

CEL-SCI Corporation

(CVM - NYSE)

CEL-SCI: Advancing with an Intent to Cure

INITIATION

Based on our DCF model and a 15% discount rate, CEL-SCI is valued at approximately \$14.00 per share. Our model applies a 50% probability of ultimate approval and commercialization for Multikine in head and neck cancer. The model includes contributions from the US, EU and rest of world.

CEL-SCI's portfolio is developing two platforms, Multikine and LEAPS. Multikine is in Phase 3 for head and neck cancer and in Phase I for HPV while LEAPS is conducting preclinical studies for RA, Pandemic Flu and breast cancer. After recent catalysts related to favorable decision against a former CRO and the lifting of a clinical hold on Multikine, investors are anticipating a near term conclusion of the Phase 3 trial and readout on the head and neck cancer study.

Multikine is an immuno-oncology biologic that contains human blood-derived cytokines that are thought to enhance the body's natural defenses against cancer. For the lead indication, SCCHN, it is used prior to and in conjunction with SOC, which includes surgery, radiation and chemotherapy. LEAPS is a peptide epitope delivery technology that can direct immune response. It is appropriate for diseases where antigenic epitope sequences have been identified.

Our valuation assumes a 2020 FDA approval of Multikine for head and neck cancer and a 2021 launch of the compound in the US, followed by a subsequent launch in the EU and global availability by 2022 that will be achieved through the efforts of partners.

Current Price (1/30/2019) **\$2.85**
Valuation **\$14.00**

SUMMARY DATA

52-Week High **4.44**
52-Week Low **0.82**
One-Year Return (%) **30.7**
Beta **2.04**
Average Daily Volume (sh) **256,996**

Shares Outstanding (mil) **28.4**
Market Capitalization (\$mil) **80.9**
Short Interest Ratio (days) **8.8**
Institutional Ownership (%) **6.6**
Insider Ownership (%) **5.6**

Annual Cash Dividend **\$0.00**
Dividend Yield (%) **0.00**

5-Yr. Historical Growth Rates
Sales (%) **N/A**
Earnings Per Share (%) **N/A**
Dividend (%) **N/A**

P/E using TTM EPS **N/A**
P/E using 2017 Estimate **N/A**
P/E using 2018 Estimate **N/A**

Zacks Rank **N/A**

Risk Level **Above Average**
Type of Stock **Small-Growth**
Industry **Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue

(In millions of USD)

	Q1	Q2	Q3	Q4	Year
	(Dec)	(Mar)	(Jun)	(Sep)	(Sep)
2017	\$0.0 A	\$0.0 A	\$0.0 A	\$0.0 A	\$0.1 A
2018	\$0.1 A	\$0.1 A	\$0.1 A	\$0.1 A	\$0.5 A
2019					\$0.4 E
2020					\$0.4 E

Earnings per Share

	Q1	Q2	Q3	Q4	Year
2017	\$0.58 A	-\$1.15 A	-\$0.53 A	-\$0.50 A	-\$1.82 A
2018	-\$0.53 A	-\$0.31 A	-\$0.36 A	-\$0.61 A	-\$1.87 A
2019					-\$0.42 E
2020					-\$0.27 E

INITIATING COVERAGE

We are initiating coverage of CEL-SCI Corporation (NYSE: CVM) with a \$14.00 price target based on our estimates for a 2021 US and 2022 EU launch of lead compound Multikine in squamous cell carcinoma of the head and neck (SCCHN). The clinical-stage company is developing this biological product which contains multiple cytokines to enable the body to mount an anti-tumor immune response. The biologic is being developed as a first line therapy that will be administered to newly diagnosed, but not yet treated, head and neck cancer patients prior to their receiving standard of care (SOC), which includes surgery, chemotherapy and radiotherapy. This approach aims to improve the patient's overall survival (OS) compared to patients that receive SOC alone. Multikine is thought to bind to receptors on both cancer and immune cells, signaling the immune system to produce an anti-tumor response and possibly making the cancer cells more susceptible to radiation and chemotherapy treatment.

CEL-SCI is currently conducting a Phase III trial, which is examining the use of Multikine in combination with and given prior to SOC treatment. It has completed enrollment of 928 SCCHN patients and is expected to provide a topline readout in the first half of 2019. The company has concluded a Phase I trial for human papilloma virus (HPV) patients using Multikine in HIV/HPV co-infected patients. The company's other technology, Ligand Epitope Antigen Presentation System (LEAPS), is currently in the preclinical stage pursuing indications in rheumatoid arthritis (RA), pandemic flu and breast cancer.

Multikine is differentiated from other cancer immunotherapy in three ways in that it is: 1) administered between diagnosis and surgery, 2) comprised of cytokines sourced from normal human donor leukocytes and 3) given to patients who are scheduled to receive "intent to cure" first line therapy. Administration occurs immediately after diagnosis allows the biologic to begin activating the immune system to eliminate micro-metastases and recognize tumor cells. It includes a broad variety of lymphoproliferative, chemotactic and necrotic cytokines that can potentially recognize and bind to multiple receptors on both immune and cancer cells. As Multikine is injected right after diagnosis in the weeks prior to normal scheduling of surgery, it does not delay subsequent treatment. A delay of surgery can negatively impact survival. Therefore, it is not ethically acceptable to delay surgery to conduct a study on another cancer product, which would be required in studies to obtain first line approval in other immunology treatments such as checkpoint inhibitors or CAR-T. Multikine is immediately available and can be administered to have its beneficial effects in the three week period routinely open to schedule and prepare for surgery. The biologic mixture is thought to overcome local immune suppression by the tumor, break tumor tolerance to tumor antigens and allow for a sustainable and effective anti-tumor immune response.

On September 30, 2018, CEL-SCI held approximately \$10 million in cash on its balance sheet. Modest amounts of capital have been raised over previous years with public offerings, stock issuances and warrant exercises. The company currently holds no debt but does have required lease payments for its manufacturing facility. We expect CEL-SCI to consume slightly greater than \$1 million per month as it completes its Phase III trial and pursues FDA approval. In parallel, we expect other Multikine and LEAPS programs to continue to advance.

Based on our review, we anticipate the Multikine Phase III "IT-MATTERS" trial to be completed in 1H:19 and topline data to be presented from the Phase III SCCHN trial in 2H:19. Assuming favorable data is presented, further interaction with the FDA will take place as will the preparation and submission of a biologic license application (BLA). After approximately a year for review we anticipate an approval and a concurrent search for a partner to distribute the product outside of the United States. If data from the trial are very strong and the FDA considers Multikine to provide a significant improvement in safety or effectiveness, CEL-SCI may receive a priority review designation, which would advance the drug more quickly through the application process. Multikine has also received Orphan Drug Designation from the FDA.

There are multiple legs supporting our positive thesis for CEL-SCI, including promising data in completed Phase II trials related to both safety and efficacy. CEL-SCI also operates its dedicated Multikine manufacturing facility, allowing for greater control over product quality and production. Phase III results are expected in the near term, which, if favorable, will support a BLA submission, approval, and ultimate commercialization in 2021.

