risk related to cash and cash equivalents. All non-interest bearing cash balances were fully insured up to $250,000 at September 30, 2022.

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, 2022 and 2021.

The Company adopted ASU No. 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*, effective October 1, 2021. The new standard includes several provisions that simplify accounting for income taxes by removing certain exceptions to the general principles in Topic 740 and increasing consistency and clarity for the users of financial statements. The adoption of ASU 2019-12 had no impact on the Company's financial statements.

On August 16, 2022, the Inflation Reduction Act of 2022 (IR Act) was signed into federal law. The IR Act provides for, among other things, a new U.S. federal 1% excise tax on certain repurchases of stock by publicly traded U.S. domestic corporations and certain U.S. domestic subsidiaries of publicly traded foreign corporations occurring on or after January 1, 2023. The excise tax is imposed on the repurchasing corporation itself, not its shareholders from which shares are repurchased. The amount of the excise tax is generally 1% of the fair market value of the shares repurchased at the time of the repurchase. However, for purposes of calculating the excise tax, repurchasing corporations are permitted to net the fair market value of certain new stock issuances against the fair market value of stock repurchases during the same taxable year. In addition, certain exceptions apply to the excise tax. The U.S. Department of the Treasury (Treasury) has been given authority to provide regulations and other guidance to carry out and prevent the abuse or avoidance of the excise tax.

Use of Estimates – The preparation of financial statements in conformity with 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, obsolescence of supplies used for R&D and manufacturing, 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 believe such differences would materially affect the financial statements in any given year. However, regarding the valuation of derivative liabilities determined using the Black-Scholes pricing model, significant fluctuations may materially affect the financial statements in a given year. Additionally, in calculating the right of use assets and lease liabilities, estimates and assumptions were used to determine the incremental borrowing rates and the expected lease terms. The Company considers the estimates used in valuing the derivative liabilities and the lease assets and liabilities to be significant.

New Accounting Pronouncements

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

4. WARRANTS AND NON-EMPLOYEE OPTIONS

The following warrants and non-employee options are outstanding at September 30, 2022:

Warrant/ Options	Issue Date	Shares Issuable upon Exercise of Warrants/Options	Exercise Price	Expiration Date
Series N	8/18/2008	85,339	$3.00	8/18/2024
Series UU	6/11/2018	93,603	$2.80	6/30/2024
Series X	1/13/2016	120,000	$9.25	7/13/2024
Series Y	2/15/2016	26,000	$12.00	8/15/2024
Series MM	6/22/2017	333,432	$1.86	6/22/2024
Series NN	7/24/2017	200,087	$2.52	7/24/2024
Series RR	10/30/2017	251,761	$1.65	10/30/2022
Series SS	12/19/2017	200,000	$2.09	12/18/2022
Series TT	2/5/2018	600	$2.24	2/5/2023
Consultant Options	7/28/2017 – 11/18/2020	15,000	$2.18 - $11.61	11/17/2022 - 7/27/2027

The following warrants and non-employee options are outstanding at September 30, 2021:

Warrant/ Options	Issue Date	Shares Issuable upon Exercise of Warrants/Options	Exercise Price	Expiration Date
Series N	8/18/2008	85,339	$3.00	8/18/2022
Series UU	6/11/2018	93,603	$2.80	6/30/2022
Series X	1/13/2016	120,000	$9.25	7/13/2022
Series Y	2/15/2016	26,000	$12.00	8/15/2022
Series Z	5/23/2016	184,800	$13.75	11/23/2021
Series CC	12/8/2016	15,845	$5.00	12/8/2021
Series HH	2/23/2017	200	$3.13	2/16/2022
Series AA	8/26/2016	100,000	$13.75	2/22/2022
Series MM	6/22/2017	333,432	$1.86	6/22/2022
Series NN	7/24/2017	210,087	$2.52	7/24/2022
Series RR	10/30/2017	251,761	$1.65	10/30/2022
Series SS	12/19/2017	200,000	$2.09	12/18/2022
Series TT	2/5/2018	600	$2.24	2/5/2023
Consultant Options	7/28/2017 – 11/18/2020	15,000	$2.18 - $11.61	11/17/2022 - 7/27/2027

A. Warrant Liabilities

Warrant liabilities outstanding at September 30 are as follows:

	2022	2021
Series Z warrants	$ -	$ 64,787
Series AA warrants	-	276,035
Series CC warrants	-	94,961
Series HH warrants	-	1,597
Total warrant liabilities	$ -	$ 437,380

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

	2022	2021
Series W warrants	$ -	$ 73,570
Series Z warrants	64,787	252,115
Series ZZ warrants	-	(98,692)
Series AA warrants	276,035	(318,823)
Series BB warrants	-	65,173
Series CC warrants	24,372	(668,605)
Series HH warrants	1,597	404
Net loss on warrant liabilities	$ 366,791	$ (694,858)

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

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

Changes in Warrant Liabilities

In February 2022, 100,000 Series AA warrants with an exercise price of $13.75 and 200 Series HH warrants with an exercise price of $3.13, expired.

