Annual Report

2023

CEL-SCI's Corporation

CEL-SCI Corporation 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; and

2) L.E.A.P.S. (Ligand Epitope Antigen Presentation System) technology, or LEAPS, with several product candidates under development for the potential treatment of rheumatoid arthritis.

None of CEL-SCI's product candidates have been approved for sale, barter or exchange by the Food and Drug Administration (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.

MULTIKINE AND THE PHASE III CLINICAL TRIAL RESULTS

Immunotherapy is a large, high growth market. Immunotherapies use the patient's own immune system to fight disease. These "targeted therapies" are at the forefront of modern cancer research. A recent Bloomberg report from January 2023 asserted that:

> The global cancer immunotherapy market is expected to reach USD $196.45 billion by 2030, registering CAGR of 7.2% during the forecast period, according to a new report by Grand View Research, Inc. The rising adoption of immunotherapy over other therapy options for cancer owing to its targeted action is anticipated to increase the adoption during the forecast period. Moreover, increasing regulatory approvals from authoritarian establishments for novel immunotherapy used for oncology is also expected to further fuel the market growth.

Source: https://www.bloomberg.com/press-releases/2023-01-18/cancer-immunotherapy-market-worth-196-45-billion-by-2030-grand-view-research-inc

CEL-SCI hopes to participate in this growing market with its lead investigational therapy Multikine® (Leukocyte Interleukin, Injection). Multikine has already been tested in approximately 750 human patients in multiple clinical trials, including a well-controlled, multicenter, global, 928 patient Phase III randomized controlled trial. Multikine is unique among approved cancer immunotherapies because it is *given first*, right after diagnosis and before surgery. CEL-SCI believes that the Phase III clinical trial demonstrated that Multikine caused tumors to reduce in size and/or caused the disease to "downstage" within just a few weeks of treatment before surgery. Importantly, patients with these reductions and/or downstages had their *risk of death cut in half at five years* of follow up. CEL-SCI is discussing with regulators in Europe, the U.K., the U.S., and Canada with a view to obtaining marketing authorization and approval for immediate patient access to Multikine without waiting for the results of a confirmatory trial.

In 2023, the Multikine target patient population is estimated to include about 145,000 patients per year worldwide, with more than two-thirds of those outside the United States. Global growth rates of eligible cases are expected to rise 30% by 2030. (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10304137)

What is Multikine and who is it for? Multikine is a biological medicinal immunotherapy comprised of a mixture of natural cytokines and small biological molecules. Multikine is injected around the tumor and adjacent lymph nodes for three weeks as a first-line treatment *before* the standard of care (SOC), which is surgery followed by either radiotherapy or chemoradiotherapy. Multikine's rationale for use is to incite a locoregional immune response against the tumor before the local immune system has been compromised by the standard of care and/or disease progression.

The Multikine target population is treatment-naïve adult patients with resectable locally advanced primary squamous cell carcinoma of the head and neck (SCCHN) in the oral cavity or soft palate and who have:

- **No lymph node involvement** (via PET scan)
- **Low PD-L1 tumor expression** (TPS<10) (via biopsy)

PD-L1 is a protein receptor on the tumor cell surface that helps the tumor repel the immune system. CEL-SCI believes that patients with tumors having low PD-L1 would be more likely to respond to Multikine because their tumors have

lower defenses against the patient's immune system. CEL-SCI estimates that patients with tumors having low PD-L1 represent about 70% of locally advanced primary SCCHN patients.

Multikine leads to longer survival with no safety issues. Clinical investigations of Multikine have demonstrated in the randomized controlled Phase III trial (RCT) the following in the target population:

- ***risk of death cut in half at five years*** versus the control;
- 28.6% absolute 5-year overall survival benefit versus control (p=0.0015);
- 0.349 hazard ratio vs control (95% CIs [0.18, 0.66], Wald p=0.0012);
- >35% rate of pre-surgery reductions and/or downstages (p<0.01); and
- low PD-L1 tumor expression (vs high PD-L1 where Keytruda and Opdivo work best).

There were no demonstrable safety signals or toxicities observed in approximately 750 Multikine-treated subjects across multiple clinical trials. Adverse event (AE) and serious adverse event (SAE) incidences were not significantly different among treatment and control groups. There were no Multikine-related deaths and only two discontinuations. Multikine-related AEs before surgery were local and resolved after surgery. Although the literature reports that some of Multikine's components may be toxic when administered systemically (e.g., TNFα, IFN γ, IL-1β), these toxicities did not emerge with Multikine, even at doses many times higher than those administered in the Phase III trial, primarily due to Multikine's delivery by local injection and dosage.

CEL-SCI published its data as abstracts and posters at the annual conferences for the 2022 American Society of Clinical Oncology (ASCO), 2022 and 2023 European Society for Medical Oncology (ESMO), the 2023 European Head and Neck Society's (EHNS's) annual European Conference On Head And Neck Oncology (ECHNO), the 2023 European Society for Therapeutic Radiology and Oncology (ESTRO) and the 2023 American Head and Neck Society (AHNS). These publications can be accessed at http://www.cel-sci.com.

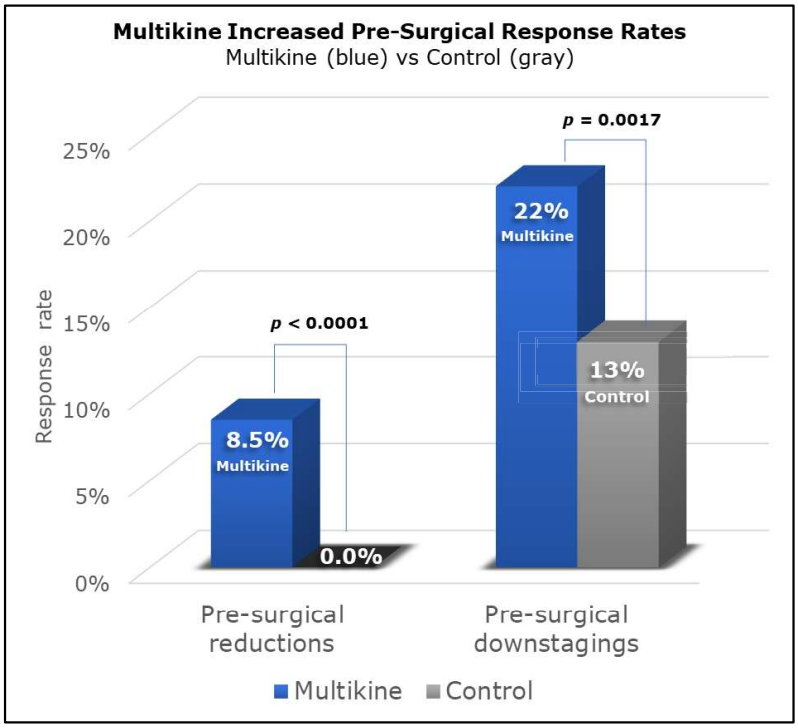
Multikine works by inducing pre-surgical responses. CEL-SCI observed statistically significant pre-surgical responses after Multikine treatment, and therefore CEL-SCI believes in the following:

- Multikine causes pre-surgical responses;
- Pre-surgical responses lead to longer life;
- Therefore, selecting more patients predicted to have a pre-surgical response should lead to much better survival in the target population.

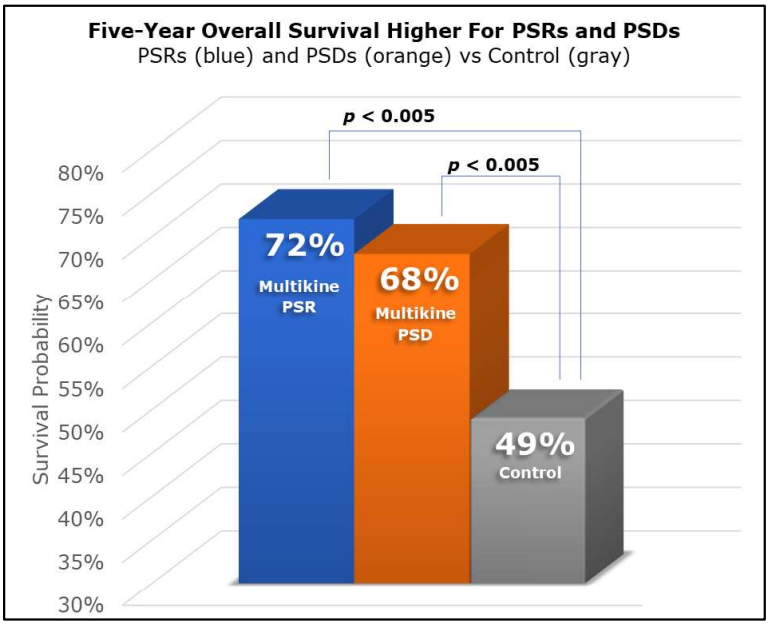
A "pre-surgical response" is a significant change in disease before surgery. CEL-SCI saw two kinds of responses in the Phase III trial. First, there were "reductions" in the size of the tumor—a reduction of 30% or more qualified as a "pre-surgical reduction" or "PSR" for short. Second, there were disease "downstages," (e.g., the disease improved from Stage IV to Stage III) pre-surgery. CEL-SCI calls this a "pre-surgical downstaging" or "PSD" for short. CEL-SCI's 2022 ESMO cancer conference presentation reported on PSR, and CEL-SCI's new 2023 ESMO presentation reported on PSD.