INVESTMENT THESIS

CEL-SCI is in the final stages of its Phase III trial for SCCHN which, if approved, will be the only first line immunotherapy for this indication targeting the “intent to cure” population for which no new drug or therapy has been approved in decades. The company has secured an orphan designation for Multikine in SCCHN which can provide for a closer working relationship with the FDA and potentially allow a more efficient approval process. Multikine is a biologic therapy that is administered immediately after diagnosis and followed by surgery and other SOC. There is clinical data supporting the biologic’s efficacy, which functions by supporting the immune system to identify and fight cancer. We expect the data provided from the in-progress Phase III trial to support a BLA and subsequent commercialization in the United States and other regions.

Multikine includes pro-inflammatory cytokines that proliferate an immune response, draw immune cells to the site of the tumor and kill tumor cells. The components of the biologic can potentially recognize and bind to cancer and immune cells, thereby enhancing the body’s normal response to rogue cells. Multikine is used prior to SOC, when the immune system is still strong and when it can have the greatest impact on tumor tissue.

Current SOC is only modestly effective in SCCHN and its impact on survival of these patients has not advanced in decades exhibiting an estimated 43% five-year survival rate. Treatment can also be disfiguring and debilitating, further emphasizing the need for a new and improved approach. Based on company and American Cancer Society data, there are approximately 60,000 US cases and about 105,000 EU cases per year. The World Health Organization (WHO) estimated about 550,000 cases globally in 2014. Additionally, Multikine may be appropriate for other cancers beyond SCCHN and CEL-SCI may pursue additional indications following approval. There are no other immunotherapies in development for the advanced primary, not yet treated SCCHN patients, which suggests high market penetration if commercialized.

We anticipate pricing of the drug to be similar to other immuno-oncology agents. Many of these therapies present an average cost of above \$150 thousand per course of treatment in the United States. Our forecasts maintain a conservative view, and anticipate a discount to these levels that is expected to capture market share. We make further reductions for regions ex-US to reflect relative prices in these economic areas.

While our target price is generated based solely on success in SCCHN, Multikine has also shown early positive indications in Phase I trials for cervical dysplasia in HIV/HPV co-infected patients and CEL-SCI has also made substantial progress in its LEAPS platform receiving a \$1.5 million grant from the NIH. We anticipate adding a valuation component for these programs as they advance further through the pipeline.

Key reasons to own CEL-SCI shares:

- **Compelling preclinical and clinical data supportive of Multikine’s effective mechanism of action**
- **Multikine is complementary to first line “intent to cure” SOC, in contrast to other monotherapies**
- **Multikine is administered prior to SOC, synchronizing with the preparation period prior to surgery**
- **Differentiated approach that employs multiple proteins for cancer cell identification & destruction**
- **Proprietary manufacturing process, patent protection and anticipated biologics exclusivity**
- **CEL-SCI maintains operation and control of its Multikine manufacturing facility**
- **Multikine source material is abundant human PBMCs**
- **Favorable drug safety profile with no reported drug-related adverse events**
- **Biologic eligible for 12 years of exclusivity in United States**
- **Global rights to intellectual property**
- **Pipeline includes LEAPS platform with additional indications**
 - **Rheumatoid Arthritis**
 - **Pandemic Flu**
 - **Breast Cancer**

In the following sections we review the immuno-oncology space and Multikine’s position in it. We also discuss related clinical data and the design of the Phase III trial, which we anticipate will provide topline data in 2019. SCCHN is reviewed along with market size and current SOC. We anticipate a BLA filing this year and a favorable response from the FDA in 2020. These positive catalysts will support capital raises sufficient to complete either internal or external commercialization of the biologic. Multikine may prove to be an excellent complement to current SOC, bringing to bear the power of the immune system to clear the body of this disease.

Immuno-Oncology

Immuno-oncology (IO), or cancer immunotherapy is an approach to fighting cancer that uses the body's own immune system to attack the disease. Normally, the body's immune system can eliminate cancer cells, but in some cases, these cells can adapt to hide. When IO drugs or biologics are administered, they allow the immune system to recognize harmful cells and destroy them, in many cases with fewer and short-lived side effects compared to surgery, chemotherapy and radiotherapy. Immunotherapy is preferred because it is frequently associated with fewer adverse events, maintains its potency, works well in conjunction with other therapies and is also able to better target the disease. Several classes of immunotherapy exist including therapeutic vaccines, checkpoint inhibitors, immune modulators, adoptive cell therapy (CAR-T), oncolytic viruses and antibody drug conjugates among others. IO can be either active or passive. Active approaches direct the immune system to kill cancer cells by targeting tumor antigens. Passive approaches augment existing tumor responses and use a variety of proteins, lymphocytes and cytokines to enhance their activity.

Multikine

Multikine, also known as Leukocyte Interleukin, Injection, can be used as an anti-cancer neo-adjuvant therapy with a broad-spectrum application for cancer, infectious disease, possibly as anti-viral therapy, or may be used in other disease states responding to immunomodulation. The biologic is CEL-SCI's lead candidate and is now in a late Phase III trial for SCCHN. It takes both an active and passive approach to boosting the immune system, which enhances its ability to mount an effective and sustainable anti-cancer response. Multikine has also completed a Phase I study for cervical dysplasia and peri-anal warts for patients co-infected with human immunodeficiency virus (HIV) and human papilloma virus (HPV). Multikine is a biological agent primarily consisting of 14 natural cytokines prepared from healthy donors' peripheral blood mononuclear cells (PBMCs). Cytokines are proteins that have abundant control over the body's immune response to an antigen. This mixture includes many of the body's natural defenses against cancer and consists of interleukins, interferons, chemokines and colony-stimulating factors. The product is mass produced, allogenic and allows the recipient's immune system to acquire specificity against their own tumor antigens when injected proximate to the tumor and draining lymph nodes of the cancer patient.

Administration of Multikine is provided prior to other cancer therapy in order to take advantage of a stronger immune system and the synergistic ability of Multikine to work with the body's innate response to cancer. Radiation, chemotherapy and surgery weaken the immune system, and leave the body less able to mount an anti-tumor response, highlighting the importance of using the biologic prior to these approaches.

Immunotherapies can be autologous or allogenic with the former using the patient's own cells and the latter using cells or therapies taken from other donors. Autologous therapies can be costly and time consuming to prepare. These approaches withdraw, modify, then re-administer a patient's own cells as the treatment and are very expensive, but present less risk of rejection. Allogenic approaches are "off-the-shelf," ready to use and can be administered rapidly and efficiently. Multikine is an allogenic approach that is being developed having both active and passive attributes, eliminating the need for external antigens as it is injected around the tumors of patients. Multikine lends itself to an allogenic approach as the isolated human cytokines do not carry any allogenic signature; therefore, they can be taken from any donor and the patient's immune system will not mount an immune response against them.

Multikine is also being investigated as a combination therapy. Many of the most promising approaches to fighting cancer use multiple agents and approaches to attack the tumor. In the case of Multikine, it is administered prior to and in conjunction with SOC.