In December 2021, 640 Series CC warrants, with an exercise price of $5.00, expired.

In November 2021, 184,800 Series Z warrants, with an exercise price of $13.75, expired.

On August 22, 2021, 16,000 Series BB warrants, with an exercise price of $13.75, expired.

On October 28, 2020, 688,930 Series W warrants, with an exercise price of $16.75, expired.

Exercise of Warrant Liabilities

The following warrants recorded as liabilities were exercised during the year ended September 30, 2022:

Warrants	Warrants Exercised	Exercise Price	Proceeds
Series CC	15,205	$5.00	$ 76,025

The following warrants recorded as liabilities were exercised during the year ended September 30, 2021:

Warrants	Warrants Exercised	Exercise Price	Proceeds
Series Z	79,200	$13.75	$ 1,089,000
Series ZZ	20,000	$13.75	275,000
Series AA	100,000	$13.75	1,375,000
Series CC	132,798	$5.00	663,990
	331,998		$ 3,402,990

B. Equity Warrants

Changes in Equity Warrants

On June 13, 2022, the expiration dates of the Series N, Series X, Series Y, Series UU, Series MM and Series NN warrants were extended two years. The incremental costs of the Series N, Series X and Series Y warrant extensions were recorded as a deemed dividend and totaled approximately $294,000 for the year ended September 30, 2022. The Series N and Series X warrants are held by the de Clara Trust. The incremental cost of the Series MM, Series NN and Series UU warrant extensions of approximately $635,000 was recorded as a deemed dividend because there were no longer any notes payable associated with these warrants at the time of modification.. The Series UU warrants and a portion of the Series MM and Series NN warrants are held by Geert Kersten, Patricia Prichep (current officers of the Company) and the de Clara Trust.

On June 28, 2021, the expiration dates of the Series N, Series X, Series Y and Series UU warrants were extended one year. On December 7, 2020, the expiration dates of the Series N, Series X, Series Y and Series UU warrants were extended six months. The incremental costs of the warrant extensions were recorded consistent with the accounting for the initial warrant issuances. The incremental costs of the Series N and Series X warrant extensions were recorded as a deemed dividend and totaled approximately $351,000 for the year ended September 30, 2021, respectively. The Series N and Series X warrants are held by the de Clara Trust. The incremental cost of the Series Y warrant extension was recorded as additional paid in capital and totaled approximately $103,000 for the year ended September 30, 2021. The incremental cost of the Series UU warrant extension was recorded as interest expense because these warrants were initially issued as an inducement to convert notes payable into common stock and totaled approximately $24,000 for the year ended September 30, 2021. The Series UU warrants are held by Geert Kersten, Patricia Prichep and the de Clara Trust.

Exercise of Equity Warrants

The following equity warrants were exercised during the year ended September 30, 2022.

Warrants	Warrants Exercised	Exercise Price	Proceeds
Series NN	10,000	$2.52	$ 25,200

The following equity warrants were exercised during the year ended September 30, 2021.

Warrants	Warrants Exercised	Exercise Price	Proceeds
Series MM	464,201	$1.86	$ 863,414
Series NN	138,755	$2.52	349,663
Series RR	165,888	$1.65	273,715
Series SS	126,064	$2.09	263,474
Series TT	370,964	$2.24	830,959
	1,265,872		$ 2,581,225

C. Options and Shares Issued to Consultants

The Company typically enters into consulting arrangements in exchange for common stock or stock options. During the years ended September 30, 2022 and 2021, the Company issued 156,547 and 75,885 shares, respectively, of common stock to consultants, all of which were restricted shares. Under these arrangements, during the periods presented, the common stock was issued with stock prices ranging from $2.86 to $24.95 per share. The weighted average grant price was $4.59 and $15.46, respectively, for stock issued during the years ended September 30, 2022 and 2021.

During the years ended September 30, 2022 and 2021, the Company recorded total expense of approximately $762,000 and $1,227,000, respectively, relating to these consulting agreements. At September 30, 2022 and 2021, unamortized balances of $295,000 and $364,000, respectively, are included in prepaid expenses as the contracts are ongoing and will be recognized in future periods as incurred.