Across the whole Phase III trial, PSRs were seen in 8.5% of Multikine patients compared to ***none*** in the control group. PSDs were seen in 22% of Multikine patients as compared to 13% in the control group. Because Multikine was the only therapy given to these patients before surgery, it is CEL-SCI's strong belief that Multikine had to be the cause of the higher rates of PSR and PSD.

These data are presented visually below. The taller blue columns show PSR and PSD rates in all 529 Multikine-treated patients in the Phase III trial, and the gray columns show PSR and PSD rates for all 394 control patients. The p-values above the columns show comparisons between Multikine and the control groups. With Multikine, statistically speaking, CEL-SCI believes there is a better than a 95% chance that the increases in PSR/PSD in the Phase III study were caused by Multikine.



It was not enough for us to show that Multikine likely leads to PSRs and PSDs as compared to a control group, CEL-SCI also had to test if PSRs and PSDs lead to improved survival. CEL-SCI's Phase III trial demonstrated that PSR patients were 72% likely to be alive after five years, whereas control patients were only about 49% likely to be alive after five years. Patients with PSD saw similar improvement in CEL-SCI's Phase III trial. Their five-year chance of survival was approximately 68%. Therefore, CEL-SCI's Phase III trial demonstrated statistically that those patients who had PSR or PSD resulting from Multikine lived longer than those who were not treated with Multikine. It is important to note that these results are from the entire Phase III study population, not from a subgroup. The p-values of less than 0.005 means there was at least a 99.5% chance that these results are due to Multikine rather than random chance. The likelihood of living at least five years is shown in the graphic below for patients with PSR (blue), patients with PSD (orange) and patients who did not receive Multikine (gray).



CEL-SCI's target population can be readily selected by doctors upon diagnoses using standard tests. Having shown a potential causal link supported by strong statistics between Multikine and survival benefit, CEL-SCI believes that Multikine should be approved quickly. But recall that the Phase III study's primary endpoint of 10% survival

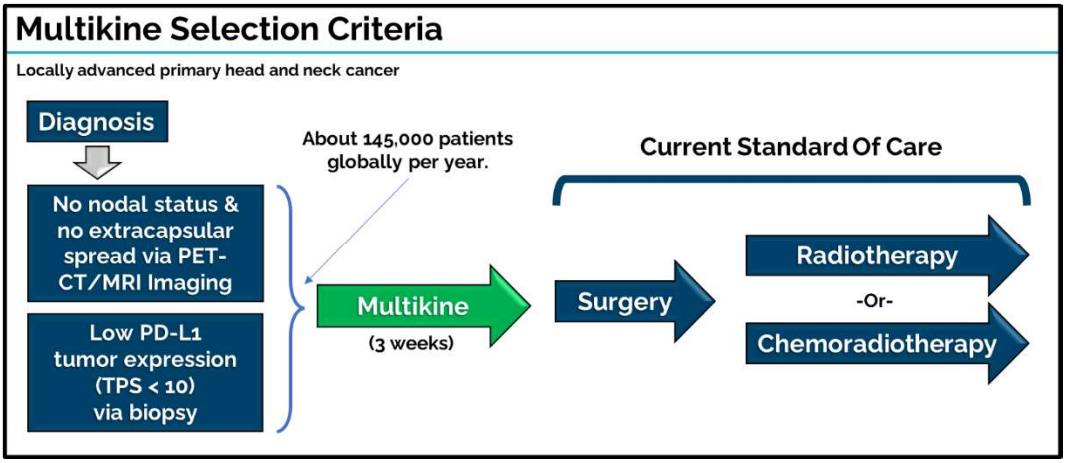
benefit was not met. How then can we say that Multikine actually benefits patients? The answer is that while Multikine has shown that it can help patients with PSR/PSD, there were not enough PSR/PSD in the Phase III study population to yield a 10% survival benefit for the whole population. In other words, the benefits from PSR/PSD were too diluted when averaged with the other patients in the study.

None of this changes the fact that CEL-SCI observed statistical significance when analyzing Multikine's ability to cause PSR/PSD and that these PSR/PSD statistically appear to lead to a higher chance of living five years or longer—CEL-SCI simply had to define a target population who would have a larger number of PSR/PSD. To do so, CEL-SCI analyzed Multikine's biological mechanism of action, talked to regulators and physicians who knew best, and were guided by the Phase III data, including patient-specific data down to the cellular level. All this of course took time, but CEL-SCI believes it has succeeded and is ready to move forward.

One of the first things we reported from the Phase III study was that Multikine was shown to work best in patients who were deemed "low risk" after surgery, about 40% of the study population. These patients saw a significant 14.1% absolute 5-year survival benefit vs the "low risk" control group not receiving Multikine. It made sense biologically that these patients would benefit most from Multikine, because they tended to have immune systems that were not yet compromised by the disease. "High risk" patients, by contrast, typically had lymph nodes invaded by the tumor, and needed chemotherapy after surgery. Because their lymph nodes were compromised, this made it harder for their immune systems to work, and they needed surgery as soon as possible without waiting an extra three weeks to receive Multikine. CEL-SCI initially developed criteria for selecting "low-risk" patients at diagnosis—i.e., those having no lymph nodes invaded by the tumor (N0) or only one lymph node invaded by the tumor (N1) as well as no extracapsular spread as determined by PET scan. CEL-SCI published these criteria at the ASCO conference in 2022. However, after discussions with regulators and physicians, CEL-SCI saw that outcomes could be improved further if the N1 patients were excluded, and only the N0 patients were included in the target population.

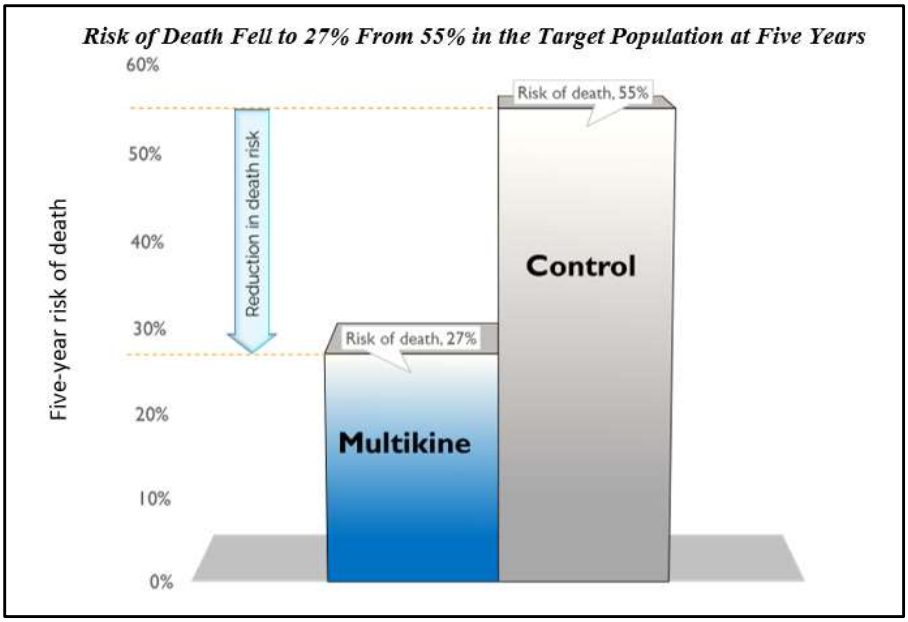
CEL-SCI also saw from the Phase III data that Multikine was more effective for patients with low PD-L1 tumor expression than for patients with high PD-L1 expression. This analysis was pre-specified in the statistical analysis plan. Targeting low PD-L1 also differentiates Multikine from other immunotherapies. For example, checkpoint inhibitors like Keytruda and Opdivo appear to best serve patients having high PD-L1, because these drugs work by blocking PD1/PD-L1 receptors interaction; when this interaction (PD1/PD-L1) happens it leads to inactivation/death of the immune cells attacking the tumor. While none of these drugs are currently approved as a first-line treatment before surgery, even if such approvals were to come in the future, the large majority of patients in this group having low PD-L1 would still be expected to need Multikine.