Multikine has a novel administration protocol compared to other single and combination therapies. It is given between diagnosis and surgery, the first component of current SOC treatment. It is given for only a short time and does not delay surgery. The biologic is administered peritumorally (around the tumor) and perilymphatically (to drain into the lymph nodes) for a three week period, five days per week. The goal of Multikine's early administration is to enlist the body's immune system to eliminate the micro-metastases that are associated with its recurrence and if possible, also the tumor. In the simplest terms, Multikine enables the body's immune system to see the tumor and kill it when the immune system is strongest, prior to surgery, radiation and chemotherapy. At present, no other therapy is able to be administered in that short window of opportunity¹ and exhibit measurable anti-tumor effect. It will also be difficult for a competing product to displace SOC, as studies to prove superior efficacy would require a

¹ Checkpoint inhibitor therapy can last up to one year and CAR-T can take several months including cell processing and required recovery time.

delay in treatment and delay in treatment initiation reduces OS. Therefore, any treatment that delays the SOC will not be able to be administered before SOC since it will worsen the patient's clinical outcome.² Many of the IO drugs and therapies approved for use or in development require a much longer administration period than the three to four week window between diagnosis and surgery for newly diagnosed patients with SCCHN. No other known treatment besides Multikine can adapt to the SOC treatment protocol in this patient population.

The cytokines included in Multikine fall into three broad families: **lymphoproliferative**, to help produce and proliferate an immune response specific to the existing tumor, **chemotactic**, to draw the immune system cells to the site of the tumor and **necrotic**, to kill the tumor. These efforts combine in a concerted effort to mount an anti-tumor specific immune response to eradicate the cancerous neoplasm. Thus, this biologic consists of a broad variety of cytokines that can potentially recognize and bind to multiple receptors on both immune and cancer cells.

Multikine is sourced from normal human donors' peripheral blood mononuclear cells (PBMCs).³ The biologic has demonstrated the ability to induce CD3+ and CD25+ cell infiltration into tumor cells. It provokes T-cell migration into the tumor microenvironment and increases the ratio of CD4+ to CD8+ immune cells which infiltrate the tumor. For the Phase I and II trials, it was prepared from human PBMCs derived from source leukocyte preparations. The same product prepared in the same manner is now undergoing Phase III testing and, if approved, will be manufactured using a proprietary validated process in CEL-SCI's GMP manufacturing facility.

Multikine Mechanism of Action

Multikine is thought to be able to overcome local immunosuppression which is a hallmark of cancer. This allows the patient's immune system to activate and recognize tumor cells and trigger a response. Multikine employs the use of several key cytokines that fall into three categories: lymphoproliferative, chemotactic and necrotic, which launch a three pronged attack on the tumor. Below we list the key components:

Exhibit I - Major Cellular Products in Multikine

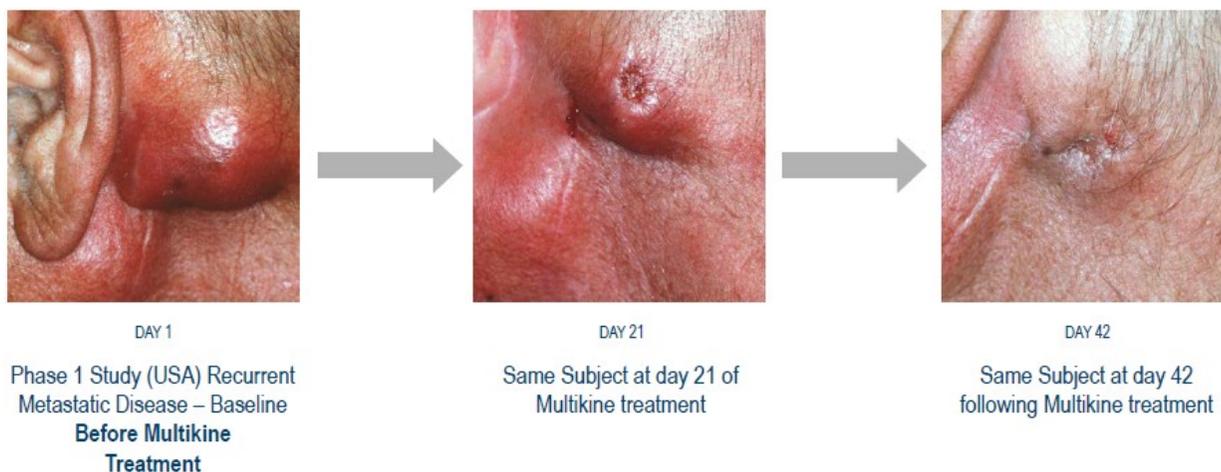
IL-1 α	IL-3	G-CSF	TNF-β	TNF-α	RANTES	IL-1β
IL-8	IL-6	IL-2	IFN-γ	MIP-1α	GM-CSF	MIP-1β

Cancer cells are able to evade the immune system using several methods such as suppressing T-cells, recruiting regulatory T-cells and myeloid-derived suppressor cells, down-regulating MHC receptors or by expressing inhibitory checkpoint molecules such as CTLA-4, PD-L1 and others. This variety of mechanisms helps the cancer thrive and gain an advantage in spite of the patient's own immune system efforts to rid the body of the cancer. To combat these methods employed by the tumor, a successful immunotherapy must challenge the cancer at multiple points in the immunity cycle and generate a variety of tumor associated antigens necessary to overcome these defenses. It is hypothesized that Multikine is able to overcome local immuno-suppression through its immunostimulatory and immunomodulatory effects. Multikine is administered in the tumor vicinity and in the draining lymph nodes where it is able to cause changes in the type of cells that infiltrate the tumor. This action modifies the tumor microenvironment and provides the tumor-infiltrating immune cells the necessary cytokines to break tolerance to tumor antigens. In turn, the immune system is able to recognize the tumor, culminating in tumor cell destruction, as can be seen by pathology examination of tumors from Multikine treated patients following the three week treatment with Multikine.

² Murphy, C. et al. Survival Impact of Increasing Time to Treatment Initiation for Patients With Head and Neck Cancer in the United States. *Journal of Clinical Oncology*, Volume 34, no. 2. January 10, 2016.

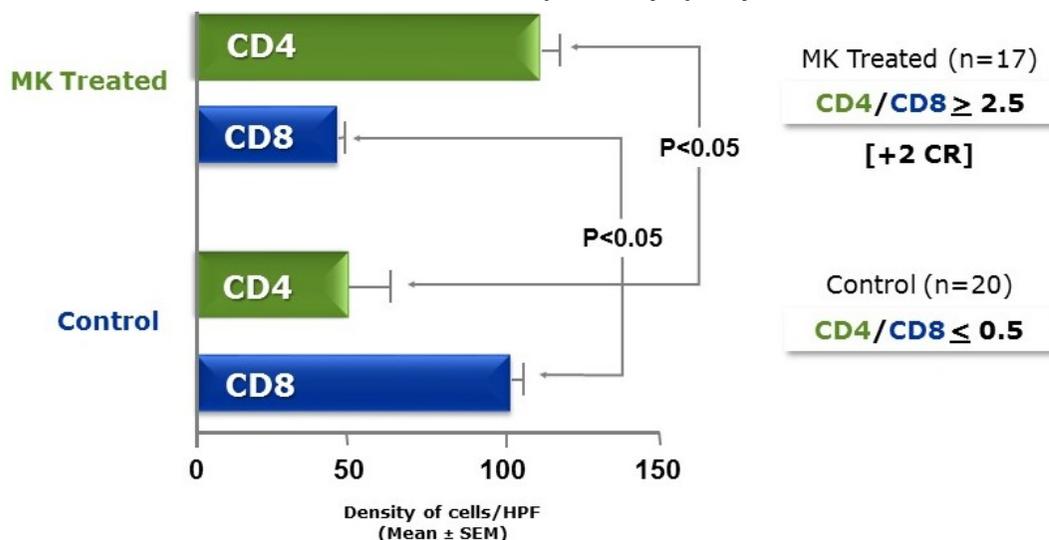
³ Timar, J. et al. Neoadjuvant Immunotherapy of Oral Squamous Cell Carcinoma Modulates Intratumoral CD4/CD8 Ratio and Tumor Microenvironment: A Multicenter Phase II Clinical Trial. *Journal of Clinical Oncology* 23, no. 15 (May 20 2005) 3421-3432.