No options were issued to consultants during the year ended September 30, 2022. During the year ended September 30, 2021, the Company issued 5,000 options to a consultant to purchase common stock with an exercise price of $11.61 and an expiration of November 17, 2022. As of September 30, 2022, 15,000 options issued to consultants as payment for services remained outstanding, all of which were issued from the Non-Qualified Stock Option plan and are fully vested.

5. PROPERTY AND EQUIPMENT

Property and equipment consisted of the following at September 30:

	2022	2021
Research equipment	$ 4,095,022	$ 4,211,124
Furniture and equipment	99,296	99,768
Leasehold improvements	13,544,394	13,465,123
	17,738,712	17,776,015
Accumulated depreciation and amortization	(5,849,683)	(4,112,453)
Net property and equipment	$ 11,889,029	$ 13,663,562

Depreciation expense for the years ended September 30, 2022 and 2021 totaled approximately $1,977,000 and $447,000 respectively.

6. PATENTS

Patents consist of the following at September 30:

	2022	2021
Patents	$ 893,833	$ 910,523
Accumulated amortization	(681,632)	(634,657)
Patents, net	$ 212,201	$ 275,866

During the years ended September 30, 2022 and 2021, there was no impairment of patent costs. Amortization expense for the years ended September 30, 2022 and 2021 totaled approximately $49,000 and $52,000, respectively. The total estimated future amortization is as follows:

Years ending September 30,	
2023	$ 38,000
2024	30,000
2025	28,000
2026	24,000
2027	21,000
Thereafter	71,000
	$ 212,000

7. INCOME TAXES

At September 30, 2022 and 2021, the Company had net deferred tax assets of $52.9 million and $44.1 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. Such ownership change could result in annual limitations on the utilization of tax attributes, including NOL carryforwards and tax credits. The Company performed an analysis to determine if any additional ownership changes occurred during the year ended September 30, 2022 and no such shifts were identified. If changes in ownership occur after year end, 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 $100.2 million and $77.1 million at September 30, 2022 and 2021, respectively. Approximately $19.2 million of the NOL carryforwards begin to expire during the year ended September 30, 2023 and become fully expired by 2038 and approximately $81.0 million of NOL carryforwards, which were generated subsequent to the Tax Cuts and Jobs Act, have an indefinite life. 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, 2022 and 2021. The R&D credit expires during the fiscal year ending September 30, 2029.

Significant components of the Company's deferred tax assets and liabilities as of September 30, 2022 and 2021 are listed below:

	2022	2021
NOL carryforwards	$ 25,346,000	$ 19,789,000
Capitalized R&D	15,042,000	15,040,000
Stock-based compensation	10,442,000	7,785,000
Lease liabilities	3,872,000	4,101,000
R&D credit	1,221,000	1,221,000
Vacation and other	307,000	126,000
Total deferred tax assets	56,230,000	48,062,000
Right of use assets	(3,244,000)	(3,786,000)
Fixed assets and intangibles	(44,000)	(172,000)
Total deferred tax liability	(3,288,000)	(3,958,000)
Net deferred tax asset	52,942,000	44,104,000
Valuation allowance	(52,942,000)	(44,104,000)
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 for the years ended September 30:

	2022	2021
Federal rate	21.00%	21.00%
State tax rate change	(1.67)	(1.37)
State tax rate, net of federal benefit	4.34	4.72
Other adjustments	(0.28)	(0.79)
Permanent differences	0.21	0.23
Change in valuation allowance	(23.61)	(23.79)
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 income tax expense. The Company has generated federal net operating losses during the tax years ended September 30, 1999 through 2022. The Company files income tax returns in the U.S. federal jurisdiction and various states. With few exceptions, the Company is no longer subject to U.S. federal and state income tax examinations by tax authorities for years September 30, 2018 and prior.

8. STOCK COMPENSATION

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

	Year Ended September 30,	
	2022	2021
Employees	$ 11,389,932	$ 13,685,046
Non-employees	$ 762,261	$ 1,226,690

During the years ended September 30, 2022 and 2021 the fair value of each option grant was estimated on the date of grant using the Black-Scholes option pricing model using the following assumptions.