CEL-SCI's target population is now directed to patients who present at diagnosis with N0 nodal involvement and also with low PD-L1 tumor expression (defined as tumor proportions score (TPS) < 10). These patients can be readily identified upon diagnosis with tests that physicians routinely use in cancer screening, a crucial achievement towards Multikine becoming available for use. For instance, a PET scan should be used to determine the N0 nodal status and a screening tumor biopsy should be used to determine the low PD-L1 expression. Doctors already routinely screen head and neck cancer patients using PET scans and biopsy. Therefore, doctors can screen for Multikine patients without new tests or new costs.

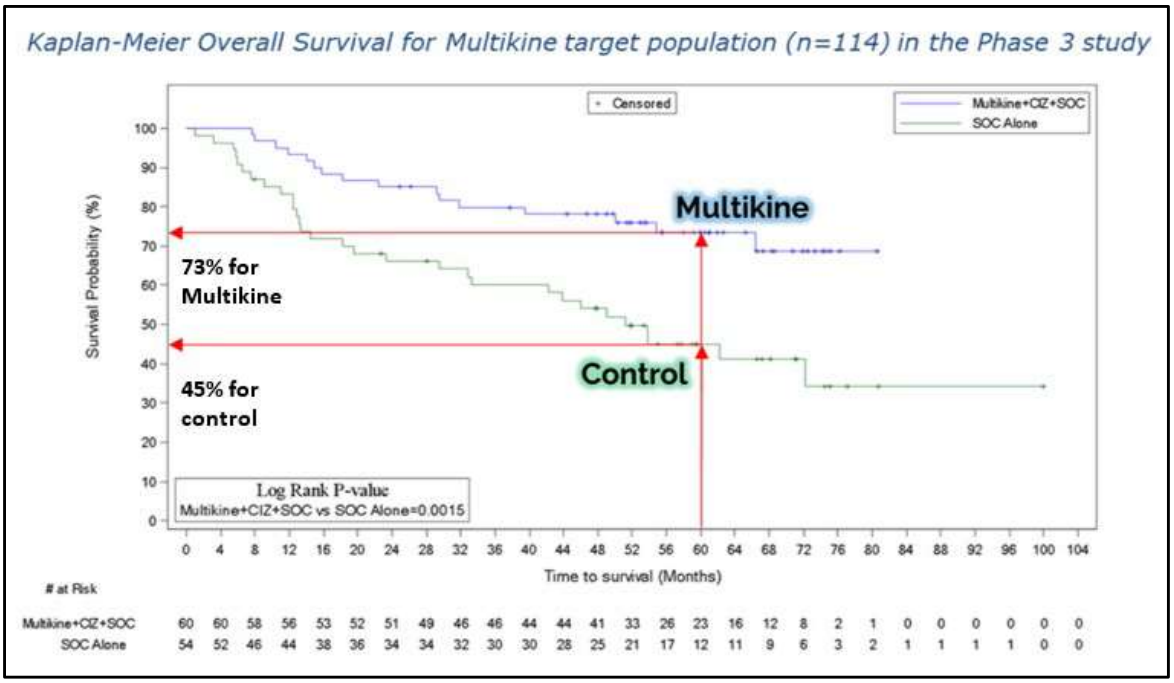


Multikine cut the 5-year risk of death in half in the target population. CEL-SCI's results show that Multikine can cut the risk of death in half at five years versus the control group in the finalized target population. Survival increased

from 45% in the control group to 73% in the Multikine group at five years. This means the risk of death fell to 27% in the Multikine group from 55% in the control, shown below.



Another way to see the survival benefit of Multikine in the target population is the Kaplan-Meier curve from our ESMO '23 poster, shown below. On the vertical axis is the probability of survival and the horizontal axis is time in months. The blue Multikine line is far above the green control line, meaning the chance of survival is much higher in the Multikine group at every point in time compared to the control. These results had a low p-value of 0.0015, which is very significant as a statistical matter.

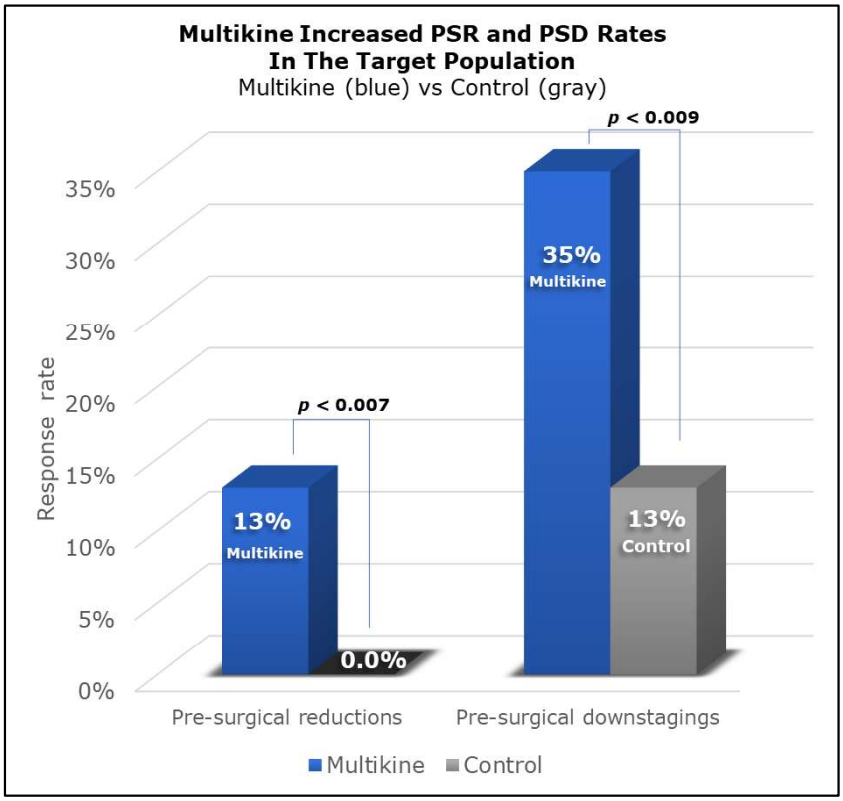


CEL-SCI's physician consultants tell it that the early separation of these two survival curves (e.g., at 12 months) adds validation to the potential positive effects of Multikine.

Another measure of survival benefit is called the "hazard ratio," which compares the chances of dying between two different groups. Here, in the Multikine target population, the hazard ratio was 0.35, which means that deaths occurred in the Multikine group about one-third as frequently as in the control group. It is also important to note that the hazard ratio's 95% confidence interval remained far below 1.0. In the case of Multikine, statistically speaking, there is a 95% chance that the hazard ratio would fall between 0.18 and 0.66 if Multikine were tested in the target population in

another study. A hazard ratio of 0.66 as the "so called worst case scenario" is still below (better) than the hazard ratio required for most drug approvals.

These positive survival outcomes—increased overall survival, reduced risk of death, widely separated Kaplan-Meier curves with early separation, low hazard ratio, low p-values, low confidence intervals—CEL-SCI believes were driven by high PSR/PSD rates in the target population, as shown in the graphic below:



CEL-SCI relies on all of these data together to support its plan to request accelerated/conditional approval in the new target population without waiting until the completion of another clinical trial.

CEL-SCI's regulatory strategy going forward is to seek immediate approval of Multikine wherever possible.
CEL-SCI intends to seek approval for Multikine based on the data generated to date, using a conditional approval pathway with a follow-on confirmatory study since the survival benefit is high and statistics are strong. This view is based on advice from regulators and consultants, and CEL-SCI believes that the accelerated/conditional approval regulatory pathways are specifically designed for our situation.

When the Phase III trial was designed, there was no evidentiary basis for excluding either of the low-risk or high-risk patient groups before surgery. Therefore, the study had to include a large percentage of high-risk patients with immune systems already compromised by disease. These subjects generally did not respond to Multikine. CEL-SCI has narrowed its target population as compared to the overall Phase III study population to focus on patients most likely to have PSR/PSD and to exclude the rest.