Exhibit II – Tumor Reduction with Multikine Administration⁴



Multikine is a collection of cytokines sourced from normal human donor leukocytes. CEL-SCI hypothesizes that the unique cytokine mixture in Multikine may signal the immune system to produce an anti-tumor response. The biologic is also thought to upregulate the production of certain lymphocytes. Prior clinical studies suggest that Multikine could augment CD4+ immune cells' ability to recognize and respond to tumor antigens present on the surface of tumor cells. The CD4+ action would increase CD8+ activity. Under normal circumstances, CD8+ T cells may be less effective against tumors within the tumor microenvironment, as tumor cells are able to both block CD8+ cytotoxic cells and evade detection through various escape mechanisms including active checkpoints.

Exhibit III - Multikine Impact on Lymphocytes⁵



Additionally, Multikine may prevent cancer recurrence by stimulating the body's immune system to recognize the cancer before it can proliferate. The drug is also thought to have a chemotactic effect and draw lymphocytes toward the cancer cells. Multikine's placement in the area where metastases may develop can alert the immune system to their presence and potentially prevent tumor spread and recurrence.

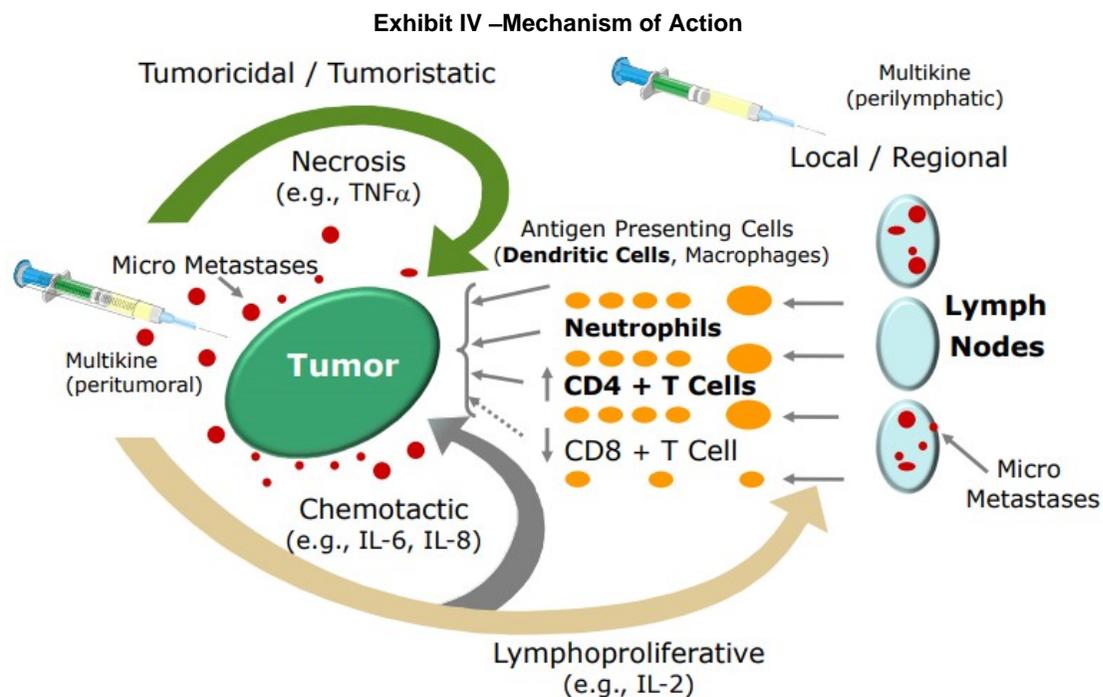
Preliminary data suggests Multikine may:

- Act on multiple receptors on both immune and cancer cells
- Act on multiple components of the immune response and on tumor cells
- Activate immune pathways necessary for destroying the tumor

⁴ Source: CEL-SCI slide deck, August 20, 2018

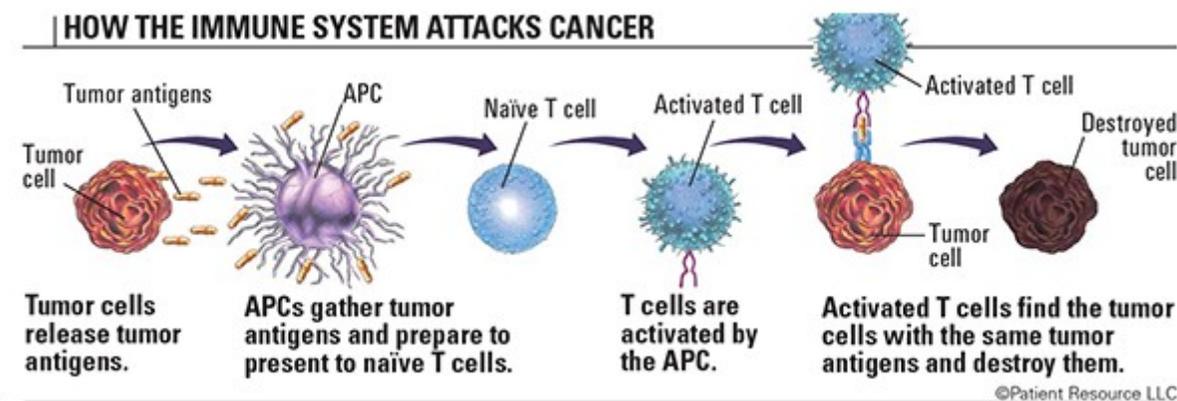
⁵ Based on: Talor et al., ASCO Annual Meeting Proceedings 22(14S): 189S, 2004 and Timar et al JCO, 2005

Below we provide visual detail illustrating Multikine's three pronged mechanism of action:



Multikine was developed in part based on understanding of the action of different cytokines in animal studies^{6,7} which demonstrated that mixed interleukins have immunomodulatory and immunostimulatory activity *in vitro*⁸, *in vivo*⁹ and in human studies. The studies demonstrated that Multikine was able to enhance natural killer cell cytotoxic activity and stimulate a cytotoxic T cell response. CEL-SCI believes that the local and regional injection of mixed interleukins such as Multikine overcomes local immuno-suppression, allowing T-cells to recognize the tumor. Subsequently, a break tolerance to tumor antigens occurs and stimulates an effective local anti-tumor immune response. This occurs through the processing of tumor associated antigens by dendritic cells, presentation of antigens to antigen-specific T cells, activation and proliferation of those T cells, and maintenance of the T cell response to support elimination of the cancer.