	2022	2021
Expected stock price volatility	96.37 – 99.26%	90.42 – 97.22%
Risk-free interest rate	1.50 – 3.43%	0.85 – 1.65%
Expected life of options	9.67 – 9.69 years	9.68 – 9.69 years
Expected dividend yield	-	-

Non-Qualified Stock Option Plans –

During the year ended September 30, 2022, the Company adopted the 2022 Non-Qualified Stock Option Plan, which provides for the issuance of up to 2,000,000 options to purchase shares of common stock. On November 19, 2021, the Company granted 250,000 performance-based stock options from the 2020 Non-Qualified Stock Option Plan to officers. Each option entitles the holder to purchase one share of the Company's common stock at a price of $10.48 per share, the fair value on the date of issuance. The stock options will vest 100% upon approval of the first marketing application for any pharmaceutical based upon the Company's Multikine technology in any of the USA, Canada, UK, Germany, France, Italy, Spain, Japan, or Australia. None of the options will be exercisable before November 19, 2022. All options which have not vested as of November 18, 2031 will be canceled. On the grant date, the options were valued using a Monte Carlo Simulation. A Monte Carlo Simulation is a statistical technique that is used to model probabilistic systems and establish the probabilities for a variety of outcomes. However, because attainment of the performance condition cannot be considered probable, no compensation cost is recognized relating to these options as of September 30, 2022. Management will reassess the probability of achieving the performance condition at each reporting date.

During the year ended September 30, 2021, the Company adopted the 2021 Non-Qualified Stock Option Plan, which provides for the issuance of up to 1,800,000 options to purchase shares of common stock. On May 14, 2021, the Company granted 1,800,000 performance-based stock options from the 2021 Non-Qualified Stock Option Plan and 72,000 performance-based stock options from the 2020 Non-Qualified Stock Option Plan to officers and directors. Each option entitles the holder to purchase one share of the Company's common stock at a price of $20.61 per share, the fair value on the date of issuance. The stock options will vest 100% upon the achievement of the following performance goals: (a) the filing of the first marketing application for any pharmaceutical based upon the Company's Multikine technology in the US, Canada, UK, Germany, France, Italy, Spain, Japan, or Australia or (b) the closing price of the Company's common stock exceeds $42.00. The options first became exercisable on May 13, 2022. All options which have not vested as of May 13, 2031, will be canceled and will no longer be exercisable. The options were recorded in permanent equity in accordance with ASC 718, *Compensation – Stock Compensation*. On the grant date, the options were valued using a Monte Carlo Simulation approach. That valuation resulted in a per share fair value of $0.34 and an aggregate value of approximately $636,000 on the grant date. The aggregate value will be expensed over the requisite service period of the options, which was determined to be 1.3 years. This resulted in compensation expense of approximately $189,000 during the year ended September 30, 2021. The remaining $447,000 was expensed during the year ended September 30, 2022.

At September 30, 2022, the Company has collectively authorized the issuance of 13,787,200 options to purchase 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, 2022, the Company had collectively authorized the issuance of 138,400 options to purchase 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, 2022 is summarized as follows:

Non-Qualified and Incentive Stock Option Plans

	Outstanding				Exercisable			
	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding at September 30, 2020	8,653,703	$7.01	8.39	$56,193,415	3,297,229	$5.85	7.48	$29,090,662
Vested					2,401,961	$6.26		
Granted (a)	2,605,000	$20.58						
Exercised	(149,788)	$4.98			(149,788)	$4.98		
Forfeited	(49,832)	$9.56						
Expired	(9,374)	$172.73			(9,374)	$172.73		
Outstanding at September 30, 2021	11,049,709	$10.08	7.93	$54,843,283	5,540,028	$5.77	6.96	$43,589,598
Vested					1,547,703	$8.60		
Granted	2,040,750	$4.24						
Exercised	(6,500)	$4.59			(6,500)	$4.59		
Forfeited	(106,331)	$11.53						
Expired	(13,614)	$97.50			(13,614)	$97.50		
Outstanding at September 30, 2022	12,964,014	$9.06	7.35	$1,866,240	7,067,617	$6.21	6.21	$1,866,105

(a) Includes 1,872,000 performance-based options issued to officers and directors, 728,000 options issued to employees and 5,000 options issued to consultants.

A summary of the status of the Company's non-vested options for the two years ended September 30, 2022 is presented below:

	Number of Options	Weighted Average Grant Date Fair Value
Unvested at September 30, 2020	5,356,474	$ 4.76
Vested	(2,401,961)	
Granted	2,605,000	
Forfeited	(49,832)	
Unvested at September 30, 2021	5,509,681	$ 5.17
Vested	(1,547,703)	
Granted	2,040,750	
Forfeited	(106,331)	
Unvested at September 30, 2022	5,896,397	$ 3.63

Incentive Stock Bonus Plan – On September 30, 2022, 614,500 of the shares granted under the 2014 Incentive Stock Bonus Plan remain outstanding, of which 463,250 shares are fully vested. The shares are being 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. 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, 2022 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, 2022 and 2021, the Company recorded expense relating to the issuance of restricted stock pursuant to the plan of approximately $45,000 and $0.3 million as of September 30, 2022, all compensation expense related to the 2014 Incentive Stock Bonus Plan has been fully recognized.