CEL-SCI acknowledges that efficacy in the target population has not been tested prospectively, but CEL-SCI believes that the data generated to date already presents a compelling patient need in the target population that justifies immediate access to Multikine. This is why the conditional approval pathways were created in the first place. CEL-SCI intends to base its request for regulatory approval, in part, on our view that patients should not have to wait many more years before gaining access to the benefits of Multikine PSRs/PSDs and increased survival, particularly given Multikine's safety profile and data that mechanistically and empirically supports the target population definition.

The benefit-risk balance favoring immediate patient access to Multikine is described below:

An "unmet need" is a factor for approval considered by all major regulatory bodies worldwide. In the Multikine target population, there is also a tremendous unmet need for improved survival. The current standard of care provides only about a 50/50 chance of surviving five years, whereas Multikine could increase that survival rate to over 70% based on the Phase III data. Chemotherapy has improved outcomes for some head and neck patients, but chemotherapy is only indicated for high-risk patients, who are not likely to fall within the Multikine target population. Currently available immunotherapies are given after surgery or where surgery is not indicated, in contrast to Multikine, which is given before surgery to patients with resectable tumors. Available checkpoint inhibitors work best on tumors with high PD-L1 expression, whereas Multikine works best in tumors with low PD-L1 expression. Therefore, Multikine's target population is underserved, and will continue to be underserved, by current therapies, but Multikine can meet the need for improved survival.

The major regulatory bodies with which we are working, U.S. FDA, Health Canada, European Medicines Agency (EMA) and the Medicines and Healthcare products Regulatory Agency (MHRA) in the United Kingdom (UK) all have conditional approval pathways designed for situations where the target population has not been fully tested prospectively and there is strong data supporting clinical benefit for patients. The reason is that regulators understand that in many cases patients should not have to wait for additional data before being offered the chance to benefit from a new drug. Every situation is different and depends on the specific facts.

CEL-SCI had meetings with the FDA and Health Canada earlier in 2023, but they have not yet seen the new data presented for the first time on October 22, 2023 at the ESMO conference, and CEL-SCI plans to provide it to the FDA in Q1 2024. In Canada, CEL-SCI plans to ask for conditional approval under their Notice of Compliance with Conditions (NOC/C) pathway, as they had suggested in 2023. This permits approval of drugs based on safety and "promising" efficacy data while a post-market confirmatory study is ongoing. The approval can be given ***before*** the post-market study. In the U.S., the FDA has an accelerated approval pathway that is similar, but a new law in December 2022 requires enrollment in the confirmatory study to be underway before approval will be given in the U.S. Therefore, CEL-SCI plans to start this confirmatory trial as soon as possible in 2024 and will then seek accelerated approval using data from that study as well.

CEL-SCI's first priority, however, is seeking approval in Europe and the UK, where CEL-SCI has submitted its final target population data. These are more than twice as many patients in the target population overseas than in North America. In Europe and the UK, CEL-SCI has submitted requests for Scientific Advice and is hopeful for meetings in H1 2024. Once a meeting date has been set, CEL-SCI will be able to discuss the data and gain advice on the path forward. It is possible that CEL-SCI may be advised at that time to proceed with a formal application.

CORPORATE HISTORY

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.

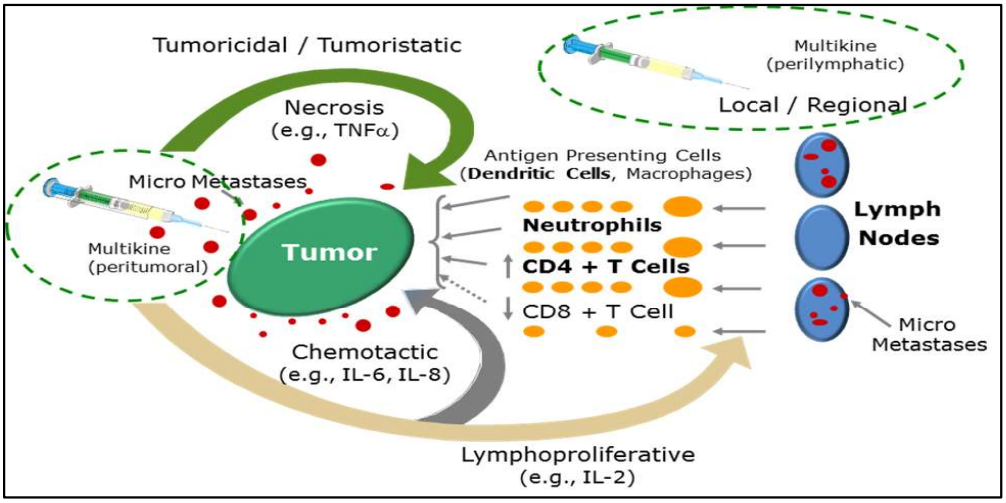
These filings are available on its website free of charge as soon as practicable after they are filed or furnished to the SEC.

MORE ABOUT MULTIKINE

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

Multikine is an immunotherapy product candidate comprised of a patented defined mixture of 14 human natural cytokines. If commercial approval is obtained, CEL-SCI intends to manufacture Multikine in a proprietary manner in CEL-SCI's manufacturing facility near Baltimore, Maryland, USA. CEL-SCI spent many years and more than $200 million developing and validating the manufacturing process for Multikine. The pro-inflammatory cytokine mixture includes interleukins, interferons, chemokines and colony-stimulating factors, which contain elements of the body's natural mix of defenses against cancer.

Multikine is designed to be used in a different way than cancer immunotherapy is generally being used. Generally, cancer immunotherapy is given to patients who have already failed other treatments such as surgery, radiation and/or chemotherapy and most of the time it is administered systemically. Multikine on the other hand is administered locally to treat tumors and their microenvironment before any other therapy has been administered because it is believed that this is the time when the immune system would be strongest and most amenable to activation against the tumor. For example, in the Phase III 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 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.



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).

In October 2023, CEL-SCI presented a poster at the European Society for Medical Oncology (EMSO) annual Congress that reported three major new advancements supporting Multikine's approvability:

- First, Multikine is most effective in patients having tumors with low PD-L1 expression, consisting of about 70% of the study population. (It should be noted that immune checkpoint inhibitors like Keytruda and Opdivo appear to work best in patients with tumors having high PD-L1 expression).
- Second, the Multikine target population can now be readily identified upon diagnosis, prior to surgery, using tests that physicians routinely use in cancer screenings.
- Third, Multikine patients in the target population saw a significant increase in 5-year overall survival, from 45% for control patients who did not receive Multikine to 73% for Multikine-treated patients.
  Link to poster: https://cel-sci.com/wp-content/uploads/2023/10/ESMO-2023-Poster_893P_FINAL.pdf

Previously, CEL-SCI published two abstracts and presented a poster related to its pivotal Phase III Multikine head and neck cancer clinical trial at the American Society of Clinical Oncology (ASCO) in June 2022. 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/

Since CEL-SCI launched its Phase III clinical trial for Multikine, CEL-SCI has incurred expenses of approximately $64.4 million as of September 30, 2023 on direct costs for the Phase III clinical trial. CEL-SCI estimates it will incur additional expenses of approximately $0.7 million for the remainder of the Phase III clinical trial and the filing of the application for marketing approval to the regulators. It should be noted that this estimate is based only on the information currently available from the CROs responsible for managing the Phase III 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. The completed Phase III clinical study for CEL-SCI's investigational drug may not be able to be used as the pivotal study supporting a marketing application in the United States, and therefore a confirmatory study would need to be conducted to support a marketing application in the United States.

Development Agreements for Multikine

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

Teva has agreed to use all reasonable efforts to obtain regulatory approval to market and sell Multikine in its territory at its own cost and expense. Pursuant to the agreement, it is CEL-SCI's responsibility to supply Multikine and Teva's responsibility to sell Multikine, if approved by regulatory authorities in the relevant countries. Net sales will be divided 50/50 between the two parties. Teva also initially agreed to fund certain activities relating to the conduct of a clinical trial in Israel as part of the global Phase III trial for Multikine. In July 2011, Serbia and Croatia were added to Teva's territory, pursuant to a joinder agreement between CEL-SCI and PLIVA Hrvatska d.o.o., or PLIVA, an affiliate of Teva's, subject to similar terms as described above. In 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 III trial in Israel to GCP.

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, or Byron, under which CEL-SCI granted Byron an exclusive license to market and distribute Multikine in the Republic of South Africa, if approved. This license will terminate 20 years after marketing approval in South Africa or after 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.