Exhibit V – Immune Response¹⁰



⁶ Kameda, A et al., Mixed lymphokines in low dose prolong life in cyclophosphamide-treated melanoma-bearing mice, *Int. J. Immunotherapy* 1992; 8:1-5.

⁷ Pully, M.S., et al Intravenous, Intralesional and Endolymphatic Administration of Lymphokines in Human Cancer. *Lymph.Res.* 1986; 5(1): S157-S163.

⁸ Chirigos, M.A.; et al. Leukocyte Interleukin, Inj. (LI) Augmentation of Natural Killer Cells and Cytolytic T-Lymphocytes. *Immunopharmacology and Immunotoxicology*, 17(2), 247-264 (1995).

⁹ Chirigos, M.A.; et al. Leukocyte Interleukin, Inj. (LI) Augmentation of Natural Killer Cells and Cytolytic T-Lymphocytes. *Immunopharmacology and Immunotoxicology*, 17(2), 247-264 (1995).

¹⁰ Facing Cancer – Understanding the Immune System. <https://www.sitcancer.org/patient/resources/melanoma-guide/immune-system/facing-cancer>

Research has demonstrated that interleukin delivery to the tumor region or the actual transfection of interleukin genes into a tumor markedly enhances the anti-tumor immune response resulting in tumor regression.¹¹ However, the studies did not anticipate the highly unexpected effect of inducing malignant cells into a cell cycle phase without causing the active proliferation of the tumor. This is beneficial because cells that are stuck in the cell cycle phase when the DNA is uncoiled are also more susceptible to radiotherapy and chemotherapy.

Secondary Indications for Multikine

CEL-SCI maintains a second indication for Multikine that it is developing to treat human papilloma virus (HPV) in human immunodeficiency virus (HIV) co-infected patients. HIV patients are immune-suppressed and have difficulty mounting an immune response against HPV and resultant diseases. CEL-SCI conducted a [Phase I](#) trial and demonstrated that Multikine was able to eradicate a number of HPV strains in infected women with cervical dysplasia.

A second Phase I trial for the treatment of anal warts in HIV/HPV co-infected subjects is a dose escalation study that was targeted to enroll 15 patients in two cohorts. Five patients were initially treated with a low dose of Multikine. The original protocol as submitted to [clinicaltrials.gov](#) consisted of five days of drug per week for two weeks, followed by a two-week break, then another five days of drug per week for two weeks matching the treatment regimen for the previous cervical Phase I study above. CEL-SCI stopped the study to focus its financial resources on the Phase 3 clinical trial. CEL-SCI has not announced plans for a Phase II trial for this indication.

Multikine In A Class By Itself

Multikine is not a direct competitor to other immuno-oncology agents that are focused on the SCCHN market. Other IO agents in development are focused on the metastatic and recurrent populations that have exhausted other options. The biologic occupies an enviable position in the treatment paradigm because it is able to be administered and produce its beneficial effect in the short period between diagnosis and surgery. This prevents a delay in surgery and delay is associated with lower OS.¹² When a patient is diagnosed with advanced primary SCCHN, a team of physicians are assembled and surgery is scheduled. The preparation and scheduling process takes approximately four weeks providing an opening for Multikine to engage the immune system. Multikine's unique mechanism of action can potentially eliminate micro-metastases and shrink the tumor in this month long period, improving the chance for surgery and other standard of care to be effective for the "intent-to-cure" population.

Multikine Manufacturing

Much of the work performed at CEL-SCI's manufacturing facility to develop their lead candidate is proprietary internal knowledge and does not appear in the patent literature. Details of the manufacturing process are considered a trade secret, which provides an additional level of protection that does not expire as patents and exclusivity do. The product is a complex biologic and is considered to be near impossible to copy. In broad terms, the manufacturing process separates mononuclear cells from human donor buffy coats¹³ using centrifugation, after which the cells are cultured with phytohemagglutinin (PHA) to enhance the volume of IL-2 and other cytokines secreted from the donor white blood cells. Subsequently, the culture supernatant is harvested, clarified and passed through viral removal and purification processes. The process' intermediate product is then further concentrated using various filtration methods and sterile filtered; human serum albumin is added and the solution is then buffered to a physiological pH and brought to a target IL-2 concentration. Further filtration steps are performed and the formulated product is aseptically dispensed at approx. +4° C into sterile vials stoppered and capped, and labeled by its IL-2 content.

Tests are conducted to ensure the consistency of the product by enzyme-linked immunosorbent assay (ELISA) to measure the presence of five marker cytokines: IL-2, IL-1β, GM-CSF, IFN-γ, and TNF-α, and then drug is labeled by the biological activity of IL-2. The final product is delivered in glass serum vials intended for peritumoral, intratumoral, perilymphatic or subcutaneous administration.

¹¹ Golumbek et al., "Treatment of Established Renal Cancer by Tumor Cells Engineered to Secrete Interleukin-4", *Science* 254:713-716 (1991).

¹² Murphy, C. et al. Survival Impact of Increasing Time to Treatment Initiation for Patients With Head and Neck Cancer in the United States. *Journal of Clinical Oncology*, Volume 34, no. 2. January 10, 2016.

¹³ A buffy coat is the portion of the blood column that contains leukocytes and platelets. It is usually white in color and comprises about 1% of total blood volume. https://en.wikipedia.org/wiki/Buffy_coat

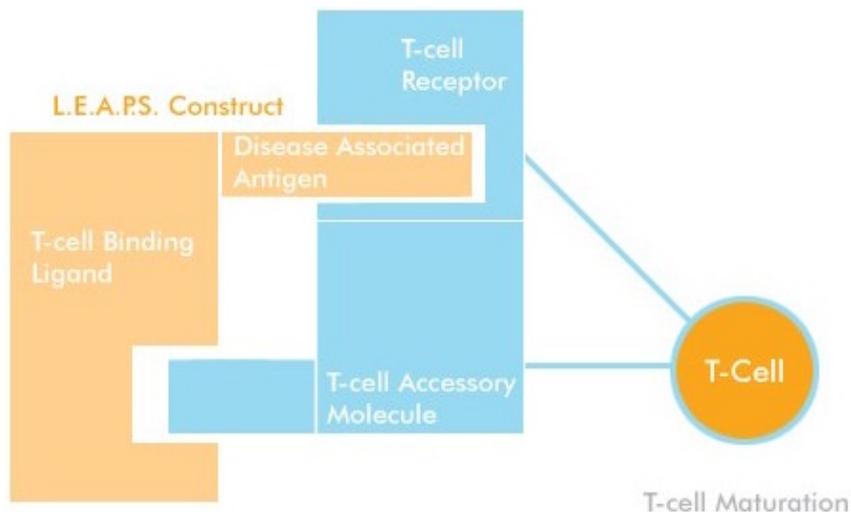
Multikine is also subjected to additional quality control tests for identity, sterility, bacterial endotoxins, pH, and total protein concentration. Each vial is inspected for particulate contamination and appearance and has a shelf life of 24 months from date of manufacture when the drug is stored at -20° Celsius.¹⁴

There is sufficient raw material supply to yield large scale Multikine production. Historically, the buffy coats (PBMCs) were discarded after fractionating blood for red- blood cells for transfusion and collecting its plasma and other component parts. According to CEL-SCI management, a single Red Cross facility near the company's manufacturing plant can yield up to approximately 1,400 buffy coats per week, and Multikine requires approximately 140 buffy coats to produce 10,000 vials of finished product. This is equivalent to over 660 treatments.¹⁵ We believe there is sufficient source material to for widespread production.