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, 2022 is presented below:

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested at September 30, 2020	304,500	$13.75
Forfeited	(2,000)	
Vested	(151,250)	
Unvested at September 30, 2021	151,250	$13.75
Forfeited	-	
Vested	-	
Unvested at September 30, 2022	151,250	$13.75

Stock Bonus Plans – As of September 30, 2022, the Company authorized to issue up to 783,760 shares of common stock under its Stock Bonus Plans and has issued a total of 415,968 shares of common stock from the Stock Bonus Plans. All employees, directors, officers, consultants, and advisors are eligible to be granted shares.

Stock Compensation Plans – On September 30, 2022, 634,000 shares were authorized for issuance pursuant to the Company's Stock Compensation Plans, of which 153,195 shares were issued and outstanding. No shares were issued from the Stock Compensation Plans to consultants for payment of services during the years ended September 30, 2022, and 2021.

9. EMPLOYEE BENEFIT PLAN

The Company maintains a defined contribution retirement plan, qualifying under Section 401(k) of the Internal Revenue Code, subject to the Employee Retirement Income Security Act of 1974, as amended, and covering substantially all Company employees. Each participant's contribution is matched by the Company with shares of common stock that have a value equal to 100% of the participant's contribution, not to exceed the lesser of $10,000 or 6% of the participant's total compensation. The Company's contribution of common stock is valued each quarter based upon the closing bid price of the Company's common stock. During the year ended September 30, 2022, 52,882 shares were issued to the Company's 401(k) plan with a cost of approximately $223,000. During the year ended September 30, 2021, 17,990 shares were issued to the Company's 401(k) plan with a cost of approximately $201,000.

10. COMMITMENTS AND CONTINGENCIES

Clinical Research Agreements

In April 2013, the Company entered into a co-development and revenue sharing agreement with Ergomed. Under the agreement, Ergomed will contribute up to $10 million towards the Company's Phase III clinical study in the form of offering discounted clinical services in exchange for a single digit percentage of milestone and royalty payments, up to a specific maximum amount. In October 2015, the Company entered into a second co-development and revenue sharing agreement with Ergomed for an additional $2 million, for a total of $12 million. The Company accounted for the co-development and revenue sharing agreement in accordance with ASC 808,

Collaborative Arrangements. The Company determined the payments to Ergomed are within the scope of ASC 730, *Research and Development*. Therefore, the Company records the discount on the clinical services as a credit to research and development expense on its Statements of Operations. Since the Company entered into the co-development and revenue sharing agreement with Ergomed, it has incurred research and development expenses of approximately $35.5 million related to Ergomed's services. This amount is net of Ergomed's discount of approximately $11.8 million. During the years ended September 30, 2022 and 2021, the Company recorded approximately $0.5 million and $1.6 million, respectively, as research and development expense related to Ergomed's services. These amounts were net of Ergomed's discount of approximately $0.1 million and $0.6 million during both the years ended September 30, 2022 and 2021.

Lease Agreements

The Company leases a manufacturing facility near Baltimore, Maryland (the San Tomas lease). The building was remodeled in accordance with the Company's specifications so that it can be used by the Company to manufacture Multikine for the Company's Phase 3 clinical trial and sales of the drug if approved by the FDA. The lease is for a term of twenty years and requires annual base rent to escalate each year at 3%. The Company is required to pay all real estate and personal property taxes, insurance premiums, maintenance expenses, repair costs and utilities. The lease allows the Company, at its election, to extend the lease for two ten-year periods or to purchase the building at the end of the 20-year lease, which expires in October 2028. The renewal options are not included in the calculation of the right of use asset and lease liability because exercise of those options is not reasonably certain.

Upon adoption of ASC 842 on October 1, 2019, the Company recorded a finance lease right of use asset of approximately $16.5 million and a finance lease liability of approximately $13.5 million. As of September 30, 2022 and 2021, respectively, the net book value of the finance lease right of use asset is approximately $10.9 million and $12.7 million and the balance of the finance lease liability is approximately $13.3 million and $13.8 million, of which approximately $1.6 million and $0.6 million is current. These amounts include the San Tomas lease as well as several other smaller finance leases for office equipment. During the years ended September 30, 2022 and 2021, the finance right of use assets are being depreciated using a straight-line method over the underlying lease terms and totaled approximately $1.8 million and $1.7 million, respectively. Total cash paid related to finance leases during the years ended September 30, 2022 and 2021 was approximately $0 and $2.5 million, respectively, of which approximately $1.2 million was for interest in both years. The weighted average discount rate of the Company's finance leases is 8.45% and the weighted average time to maturity is 6.08 years.