ABOUT 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 ligand peptides 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) (aka, CEL-5000)

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.

As part of the follow-up to the grant funded work, CEL-SCI published a review comparing CEL-4000 and the new LEAPS peptide CEL-5000 to both the Janus kinase (JAK) inhibitors and disease modifying anti-rheumatic drugs (DMARDs) in use for RA and autoimmune arthritis. The article reviewed the mechanism of action and targets with pictorial graphics in the journal Biomedicines and can be found online at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8772713/.

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 the newly discovered LEAPS conjugate, CEL-5000. 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.

MANUFACTURING FACILITY

Before starting the Phase III 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 III 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 approval to sell the drug is granted. This expansion was completed at the end of 2021, allowing CEL-SCI employees to return to work inside the manufacturing facility. In October 2023, CEL-SCI announced that the commissioning of the manufacturing facility was substantially complete, a significant milestone toward a planned Biologics License Application (BLA) with several regulatory agencies for approval of Multikine in the treatment of head and neck cancer.

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, 2023, there were approximately 500 record holders of CEL-SCI's common stock. CEL-SCI's common stock is traded on the NYSE American under the symbol "CVM".

Shown below are the range of high and low quotations for CEL-SCI's common stock for the periods indicated as reported by the NYSE American.

Quarter Ending	High	Low
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
12/31/2022	$3.68	$1.88
3/31/2023	$3.33	$2.15
6/30/2023	$2.94	$1.86
9/30/2023	$2.99	$1.08

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 $31.5 million for the twelve months ended September 30, 2023. This net operating loss consists of significant non-cash expenses accounting for approximately 33% of the operating loss. The non-cash operating expenses include approximately $6.3 million in stock-based employee compensation and approximately $4.0 million in depreciation and amortization expense.

During the year ended September 30, 2023, research and development expenses decreased by approximately $2.9 million, or 11%, compared to the year ended September 30, 2022. Major components of this decrease include an approximately $2.9 million decrease in employee stock compensation expense and a decrease of approximately $1.7 million in costs related to the Phase III clinical study. These decreases were offset by an increase of approximately $1.7 million of costs incurred to prepare for the potential commercial sale of Multikine.

During the year ended September 30, 2023, general and administrative expenses decreased by approximately $1.7 million, or 16%, compared to the year ended September 30, 2022. This decrease is primarily due to a decrease in employee stock compensation expense of approximately $2.2 million offset by a $0.5 million increase in other net general and administrative expenses.

During the years ended September 30, 2023 and 2022, CEL-SCI recorded a derivative gain of approximately $0.0 million and a gain of approximately $0.4 million, respectively. This variation was the result of no fair value adjustments made during the period since all of the derivative warrants expired during the year ended September 30, 2022. No derivative gains or losses were recorded during the year ended September 30, 2023.

Net interest expense decreased by approximately $0.4 million for the year ended September 30, 2023 compared to the year ended September 30, 2022. This decrease is primarily due to the Company earning approximately $0.3 million more in interest income and approximately $0.1 million less in interest expense from its finance leases during the year ended September 30, 2023 compared to the year ended September 30, 2022.

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, 2023	2022
Multikine	$ 22,098,222	$ 24,251,629
LEAPS	373,274	1,103,717
Total research and development	$ 22,471,496	$ 25,355,346

CEL-SCI's Phase III clinical trial began in December 2010 after the completion and validation of CEL-SCI's dedicated manufacturing facility. The Phase III 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, ESMO 2022, ECHNO 2023, ESTRO 2023, AHNS 2023 and ESMO 2023. As part of CEL-SCI's global regulatory approval strategy, CEL-SCI concurrently plans to pursue filings for marketing authorization in the United States, Canada, United Kingdom and Europe.

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 year 2023 and 2022, CEL-SCI raised net proceeds of approximately $6.4 million and $0.1 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 $2.6 million during the twelve months ended September 30, 2023.

The following charts list the warrants that were exercised and the proceeds received during the years ended September 30, 2023 and 2022.

Fiscal Year 2023

Warrants	Warrants Exercised	Exercise Price	Proceeds
Series RR	17,752	$1.65	$ 29,291
Series SS	200,000	$2.09	418,000
	217,752		$ 447,291

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

During the year ended September 30, 2023, the Company's cash decreased by approximately $18.5 million. The significant component of this decrease included cash used to fund the Company's regular operations of approximately $22.8 million, which includes the approximate $2.3 million deposit made to the Company's landlord as a result of falling below certain cash requirements per the San Tomas lease. Other components of this decrease include approximately $0.4 million used to make leasehold improvements and acquire research and development equipment, and approximately $1.6 million in payments on the Company's finance leases. These decreases were offset by approximately $5.8 million and $0.5 million of cash received from issuance of common stock and exercise of warrants, respectively.

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, 2023, 217,752 warrants were exercised at a weighted average exercise price of $2.05 for total proceeds of approximately $0.45 million.

Prepaid expenses decreased by approximately $0.2 million during the year ended September 30, 2023 as compared to September 30, 2022 primarily due to the timing of payments and recognition of related expenses.

Supplies are purchased for use in the Company's manufacturing and R&D efforts. During the year ended September 30, 2023, 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 III trial. The timing of these obligations cannot be determined at this time. CEL-SCI estimates it will incur additional expenses of approximately $0.7 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 III 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 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 and nonemployees 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.

Impairment of long-lived assets – CEL-SCI's fixed assets are made up of leasehold improvements, furniture, and equipment. ASC 360-10 requires that a long-lived asset group be reviewed for impairment only when events or changes in circumstances indicate that the carrying amount of the long-lived asset (group) might not be recoverable. CEL-SCI's recurring losses are a triggering event that could indicate impairment of long-lived assets such as fixed assets. CEL-SCI reviews these assets in accordance with ASC 360-10-35-21 to determine if events or changes in circumstances indicate the existence of impairment. If indicators of impairment exist, the Company tests for recoverability, then, if necessary, measures and records the impairment. The amount of the impairment loss would be the amount by which the carrying amount of the asset (group) exceeds its fair value.

CEL-SCI CORPORATION

Financial Statements for the Years
Ended September 30, 2023 and 2022, 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, 2023 and 2022, 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, 2023 and 2022, 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 audits 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 – See also Going Concern Uncertainty explanatory paragraph above

As described in Note 2 to the financial statements, 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 will be required to raise additional capital or find additional long-term financing to continue with its efforts to bring its lead product candidate to market. 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.

We identified management's evaluation of the Company's liquidity as a critical audit matter due to certain significant judgments and assumptions used by management in preparing its forecast of cash expenditures that are used to support the Company's liquidity disclosure. Auditing the timing and amount of forecasted cash expenditures 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 the timing and amount of forecasted cash expenditures by comparing (i) the timing of the Company's forecasted cash expenditures with the ongoing drug development pipeline and (ii) the disaggregated actual current year expenditures with historical forecasted expenditures.

- Testing the completeness and accuracy of underlying data used in the forecasted cash expenditures by inspecting contractual arrangements with third-party clinical research organizations and suppliers.

/s/ BDO USA, P.C.

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

Potomac, Maryland
December 21, 2023

CEL-SCI CORPORATION
BALANCE SHEETS
SEPTEMBER 30, 2023 AND 2022

	2023	2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 4,145,735	$ 22,672,138
Prepaid expenses	520,368	762,063
Supplies used for R&D and manufacturing	2,248,072	2,001,715
Deposits	4,245	-
Total current assets	6,918,420	25,435,916
Finance lease right of use assets	9,131,987	10,937,797
Operating lease right of use assets	1,698,243	1,884,464
Property and equipment, net	10,188,126	11,889,029
Patent costs, net	197,704	212,201
Deposits	2,319,101	-
Supplies used for R&D and manufacturing	74,669	164,299
Total assets	$ 30,528,250	$ 50,523,706
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 2,009,786	$ 1,618,290
Accrued expenses	1,049,581	842,492
Due to employees	557,244	471,488
Finance lease obligation, current portion	1,771,804	1,560,553
Operating lease obligation, current portion	197,431	170,928
Total current liabilities	5,585,846	4,663,751
Finance lease liabilities, net of current portion	9,949,565	11,721,368
Operating lease liabilities, net of current portion	1,652,949	1,850,380
Other liabilities	125,000	125,000
Total liabilities	17,313,360	18,360,499
Commitments and contingencies		
STOCKHOLDERS' EQUITY		
Preferred stock, $0.01 par value; 200,000 shares authorized; 0 shares issued and outstanding Common stock, $0.01 par value; 600,000,000 shares authorized; 47,422,304 and 43,448,317 shares issued and outstanding at September 30, 2023 and September 30, 2022, respectively	474,223	434,484
Additional paid-in capital	499,832,063	486,625,816
Accumulated deficit	(487,091,396)	(454,897,093)
Total stockholders' equity	13,214,890	32,163,207
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 30,528,250	$ 50,523,706