Ligand Epitope Antigen Presentation System (LEAPS)

Ligand Epitope Antigen Presentation System (LEAPS) is a T cell modulation, peptide epitope delivery system and is CEL-SCI's second therapeutic platform. The technology allows CEL-SCI to attach a disease-associated peptide immunogen to a small T cell binding peptide ligand and create a vaccine. LEAPS converts small peptides into immunogens by chemical conjugation to an immune cell binding ligand. It allows the body to develop the appropriate immune response and the peptide immunogen is key for specifically reprogramming the correct immune response.

Exhibit VI – Representation of T-cell Activation by LEAPS



The LEAPS pipeline boasts two candidates pursuing a rheumatoid arthritis (RA) indication, CEL-2000 and CEL-4000. Research suggests that CEL-4000 could be effective in cases of RA where a Th1 signature cytokine (IFN- γ) is dominant.

CEL-SCI was awarded a Small Business Innovation Research (SBIR) grant by the National Institute of Arthritis and Musculoskeletal and Skin Diseases in September 2017. The \$1.5 million grant is intended to support preclinical studies for the LEAPS peptide vaccine (CEL-4000) and its focus on rheumatoid arthritis. The study is based on research showing that the technology can reduce the severity of inflammation in experimental proteoglycan induced arthritis in animal models. Research will take place at both CEL-SCI's research facilities and the Rush University Medical Center in Chicago. About \$550,000 of the grant has been spent as of fiscal year end 2018 and we expect the remainder to be used over the next two years.

In September 2018, the National Institute of Health (NIH) selected the CEL-4000 program as a Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) Commercialization Accelerator Program Phase II awardee for 2018/2019. This award is expected to advance the technology towards clinical trials.

The LEAPS platform is also pursuing influenza, focusing on the conserved epitopes that present themselves on each of the different strains of Type A Influenza. This includes the well-known swine flu, bird flu and Spanish

¹⁴ From US patent application. 6,896,879

¹⁵ Each Multikine treatment regimen is equivalent to five administrations per week for three weeks, or 15 vials of product.

Influenza. With broad applicability, the LEAPS influenza treatment can be framed more accurately as a potential pandemic flu vaccine. While still in early pre-clinical stages, we anticipate that the LEAPS development platform will assume a more prominent role as Multikine is commercialized.

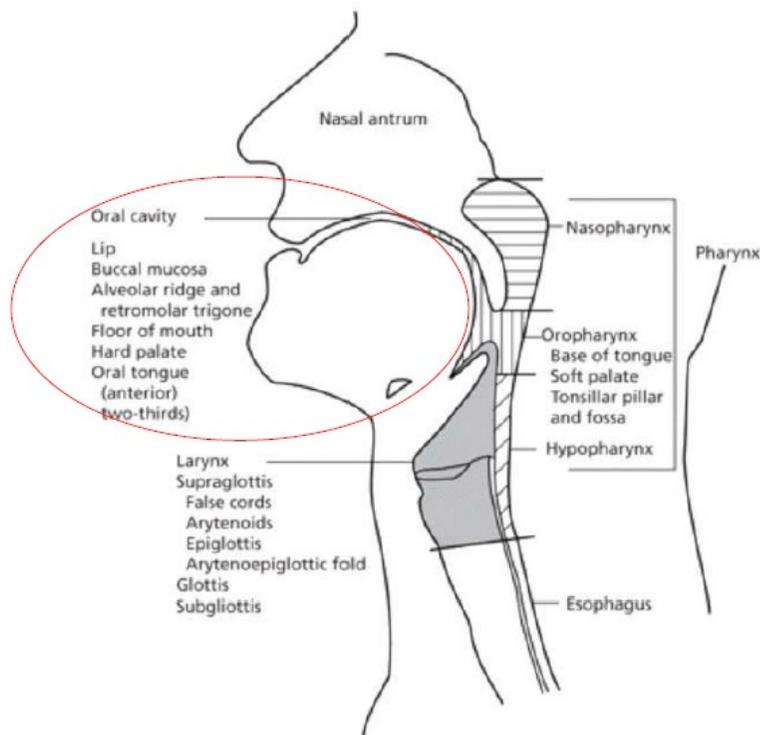
Benefits of LEAPS:

- Increased disease specificity
- Less expensive to manufacture compared to biologics
- Provide therapy earlier in the disease process
- Useful in patients not responding to current therapies

Head and Neck Cancer

Squamous cell carcinoma of the head & neck (SCCHN) is found in the tongue, mouth, soft palate, pharynx¹⁶ or other oral cavity. According to the American Cancer Society, this will represent approximately 52,000 new cases for the US in 2018. CEL-SCI has found similar prevalence with about 60,000 cases per annum in the US and 105,000 new cases per year in Europe. The World Health Organization estimates 550,000¹⁷ cases developed worldwide in 2014. It is estimated that about 4% - 6% of all cancers are in the head and neck¹⁸ and more than 90% of tumors in the head and neck are squamous cell carcinomas. It is the seventh most common cancer worldwide. The majority of current therapy for this cancer is surgery in combination with radiotherapy or surgery followed by radiation with concurrent chemotherapy. While there have been significant advances in immunotherapy made for lung cancer, melanoma, breast cancer and others common carcinomas, head and neck cancer has been left behind, creating an unmet medical need that is well aligned with Multikine’s abilities.

Exhibit VII – Locus of Head and Neck Cancer¹⁹



Contributing factors for the disease include excessive drinking, excessive smoking and a poor diet. Outside of western patient populations, other factors such as chewing betel or areca nuts, smoking bidis, and inhaling snuff are contributors. Epstein-Barr virus, one of eight known human herpesvirus types, has been implicated in nasopharyngeal carcinoma. Certain strains of HPV have also been associated with the disease and are a more common cause in young people.

¹⁶ CEL-SCI’s target does not include the pharynx given the difficulties of peritumoral injections in these sites.