In August 2020, the Company entered into an amendment to the San Tomas lease agreement under which the landlord agreed to allow the Company to substantially upgrade the manufacturing facility in preparation for the potential commercial production of Multikine. The upgrades were completed and the improvements were placed in service in October 2021. The total cost of the upgrades was $11.1 million. The landlord agreed to finance the final $2.4 million of the costs incurred which will be repaid through increased lease payments over the remaining lease term starting on March 1, 2021. The repayment includes a base rent which escalates at 3% each year plus interest that accrues at 13.75% per year. The Company remeasured the lease liability to account for the modified payments using an 8.45% incremental borrowing rate (IBR). The rate was determined using a synthetic credit rating analysis prepared by an outside valuation specialist. Additionally, this financing is considered to be a lease incentive from the landlord and has been included in the calculation of the lease liability as it is realized. The entire $2.4 million was received from the landlord as of September 30, 2022. The leasehold improvements are recorded in property and equipment and are being amortized over the remaining lease term.

During June 2021, the Company determined that it used an incorrect discount rate to calculate the opening ROU asset and lease liability balances upon adoption of ASC 842. Management engaged an outside valuation specialist to perform a synthetic credit rating analysis which resulted in a revised rate to be used upon adoption of ASC 842 of 10.19% compared to the previously used rate of 8.80%. This change resulted in an immaterial difference to the September 30, 2020 financial statements, and was corrected in the quarterly period ended June 30, 2021 as an out of period adjustment.

The Company was required to deposit the equivalent of one year of base rent in accordance with the original lease. Under the landlord's $2.4 million financing arrangement, the Company was required to deposit an additional $0.2 million in March 2021. Because the Company met the minimum cash balance required by the lease, the full amount of the deposit was returned to the Company in January 2022. If the Company's cash balance

falls below the required balance, the Company will be required to re-deposit these funds with the landlord. The approximate $1.9 million deposit is included in non-current assets as of September 30, 2021.

Approximate future minimum lease payments under finance leases as of September 30, 2022 are as follows:

Year ending September 30,	
2023	$ 2,576,000
2024	2,655,000
2025	2,741,000
2026	2,832,000
2027	2,923,000
Thereafter	3,267,000
Total future minimum lease obligations	16,994,000
Less imputed interest on finance lease obligations	(3,712,000)
Net present value of finance lease obligations	$ 13,282,000

The Company leases two facilities under operating leases. The lease for the Company's office headquarters will expire on November 30, 2025. The lease for its research and development laboratory was renewed in September 2021 for an additional ten years and will expire on February 29, 2032. The renewal was considered a modification for accounting purposes and the right of use asset and liability were remeasured as of the date of the renewal. This resulted in an increase of approximately $1.1 million to the operating lease right of use asset and liability. The operating leases include escalating rental payments. The Company is recognizing the related rent expense on a straight-line basis over the terms of the leases.

Upon adoption of ASC 842 on October 1, 2019, the Company recorded an operating lease right of use asset and an operating lease liability of approximately $1.0 million. As of September 30, 2022, the net book value of the operating lease right of use asset is approximately $1.9 million and the balance of the operating lease liability is approximately $2.0 million, of which approximately $0.2 million is current. As of September 30, 2021, the net book value of the operating lease right of use asset is approximately $2.1 million and the balance of the operating lease liability is approximately $2.1 million, of which approximately $0.1 million is current. During the years ended September 30, 2022 and 2021, the Company incurred lease expense under operating leases of approximately $0.4 million and $0.2 million, respectively. Total cash paid related to operating leases during the years ended September 30, 2022 and 2021 was approximately $0.3 million for each year. The weighted average discount rate of the Company's operating leases is 9.09% and the weighted average time to maturity is 8.83 years.