CEL-SCI CORPORATION
STATEMENTS OF OPERATIONS
YEARS ENDED SEPTEMBER 30, 2023 AND 2022

	2023	2022
Operating expenses:		
Research and development	$ 22,471,496	$ 25,355,346
General & administrative	9,004,578	10,707,447
Total operating expenses	31,476,074	36,062,793
Operating loss	(31,476,074)	(36,062,793)
Gain on derivative instruments	-	366,791
Other non-operating losses	-	(30,793)
Interest expense, net	(675,416)	(1,081,034)
Other (expense) income	(42,813)	107,148
Net loss	$ (32,194,303)	$ (36,700,681)
Modification of warrants	(171,552)	(929,122)
Net loss available to common shareholders	$ (32,365,855)	$ (37,629,803)
Net loss per common share – basic and diluted	$ (0.73)	$ (0.87)
Weighted average common shares outstanding – basic and diluted	44,479,865	43,148,888

CEL-SCI CORPORATION
STATEMENT OF STOCKHOLDERS' EQUITY
YEARS ENDED SEPTEMBER 30, 2023 AND 2022

	Common Stock		Additional Paid-In	Accumulated	
	Shares	Amount	Capital	Deficit	Total
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
Warrant exercises	217,752	2,177	445,114	-	447,291
401(k) contributions paid in common stock	97,004	970	206,623	-	207,593
Stock issued to nonemployees for service	249,997	2,500	563,480	-	565,980
Proceeds from the sale of common stock	3,413,234	34,132	6,518,365	-	6,552,497
2014 Incentive Stock Forfeited	(4,000)	(40)	(22,160)	-	(22,200)
Equity based compensation - employees	-	-	6,308,431	-	6,308,431
Share issuance costs	-	-	(813,606)	-	(813,606)
Net loss	-	-	-	(32,194,303)	(32,194,303)
BALANCE, SEPTEMBER 30, 2023	47,422,304	$ 474,223	$ 499,832,063	$ (487,091,396)	$ 13,214,890

CEL-SCI CORPORATION
STATEMENTS OF CASH FLOWS
YEARS ENDED SEPTEMBER 30, 2023 AND 2022

	2023	2022
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (32,194,303)	$ (36,700,681)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	3,958,334	3,828,917
Non-cash lease expense	15,292	54,469
Share-based payments for services	655,740	762,261
Equity based compensation	6,286,231	11,389,932
Common stock contributed to 401(k) plan	207,593	223,043
Gain on short term investments	-	(615)
Gain on derivative instruments	-	(366,791)
Impairment loss on abandonment of patents	-	30,793
Loss on Receivables	-	54,922
(Increase)/decrease in assets:		
Prepaid expenses	151,935	167,651
Supplies used for R&D and manufacturing	(156,727)	(159,430)
Deposits	(2,323,346)	1,910,917
Increase/(decrease) in liabilities:		
Accounts payable	257,845	374,890
Accrued expenses	207,089	(16,724)
Due to employees	85,756	205,495
Net cash used in operating activities	(22,848,561)	(18,240,951)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Proceeds from maturity of U.S. Treasury Bills	-	6,152,000
Purchases of property and equipment	(361,892)	(637,892)
Expenditures for patent costs	(10,370)	(22,741)
Net cash (used in) provided by investing activities	(372,262)	5,491,367
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock	6,552,497	-
Payments of stock issuance costs	(744,913)	(169,445)
Proceeds from the exercise of warrants	447,291	101,225
Proceeds from the exercise of options	-	29,835
Proceeds from landlord funding of lease improvements	-	786,454
Payments on obligations under finance leases	(1,560,455)	(1,386,495)
Net cash provided by (used in) financing activities	4,694,420	(638,426)
NET DECREASE IN CASH AND CASH EQUIVALENTS	(18,526,403)	(13,388,010)
CASH AND CASH EQUIVALENTS, BEGINNING OF YEAR	22,672,138	36,060,148
CASH AND CASH EQUIVALENTS, END OF YEAR	$ 4,145,735	$ 22,672,138

CEL-SCI CORPORATION
STATEMENTS OF CASH FLOWS
YEARS ENDED SEPTEMBER 30, 2023 AND 2022

SUPPLEMENTAL SCHEDULE OF NON-CASH INVESTING AND FINANCING ACTIVITIES:

	2023	2022
Property and equipment purchases included in current liabilities	$ 51,650	$ -
Capitalized patent costs included in current liabilities	$ 13,211	$ -
Assets purchased under finance leases	$ -	$ 32,409
Changes to right of use assets and liabilities	$ -	$ 16,268
Finance lease obligation included in accounts payable	$ 1,451	$ 1,354
Prepaid consulting services paid with issuance of common stock	$ 565,980	$ 295,143
Financing costs included in current liabilities	$ 77,703	$ 9,010
Exercise of derivative liabilities	$ -	$ 70,589
Accrued consulting services to be paid with common stock	$ 55,000	$ 55,000
Cash paid for interest	$ 1,062,564	$ 1,157,069

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 III 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) or from the regulators in Canada, the UK or Europe 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.

To finance the Company through marketing approval, the Company plans to raise additional capital in the form of 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 Multikine showed great survival benefit in the Phase III 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 funding, 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.

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 is recorded at cost and depreciated using the straight-line method over estimated useful lives of five to seven years. Leasehold improvements are depreciated over the shorter of the estimated useful life of the asset or the term of the lease. Repairs and maintenance which do not extend the life of the asset are expensed when incurred. Property and equipment 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.

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 reporting 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 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 Update 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 was effective for fiscal years beginning after December 15, 2021, however, as permitted, the Company elected to prospectively adopt the standard, effective as of October 1, 2021. Adoption of this standard had no impact on the Company's financial statements.

Stock-Based Compensation – Compensation cost for all stock-based awards is measured at fair value as of the grant date in accordance with the provisions of ASC 718, *Compensation – Stock Compensation*. The fair value of stock options is calculated using the Black-Scholes option pricing model. The Black-Scholes model requires

various judgmental assumptions including volatility and expected option life. The stock-based compensation cost is recognized 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, 2023 and September 30, 2022.

Income Taxes –The Company follows ASC 740-10-25 for recording the provision for income taxes. Deferred tax assets and liabilities are computed based upon the difference between the financial statement and income tax basis of assets and liabilities using the enacted marginal tax rate applicable when the related assets or liability is expected to be realized 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, 2023 and 2022.

The Company adopted ASU 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 (the "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 (the "Treasury") has been given authority to provide regulations and other guidance to carry out and prevent the abuse or avoidance of the excise tax.

Impairment of long-lived assets – CEL-SCI's fixed assets are made up of leasehold improvements, furniture, and equipment. ASC 360-10 requires that a long-lived asset group be reviewed for impairment only when events or changes in circumstances indicate that the carrying amount of the long-lived asset (group) might not be recoverable. CEL-SCI's recurring losses are a triggering event that could indicate impairment of long-lived assets such as fixed assets. CEL-SCI reviews these assets in accordance with ASC 360-10-35-21 to determine if events or changes in circumstances indicate the existence of impairment. If indicators of impairment exist, the Company tests for recoverability, then, if necessary, measures and records the impairment. The amount of the impairment loss would be the amount by which the carrying amount of the asset (group) exceeds its fair value.

Use of Estimates – The preparation of financial statements in conformity with U.S. generally accepted accounting principles (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 research and development (R&D) and manufacturing, accruals, stock options, useful lives for depreciation and amortization of long-lived assets, right of use assets and lease liabilities, deferred tax assets and the related valuation allowance, and the valuation of derivative liabilities. Actual results could differ from estimates, although management does not generally believe such differences would materially affect the financial statements in any given year. 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

In June 2016, the Financial Accounting Standards Board issued ASU 2016-13, *Financial Instruments–Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments* (ASU 2016-13), as amended. The amendments in ASU 2016-13 require, among other things, financial assets measured at amortized cost basis to be presented at the net amount expected to be collected as compared to previous U.S. GAAP which delayed recognition until it was probable a loss had been incurred. The amendments in ASU 2016-13 are effective for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years, with early adoption permitted. The Company currently does not have any such financial assets reported as of September 30, 2023, however, the Company will continue to evaluate the impact that adoption of ASU 2016-13 will have on its financial statements and related disclosures.