¹⁷ http://www.who.int/selection_medicines/committees/expert/20/applications/HeadNeck.pdf

¹⁸ <https://www.cancer.net/cancer-types/head-and-neck-cancer/statistics>

¹⁹ Source: NCCN Guidelines / CEL-SCI Multikine Scientific Presentation

The majority of current therapy for this cancer is surgery in combination with radiotherapy or surgery followed by radiation with concurrent chemotherapy. According to cancer.net, there were 65,000 individuals who developed head and neck cancer in 2017 and just under 14,000 who died from the disease that year, with about three-quarters of them men. The long term survival rate for SCCHN is poor, especially in Stage III and IV advanced disease. The 3.5 year average survival rate for advanced (Stage III & IV) head and neck cancer is approximately 47.5%, as indicated in a survey of 55 clinical trials in primary advanced head and neck cancer.²⁰ CEL-SCI notes in its clinicaltrials.gov [record](#) a three year OS rate of between 52% and 55% and a five year OS of 43% for SOC therapy. Another set of studies that examined site specific head and neck cancer found the five year survival rate for the disease ranged from 42%²¹ to 72%,²² depending on tumor site location and disease stage. Disease Stages I and II have a better survival rate than Stages III and IV. Advanced primary, not yet treated, Stage III and IV SCCHN is the more difficult advanced primary population that CEL-SCI is targeting with Multikine.

Symptoms

Head and neck cancer presents itself as swelling in the oral cavity, nasal cavity, pharynx or larynx area and a sore that does not heal. Symptoms can also include voice changes, hoarseness, a neck mass, a sore throat that doesn't respond to an antibiotic, coughing up blood, trouble swallowing or breathing, a red or white patch in the mouth, frequent nose bleeds or unusual discharge, ear pain or trouble hearing, headaches and frequent coughing.

Diagnosis

Head and neck cancer is initially identified through a physical examination to find lumps or abnormalities, along with blood and urine tests. If the examination suggests cancer is present, then an endoscopy or imaging will be performed to confirm results. A biopsy is the best way to obtain a certain diagnosis which includes a cytologic examination. The examining physician will also seek to determine the stage of the disease and whether or not it has spread.

Treatment

SOC "intent to cure" treatment for head and neck cancer consists of surgery, radiation therapy and chemotherapy. Surgery may include laser ablation, excision, and/or lymph node dissection followed by reconstructive surgery. Radiation therapy is most commonly external-beam radiation therapy which is precisely directed at the tumor cells, reducing damage to nearby tissue. Other treatments approved only for patients unable to receive SOC include epidermal growth factor receptor (EGFR) inhibitors such as cetuximab and immunotherapy such as checkpoint inhibitors pembrolizumab and nivolumab²³ which were approved in 2016. These classes of drugs are only used when chances of survival are low and none are approved for use in patients that are destined for an "intent to cure" treatment.

There is no known direct competition for Multikine in the newly diagnosed but not yet treated advanced primary head and neck cancer patient population. This includes IO drugs such as checkpoint inhibitors and others currently on the market or in development. In these newly diagnosed "intent to cure" patients it is not acceptable to delay surgery since doing so may harm the patients. Therefore, drugs given before surgery have a treatment duration limited to three to four weeks. This is in contrast to the months of treatment required to show benefit for other immuno-oncology offerings. We highlight the rapid efficacy shown in the Phase II data in the three weeks prior to the start of SOC. While Multikine is differentiated from other therapies by its ability to show clinical impact in a three week period, it is at present the only therapy that can be used in the neoadjuvant setting for the 'intent to cure' (by SOC) cancer population.

Competing/Complementary Therapies in Development for SCCHN

There have been no approved first line therapies in SCCHN since the approval of the highly toxic methotrexate in the 1960s. The current standard of care is surgery followed by radiotherapy and chemotherapy in this therapeutic area with substantial unmet need. Many research pharmaceutical companies have recognized the unmet need in SCCHN and are exploring the use of currently approved drugs for as-yet non-approved indications and working on developing new compounds to address the disease. However, none of these focus on the advanced primary

²⁰ Inclusive dates of 55 clinical trials was from 1987 to 2007 as compiled by CEL-SCI.

²¹ Data compiled by Seattle Cancer Care Alliance from National Cancer Data Base (NCDB) including all reported cases between 2003 and 2006 for Stage IV Head & Neck Cancer.

²² cancer.net - <https://www.cancer.net/cancer-types/head-and-neck-cancer/statistics>

²³ Forster, Martin; et al. Immune Checkpoint Inhibition in Head and Neck Cancer. *Front Oncol.* 2018; 8: 310.

market that Multikine is pursuing. Below we highlight several of the key therapies that are in development. Again, we note that these are for metastatic, recurrent or unresectable SCCHN and are not direct competitors for Multikine.

Exhibit VIII – Phase III SCCHN Recruiting or Active Trials²⁴

Drug	Sponsor	Class	NCT #
Atezolizumab	Hoffmann-La Roche	Checkpoint	NCT03452137
Afatinib	Boehringer Ingelheim	Tyrosine kinase inhibitor	NCT01427478
Avelumab	Pfizer	Checkpoint	NCT02952586
Pembrolizumab	Incyte/Merck	Checkpoint	NCT03358472
Durvalumab/Tremelimumab	AstraZeneca	Checkpoints	NCT02551159
Pembrolizumab/Cisplatin	Merck (US)	Checkpoint/Chemo	NCT03040999
Nivolumab/Cetuximab	Bristol-Myers Squibb	Checkpoint/EGFR Inhibit	NCT03349710
Cetuximab	Merck (Germany)	EGFR Inhibitor	NCT02383966
Methotrexate/Afatinib	Boehringer Ingelheim	Chemo/Tyrosine kinase inhibitor	NCT01856478

Orphan Designation

Multikine was granted an orphan designation for its primary indication in SCCHN. The FDA provides special incentives for drug products developed for orphan patient populations of 200,000 or fewer or populations greater than 200,000 where it is unlikely that drug development costs can be recovered. Several benefits accrue from the award of an orphan designation including protocol assistance from the FDA, tax credits of 50% of clinical drug testing cost following approval, the opportunity for special research grants, a waiver of the application fee and seven years of exclusivity following approval. As Multikine is a biologic, it will receive 12 years of exclusivity upon approval, superseding the orphan exclusivity benefit.

Clinical Trials

Multikine Pilot, Phase I/II and Phase II Trials

A Multikine pilot study was launched in 1994 for recurrent metastatic head and neck cancer and as of today, the candidate has completed 11 different clinical trials including pilot, Phase I and Phase II studies. In the Phase I and II Studies with Multikine 224 patients have been treated, providing a useful data set for initial safety evaluation. The first study enrolled 16 patients and was conducted in the US and Canada and served as a stepping stone to a variety of other clinical work in several settings and tumor types. Other early stage clinical work included indications in pre-surgery head and neck cancer, pre-surgery prostate cancer, a UK study for a variety of cancer tumors, HIV and cervical dysplasia in HPV induced cervical cancer.

The last Phase II trial, which followed up with 19 evaluable subjects, demonstrated favorable survival and other outcomes relative to SOC. This study, which initially enrolled 21 patients, found a 33% higher overall survival (OS) rate compared to an identified control group as compiled from the scientific literature. Two subjects in this study were later found to be not evaluable for the trial as their original diagnosis for oral squamous cell carcinoma was reversed by a pathology review. The results demonstrated OS in 12 of 19 patients at 3 years 4 months from surgery, equivalent to a 63.2% rate of success. This compares to results compiled from a meta-analysis commissioned by CEL-SCI including 7,294 patients with the same disease indication, which documented a survival rate of 47.5% over a similar time period. Other observations from the Phase II reported a 50% decrease in tumor size as measured by pathology during the three week Multikine treatment prior to SOC and a 10.5% complete response.