As of September 30, 2022, future minimum lease payments under operating leases are as follows:

Year ending September 30,	
2023	$ 348,000
2024	357,000
2025	366,000
2026	287,000
2027	277,000
Thereafter	1,325,000
Total future minimum lease obligations	2,960,000
Less imputed interest on operating lease obligation	(939,000)
Net present value of operating lease obligation	$ 2,021,000

Vendor Obligations

The Company has contingent obligations with vendors for work that will be completed in relation to the Phase 3 clinical trial. The timing of these obligations cannot be determined at this time. The Company estimates it will incur additional expenses of approximately $0.6 million for the remainder of the Phase 3 clinical trial and the filing of the clinical study report with the FDA. This estimate is based only on the information currently available from the Clinical Research Organizations responsible for managing the Phase 3 clinical trial and does not include other related costs.

11. RELATED PARTY TRANSACTIONS

During the year ended September 30, 2022, no restricted shares of the Company's common stock were purchased by related parties. During the year ended September 30, 2021, the de Clara Trust, of which the Company's CEO, Geert Kersten, is a trustee and beneficiary, and two directors purchased a total of 27,500 restricted shares of the Company's common stock at an aggregate fair market value of approximately $220,000. The shares are subject to the conditions of Rule 144 under the Securities Act of 1933.

On June 13, 2022, the expiration dates of the Series N, Series X, Series Y, Series UU, Series MM and Series NN warrants were extended two years (Note 4). The incremental costs of the Series N, Series X and Series Y warrant extensions were recorded as a deemed dividend and totaled approximately $294,000 for the year ended September 30, 2022. The Series N and Series X warrants are held by the de Clara Trust. The incremental cost of the Series MM, Series NN and Series UU warrant extensions of approximately $635,000 was recorded as a deemed dividend because there are no longer any notes payable associated with these warrants at the time of modification. The Series UU warrants and a portion of the Series MM and Series NN warrants are held by Geert Kersten, Patricia Prichep (current officers of the Company) and the de Clara Trust.

In June 2021, the expiration dates of the Series N, Series X, and Series UU warrants were extended one year. In December 2020, the expiration dates of the Series N, Series X, Series UU warrants were extended six months. The incremental costs of the warrant extensions were recorded consistent with the accounting for the initial warrant issuances. The incremental costs of the Series N and Series X warrant extensions were recorded as a deemed dividend and totaled approximately $351,000 for the year ended September 30, 2021. The Series N and Series X warrants are held by the de Clara Trust. The incremental cost of the Series UU warrant extension was recorded as interest expense and totaled approximately $24,000 for the year ended September 30, 2021. The Series UU warrants are held by certain officers of the Company and were originally issued with convertible debt.

12. STOCKHOLDERS' EQUITY

Exercise of Warrants

During the years ended September 30, 2022 and 2021, the Company received proceeds of approximately $0.1 million and $6.0 million, respectively, from the exercise of warrants, as detailed in Note 4. Upon exercise, 25,205 and 1,597,870 shares of common stock were issued during the years ended September 30, 2022 and 2021, respectively.

Sales of Securities

There were no sales of securities during the fiscal year ended September 30, 2022.

In June 2021, the Company sold 1,400,000 shares of common stock at a public offering price of $22.62 per share and received aggregate net proceeds of approximately $29.4 million. At that time, the underwriters fully exercised their option to purchase up to 210,000 additional shares of common stock to cover over-allotments, resulting in additional net proceeds to the Company of approximately $4.4 million.

In December 2020, the Company sold 1,000,000 shares of common stock at a public offering price of $14.65 per share and received aggregate proceeds of approximately $13.6 million.

Other Equity Transactions

The Company entered into Securities Purchase Agreements (SPA) with Ergomed plc, one of the Company's Clinical Research Organizations responsible for managing the Company's Phase 3 clinical trial, to facilitate payment of amounts due Ergomed. Under the Agreements, the Company issued Ergomed shares of common stock and the net proceeds from the sales of those shares reduces outstanding amounts due Ergomed. Upon issuance, the Company expenses the full value of the shares as Other non-operating gain/loss and subsequently offsets the expense as amounts are realized through the sale by Ergomed and reduces accounts payable to Ergomed.

During the years ended September 30, 2022 and 2021, CEL-SCI did not issue Ergomed any shares of common stock. Additionally, no shares were sold during the year ended September 30, 2022. During the year ended

September 30, 2021, the company recorded Other Non-operating gains of approximately $1.7 million upon the resale of shares from the SPA. All outstanding shares have been resold as of September 30, 2022 and the Company has approximately $22,000 in amounts remaining in prepaid to Ergomed.