Other accounting standard updates effective for interim and annual periods beginning after September 30, 2023 are not expected to have a material impact on the Company's financial statements.

4. WARRANTS AND NON-EMPLOYEE OPTIONS

The following warrants and non-employee options are outstanding at September 30, 2023:

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	234,009	$1.65	10/30/2024
Consultant Options	7/28/2017 – 9/2/2023	110,000	$1.39 - $2.18	7/27/2027 – 9/1/2028

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

A. Warrant Liabilities

There were no warrant liabilities outstanding at September 30, 2023 and 2022.

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

	2023	2022
Series W warrants	$ -	$ -
Series Z warrants	-	64,787
Series ZZ warrants	-	-
Series AA warrants	-	276,035
Series BB warrants	-	-
Series CC warrants	-	24,372
Series HH warrants	-	1,597
Net loss on warrant liabilities	$ -	$ 366,791

The Company reviews all outstanding warrants in accordance with the requirements of ASC 815, *Accounting for Derivative Instruments and Hedging Activities*. 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.

Exercise of Warrant Liabilities

No warrants recorded as liabilities were exercised during the year ended September 30, 2023.
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

B. Equity Warrants

Changes in Equity Warrants

On October 28, 2022, the expiration date of the Series RR warrants was extended two years from October 30, 2022 to October 30, 2024. The incremental cost of this extension was approximately $172,000, which was recorded as a deemed dividend. The Series RR warrants are held by Geert Kersten, Patricia Prichep (current officers of the Company) and the de Clara Trust, of which the Company's CEO, Geert Kersten, is a beneficiary.

On 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.

Exercise of Equity Warrants

The following equity warrants were exercised during the year ended September 30, 2023.

Warrants	Warrants Exercised	Exercise Price	Proceeds
Series RR	17,752	$1.65	$ 29,291
Series SS	200,000	2.09	418,000
	217,752		$ 447,291

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

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, 2023 and 2022, the Company issued 249,997 and 156,547 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 $1.26 to $11.20 per share. The weighted average grant price was $1.83 and $4.59, respectively, for stock issued during the years ended September 30, 2023 and 2022.

During the years ended September 30, 2023 and 2022, the Company recorded total expense of approximately $656,000 and $762,000, respectively, relating to these consulting agreements. At September 30, 2023 and 2022, costs of approximately $205,000 and $295,000, respectively, are included in prepaid expenses.

During the year ended September 30, 2023, the Company issued 100,000 options to a consultant to purchase common stock with an exercise price of $1.39. These options vest 50% on September 2, 2024 and 50% on September 2, 2025 and expire on September 1, 2028. No options were issued to consultants during the year ended September 30, 2022. As of September 30, 2023, 110,000 options issued to consultants as payment for services remained outstanding, all of which were issued from the Non-Qualified Stock Option Plan.

5. PROPERTY AND EQUIPMENT

Property and equipment consisted of the following at September 30:

	2023	2022
Research equipment	$ 4,109,070	$ 4,095,022
Furniture and equipment	99,296	99,296
Leasehold improvements	13,924,724	13,544,394
	18,133,090	17,738,712
Accumulated depreciation and amortization	(7,944,964)	(5,849,683)
Net property and equipment	$ 10,188,126	$ 11,889,029

Depreciation expense for the years ended September 30, 2023 and 2022 totaled approximately $2,114,000 and $1,977,000 respectively.

6. PATENTS

Patents consist of the following at September 30:

	2023	2022
Patents	$ 853,445	$ 893,833
Accumulated amortization	(655,741)	(681,632)
Patents, net	$ 197,704	$ 212,201

During the years ended September 30, 2023 and 2022, there was no impairment of patent costs. The weighted average amortization period for patents is approximately 8 years. Amortization expense for the years ended September 30, 2023 and 2022 totaled approximately $38,000 and $49,000, respectively. The total estimated future amortization is as follows:

Years ending September 30,	
2024	$ 32,000
2025	29,000

2026	25,000
2027	22,000
2028	19,000
Thereafter	71,000
	$ 198,000

7. INCOME TAXES

At September 30, 2023 and 2022, the Company had net deferred tax assets of $60.0 million and $52.9 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 assets 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 estimated analysis to determine if any additional ownership changes occurred during the year ended September 30, 2023 and no such changes 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 $123.1 million and $100.2 million at September 30, 2023 and 2022, 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 $103.9 million of NOL carryforwards, which were generated after the enactment of 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, 2023 and 2022. The R&D credit expires during the fiscal year ended 2029.

Significant components of the Company's deferred tax assets and liabilities as of September 30, 2023 and 2022 are listed below:

	2023	2022
NOL carryforwards	$ 30,829,000	$ 25,346,000
Capitalized R&D	15,196,000	15,042,000
Stock-based compensation	11,579,000	10,442,000
Lease liabilities	3,400,000	3,872,000
R&D credit	1,221,000	1,221,000
Vacation and other	298,000	307,000
Fixed assets and intangibles	168,000	-
Total deferred tax assets	62,691,000	56,230,000
Right of use assets	(2,713,000)	(3,244,000)
Fixed assets and intangibles	-	(44,000)
Total deferred tax liabilities	(2,713,000)	(3,288,000)
Net deferred tax asset	59,978,000	52,942,000
Valuation allowance	(59,978,000)	(52,942,000)
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:

	2023	2022
Federal rate	21.00%	21.00%
State rate change	(1.58)	(1.67)
State tax rate, net of federal benefit	4.05	4.34
Other adjustments	(1.62)	(0.28)
Permanent differences	0.00	0.21
Change in valuation allowance	(21.85)	(23.61)
Effective tax rate	0.00%	0.00%

The Company applies the provisions of ASC 740, *Accounting for Uncertainty in Income Taxes,* which requires financial statement benefits to be recognized for positions taken for tax return purposes when it is more likely than not that the position will be sustained. The Company has elected to reflect any tax penalties or interest resulting from tax assessments on uncertain tax positions as a component of tax expense. The Company has generated federal net operating losses in tax years ending September 30, 1999 through 2023. 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 before September 30, 2020.

8. EQUITY-BASED COMPENSATION

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

	Year Ended September 30,	
	2023	2022
Employees	$ 6,286,231	$ 11,389,932
Non-employees	$ 655,740	$ 762,261

As of September 30, 2023, the total compensation cost related to non-vested options and restricted stock awarded to employees and non-employees not yet recognized was approximately $6.9 million and $0.3 million, respectively, and the weighted-average period over which it is expected to be recognized is 1.78 and 0.94 years, respectively.

During the years ended September 30, 2023 and 2022 the fair value of each option grant was estimated on the date of grant using the Black-Scholes option pricing model with the following assumptions.

	2023	2022
Expected stock price volatility	99.18 – 100.18%	96.37 – 99.26%
Risk-free interest rate	3.41 – 4.25%	1.50 – 3.43%
Expected life of options	9.63 – 9.66 years	9.67 – 9.69 years
Expected dividend yield	-	-

Non-Qualified Stock Option Plans

During the year ended September 30, 2023, the Company adopted the 2023 Non-Qualified Stock Option Plan, which provides for the issuance of up to 2,000,000 options to purchase shares of common stock. On August 8, 2023, the Company granted 1,958,500 options to purchase shares of common stock from the 2023 Non-Qualified Stock Option Plan to officers, directors and employees. Each option entitles the holder to purchase one share of the Company's common stock at a price of $1.36 per share, vests in three equal annual installments commencing one year after the grant date and expires on August 7, 2033.

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 approach. 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 was recognized relating to these options as of September 30, 2023. Management will re-assess the probability of achieving the performance condition at each reporting date.

At September 30, 2023, the Company has collectively authorized the issuance of 15,787,200 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, 2023, 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, 2023 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, 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 (a)	2,040,750	$4.24			-			
Exercised	(6,500)	$4.59		$45,725	(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
Vested					952,256	$8.41		
Granted (b)	2,065,500	$1.37						
Exercised	-				-			
Forfeited	213,165	$9.19						
Expired	(58,791)	$61.05			(58,791)	$61.05		
Outstanding at September 30, 2023	14,757,558	$7.78	6.81	$0	7,961,082	$6.07	5.60	$0

(a) The weighted average grant date fair value was $3.01.
(b) Includes 1,965,500 performance based options issued to officers and directors, 100,000 options issued to consultants. The weighted average grant date fair value was $1.22.

A summary of the status of the Company's unvested options for the two years ended September 30, 2023 is presented below:

	Number of Options	Weighted Average Grant Date Fair Value
Unvested at September 30, 2021	5,509,681	$ 5.17
Vested	(1,547,703)	$ 7.37
Granted	2,040,750	
Forfeited	(106,331)	
Unvested at September 30, 2022	5,896,397	$ 3.63
Vested	(952,256)	$ 7.30
Granted	2,065,500	
Forfeited	(213,165)	
Unvested at September 30, 2023	6,796,476	$ 2.25

Incentive Stock Bonus Plan – On September 30, 2023, 610,500 of the shares granted under the 2014 Incentive Stock Bonus Plan remain outstanding, of which 463,250 shares are fully vested. During the year ended September 30, 2023, 4,000 unvested shares were forfeited. 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, 2023 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, 2023 and 2022, the Company recorded expense relating to the issuance of restricted stock pursuant to the plan of approximately $(22,000) and $45,000, respectively. As of September 30, 2023, 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, 2023 is presented below:

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested at September 30, 2021	151,250	$13.75
Forfeited	-	
Vested	-	
Unvested at September 30, 2022	151,250	$13.75
Forfeited	(4,000)	
Vested	-	
Unvested at September 30, 2023	147,250	$13.75

Stock Bonus Plans – As of September 30, 2023, the Company authorized to issue up to 1,283,760 shares of common stock from the Stock Bonus Plans and has issued a total of 512,972 shares of common stock under its Stock Bonus Plans. All employees, directors, officers, consultants, and advisors are eligible to be granted shares.

Stock Compensation Plans – On September 30, 2023, 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 during the years ended September 30, 2023 and 2022.

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, 2023, 97,004 shares were issued to the Company's 401(k) plan for a cost of approximately $208,000. During the year ended September 30, 2022, 52,882 shares were issued to the Company's 401(k) plan for a cost of approximately $223,000.

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 $35.7 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, 2023 and 2022, the Company recorded approximately $0.2 million and $0.5 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 during both the years ended September 30, 2023 and 2022.

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 III clinical trial and sales of the drug if approved by the FDA or regulators in Canada, the UK or Europe. 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.

As of September 30, 2023 and 2022, respectively, the net book value of the finance lease right of use asset is approximately $9.1 million and $10.9 million and the balance of the finance lease liability is approximately $11.7 million and $13.3 million, of which approximately $1.8 million and $1.6 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, 2023 and 2022, the finance right of use assets are being depreciated using a straight-line method over the underlying lease terms and depreciation expense totaled approximately $1.8 million and $1.8 million, respectively. Total cash paid related to finance leases during the years ended September 30, 2023 and 2022, respectively, was approximately $2.6 million and $2.5 million, of which approximately $1.1 million and $1.2 million was for interest in both years. The weighted average discount rate of the Company's finance leases is 8.44% and the weighted average time to maturity is 5.09 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. Because the Company met the minimum cash balance required by the lease, the full balance of the deposit was returned to the Company in January 2022. However, on January 11, 2023, the Company was required to deposit approximately $2.3 million to its landlord, equivalent to one year's rent, for falling back below the stipulated cash threshold in accordance with the San Tomas lease. The amount will be included as an asset on the balance sheet until the Company meets the minimum cash balance required and the deposit is returned.

Approximate future minimum lease payments under finance leases as of September 30, 2023 are as follows:

Year ending September 30,	
2024	2,655,000
2025	2,740,000
2026	2,832,000
2027	2,923,000
2028	3,015,000
Thereafter	252,000
Total future minimum lease obligation	14,417,000
Less imputed interest on finance lease obligations	(2,696,000)
Net present value of lease finance lease obligations – current portion	1,772,000
Net present value of lease finance lease obligations – non-current portion	$9,949,000

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 and will expire on February 29, 2032. 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.

As of September 30, 2023, the net book value of the operating lease right of use asset is approximately $1.7 million and the balance of the operating lease liability is approximately $1.9 million, of which approximately $0.2 million is current. 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 $2.1 million, of which approximately $0.2 million is current. During the years ended September 30, 2023 and 2022 the Company incurred lease expense under operating leases of approximately $0.4 million each year. Total cash paid related to operating leases during the years ended September 30, 2023 and 2022 was approximately $0.3 million each year. The weighted average discount rate of the Company's operating leases is 10.2% and the weighted average time to maturity is 7.74 years.

As of September 30, 2023, future minimum lease payments on operating leases are as follows:

Year ending September 30,	
2024	357,000
2025	366,000
2026	287,000
2027	277,000

2028	285,000
Thereafter	1,040,000
Total future minimum lease obligation	2,612,000
Less imputed interest on operating lease obligation	(762,000)
Net present value of operating lease obligation – current portion	197,000
Net present value of operating lease obligation – non-current portion	$1,653,000

Vendor Obligations

The Company has contingent obligations with vendors for work that will be completed in relation to the Phase III clinical trial. The timing of these obligations cannot be determined at this time. The Company estimates it will incur additional expenses of approximately $0.7 million for the remainder of the Phase III 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 III clinical trial and does not include other related costs.

11. RELATED PARTY TRANSACTIONS

During the year ended September 30, 2023, no restricted shares of the Company's common stock were purchased by related parties.

On October 28, 2022, the expiration date of the Series RR warrants was extended two years from October 30, 2022 to October 30, 2024 (Note 4). The incremental cost of this extension was approximately $172,000, which was recorded as a deemed dividend. The Series RR warrants are held by Geert Kersten, Patricia Prichep (current officers of the Company) and the de Clara Trust, of which the Company's CEO, Geert Kersten, is a beneficiary.

On 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 warrant extensions were recorded consistent with the accounting for the initial warrant issuances. 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, of which the Company's CEO, Geert Kersten, is a trustee and beneficiary. 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 and the de Clara Trust.

12. STOCKHOLDERS' EQUITY

Exercise of Warrants

During the years ended September 30, 2023 and 2022, the Company received proceeds of approximately $0.4 million and $0.1 million, respectively, from the exercise of warrants, as detailed in Note 4. Upon exercise, 217,752 and 25,205 shares of common stock were issued during the years ended September 30, 2023 and 2022, respectively.

Sales of Securities

On May 2, 2023, the Company sold 913,234 shares of common stock at a public offering price of $1.70 per share and received aggregate proceeds of approximately $1.55 million. On July 20, 2023, the Company sold 2,500,000 shares of common stock at a public offering price of $2.00 per share and received aggregate proceeds of approximately $5.0 million.

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

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 III 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, 2023 and 2022, CEL-SCI did not issue Ergomed any shares of common stock. Additionally, no shares were sold during the years ended September 30, 2023 and 2022. All outstanding shares have been resold as of September 30, 2023 and 2022 and the Company had approximately $0 and $22,000 in amounts remaining in prepaid to Ergomed as of September 30, 2023 and 2022, respectively.

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 that are observable for the asset or liability are observable in active markets
- Level 3 – Unobservable inputs that reflect management's assumptions

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

The 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 yield a weighted average interest rate of 0.10%. The Company is not holding any T-bills as of September 30, 2023 and September 30, 2022.

As of September 30, 2023 and 2022, there were no derivative liabilities outstanding.

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:

	2023	2022
Beginning balance	$ -	$ 437,380
Issuances	-	-
Exercises	-	(70,589)
Net realized and unrealized derivative loss	-	(366,791)
Ending balance	$ -	$ -

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.

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,	
	2023	**2022**
Loss per share – basic and diluted		
Net loss available to common shareholders – basic and diluted	$ (32,365,855)	$ (37,629,803)
Weighted average shares outstanding – basic and diluted	44,479,865	43,148,888
Basic and diluted loss per common share	$ (0.73)	$ (0.87)

In accordance with the contingently issuable shares guidance of ASC 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:

	2023	**2022**
Options and warrants	15,850,028	14,274,836
Unvested restricted stock	147,250	151,250
Total	15,997,278	14,426,086

15. SUBSEQUENT EVENTS

On November 20, 2023, the Company sold 2,490,000 shares of common stock to a single investor at a public offering price of $2.00 per share for aggregate net proceeds of approximately $4.5 million.

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
Director
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

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

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

Website: www.cel-sci.com

Independent Auditors

BDO USA, P.C.
Potomac, MD

Counsel

Hart & Hart
Denver, CO

Transfer Agent and Registrar

Computershare Investor Services
PO BOX 43078
Providence, RI 02940-3078
(800) 962-4284

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 500 stockholders of record as of February 23, 2024. 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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