13. FAIR VALUE MEASUREMENTS

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

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

- Level 1 – Observable inputs such as quoted prices in active markets for identical assets or liabilities
- Level 2 – Inputs other than quoted prices that are observable for the asset or liability, either directly or indirectly. These include quoted prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active and amounts derived from valuation models where all significant inputs other than quoted prices are observable for the asset or liability.
- 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 Company purchased short-term T-bills during the year ended September 30, 2021 that are classified as trading securities. Quoted market prices were applied to determine the fair value of short-term investments, therefore they were categorized as Level 1 on the fair value hierarchy. The T-bills were recorded at fair market value, which includes an unrealized gain of approximately $6,000. The T-bills matured in December 2021 and yielded a weighted average interest rate of 0.10%. The Company is not holding any T-bills as of September 30, 2022.

As of September 30, 2022 and 2021, all of the Company's derivative liabilities are classified as Level 3.

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

	2022	2021
Beginning balance	$ 437,380	$ 3,765,613
Issuances	-	-
Exercises	(70,589)	(4,023,091)
Net realized and unrealized derivative loss	(366,791)	694,858
Ending balance	$ -	$ 437,380

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 were used. At September 30, 2022, the Company does not have any Level 3 derivative instruments. At September 30, 2021, the Company's Level 3 derivative instruments have a weighted average fair value of $1.45 per share and a weighted average exercise price of $13.28 per share. Fair values were determined using a weighted average risk free interest rate of 0.05% and volatility of 109%. The instruments have a weighted average time to maturity of 0.3 years.

14. NET LOSS PER COMMON SHARE

Basic loss per share is computed by dividing net loss available to common shareholders by the weighted average number of common shares outstanding during the period. The Company's potentially dilutive shares, which include outstanding common stock options, common stock warrants and restricted stock are not included in the computation of diluted net loss per share if their effect would be 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,	
	2022	2021
Loss per share – basic		
Net loss available to common shareholders - basic	$ (37,629,803)	$ (36,711,970)
Weighted average shares outstanding - basic	43,148,888	40,662,137
Basic loss per common share	$ (0.87)	$ (0.90)
Loss per share – diluted		
Net loss available to common shareholders - basic	$ (37,629,803)	$ (36,711,970)
Unrealized gain on derivatives [1]	-	(1,085,540)
Net loss available to common shareholders - diluted	$ (37,629,803)	$ (37,797,510)
Weighted average shares outstanding – basic	43,148,888	40,662,137
Incremental shares underlying dilutive warrants [1]	-	32,111
Weighted average shares outstanding - diluted	43,148,888	40,694,248
Diluted loss per common share	$ (0.87)	$ (0.93)

[1] *Includes Series Z, AA, CC and HH warrants for the year ended September 30, 2021.*

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:

	2022	2021
Options and Warrants	14,274,836	10,604,850
Unvested Restricted Stock	151,250	151,250
Total	14,426,086	10,756,100

15. SUBSEQUENT EVENTS

On October 28, 2022, the expiration date of the Series RR warrants were extended two years. The incremental cost of extending the Series RR warrants will be recorded as a deemed dividend and totaled approximately $172,000. The Series RR warrants are held by Geert Kersten, Patricia Prichep (current officers of the Company) and the de Clara Trust.

Between October 1, 2022 and December 27, 2022 the company received approximately $0.5 million through the exercise of warrants to purchase shares of the Company's common stock.

CORPORATE INFORMATION

Board of Directors

Geert R. Kersten
Chief Executive Officer
CEL-SCI Corporation

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

Bruno Baillavoine
Director
Pericles Group UK

Robert Watson
President and CEO
Juvare, LLC

Gail Naughton, Ph.D.
Founder
Histogen Inc.

Corporate Officers

Geert R. Kersten
Chief Executive Officer
Treasurer

Eyal Talor, Ph.D.
Chief Scientific Officer

Patricia B. Prichep
Senior Vice President of Operations
Corporate Secretary

John Cipriano
Senior Vice President of
Regulatory Affairs

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

Corporate Headquarters

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Website: www.cel-sci.com

Independent Auditors

BDO USA, LLP
Potomac, MD

Counsel

Hart & Hart
Denver, CO

Transfer Agent and Registrar

Computershare Investor Services
8742 Lucent Boulevard, Suite 300
Highlands Ranch, CO 80129
(303) 262-0600

Inquiries regarding transfer requirements, lost certificates and change of address should be directed to the transfer agent.

Stock Profile

CEL-SCI Corporation's Common Stock is traded on the NYSE American exchange under the symbol ***CVM***. CEL-SCI also trades on five German stock exchanges under the Symbol **LSR**, German Securities Code (Wertpapierkennnummer) 871006.

There are approximately 512 stockholders of record as of March 29, 2023. CEL-SCI has not paid cash dividends on its Common Stock since its inception.

SEC Form 10-K

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

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

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