Safety outcomes for Multikine in the Phase II trials were favorable overall as reported by the clinical investigators. Adverse events included injection site pain, local minor bleeding, injection site edema, diarrhea, headache, nausea, and constipation which were all minor in severity. No serious adverse events directly related to Multikine were reported by the investigators in any of the completed trials. In the human trials up to the latest complete Phase II, Multikine was tested in over 220 patients, providing a robust safety data set that along with preliminary efficacy results was sufficiently strong to support the launch of a Phase III trial.

²⁴ Source: clinicaltrials.gov database.

The important takeaways from the Phase II trial are the greater than 10% (2/19) complete responses achieved and 50% reduction in tumor cells in only three weeks of Multikine treatment. The high level of safety with no reported serious side effects makes a strong case for an “intent to cure” therapy.

Multikine Phase III Trial

In 2011, CEL-SCI launched its Phase III trial for patients with advanced primary squamous cell carcinoma of the oral cavity and soft palate. The pivotal Phase III trial is being conducted in the US, Canada, UK, France and 20 other countries globally. The 93-site trial is designated **IT-MATTERS** and is listed on the [clinicaltrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT01265849) site under NCT01265849. The primary endpoint for IT-MATTERS is overall survival of 10% greater than SOC alone in the defined anatomical areas of oral cavity including oral portion of the tongue, floor of mouth, cheek and soft palate.

The trial has completed enrollment of 928 newly diagnosed advanced primary, Stage III and IV patients, with the final patient enrolled in September 2016. The trial seeks to demonstrate that the local/regional injection of mixed interleukins (Multikine) with a prescribed non-chemotherapeutic regimen of cyclophosphamide, indomethacin and zinc-multivitamins (CIZ) for only three weeks prior to SOC will overcome local immunosuppression, break tumor tolerance to tumor antigens and allow for a sustainable and effective anti-tumor immune response and improve OS. The agent is injected around the tumor and near the lymph nodes prior to SOC therapy.

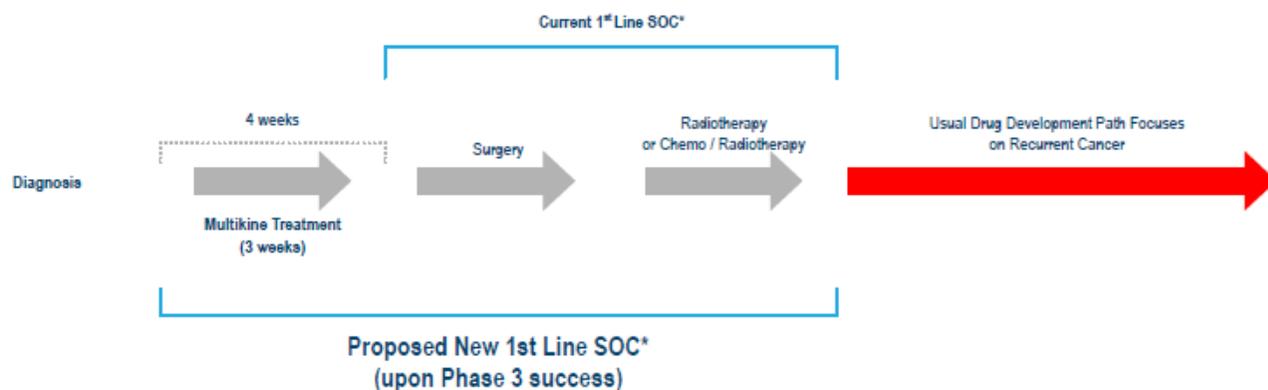
There are three arms examining squamous cell carcinoma of the oral cavity and of the soft palate; however, the CIZ-exclusion arm will be omitted for survival comparison:

- 1) Multikine plus CIZ followed by SOC
- 2) Multikine (CIZ-exclusion) followed by SOC
- 3) SOC therapy as the active comparator

The trial design calls for a 3:1:3 randomization among three groups, and the OS comparison will be made between groups one and three. The purpose of group two is to obtain information on toxicity and drug mechanism of action.

Exhibit IX - Multikine Phase III Study Design

Advanced Primary Head and Neck Cancer



The primary endpoint for the trial requires a 10% increase in OS for the Multikine plus CIZ and SOC compared to SOC only. The trial is event driven and will measure 298 deaths in the combined comparison arms prior to completion. Secondary endpoints include Local Regional Control (LRC), which measures the spread of metastases and spread of the disease outside the head and neck area, Progression Free Survival (PFS) and Quality of Life (QoL), based on the European Organization for Research and Treatment of Cancer (EORTC) QoL questionnaire.

In August 2018, the Phase III study’s Independent Data Monitoring Committee (IDMC) conducted its most recent periodic review of all 928 patients. It recommended that the study continue until all the necessary events have occurred. This was the second review by the IDMC that reviewed all 928 patients following the lifting of the clinical hold by the FDA in August of 2017. Based on current trends and historical survival rates, we anticipate that the trial will be completed in the first half of 2019.

Adverse Events

In the Phase I and Phase II trials conducted by CEL-SCI for Multikine, no serious adverse events related to the investigational drug were reported. Side effects from the administration of Multikine include pain, edema and local bleeding at the injection site, diarrhea, headache, nausea and constipation. 224 patients have participated in the completed Phase I and II Multikine trials, providing a baseline with no significant toxic effect before or after the treatment. In the Phase III IT-MATTERS trial, the IDMC reviewed the data from all 928 patients enrolled in the study and found no evidence of any significant safety questions and recommended the study continue as planned.

Manufacturing Facility

CEL-SCI designed, built and commissioned a manufacturing facility specifically for Multikine, which has been validated and has produced multiple lots of Multikine for use in the Phase III clinical trial. Construction of the facility near Baltimore, Maryland began in 2007 and plant and process validation was completed in 2010. Total space is approximately 73,000 square feet, with just under half of this area built out, providing additional capacity for growth and opportunity for manufacture of other products. Subcontracted service could be offered for products that require a cold fill and finish in temperatures of 4° Celsius; however, Multikine production is the primary role for the facility.

About \$25 million was invested in the plant and another \$80 million was spent to develop and validate the Multikine manufacturing process. The facility is both current good manufacturing practice (cGMP) and biosafety (BSL-1) CDC compliant, conforming to FDA and EU requirements for the manufacture of a sterile medicinal product. These qualifications ensure that proper design, monitoring, and control of processes and facilities is used and that biological matter is handled safely with disposal, decontamination and protective equipment in place.

Chemistry, Manufacturing and Control (CMC)

Product testing is performed both internally and externally, with the majority of this process taking place in-house. CEL-SCI has undergone periodic inspection by a Qualified Person in compliance with the European Medicines Agency, which requires product used in Phase III clinical trials to meet a similar standard as approved products do. The inspection ensured that the facility was in compliance with cGMP standards and that each batch of investigational product matches requirements of laws in force, product specification file and request for clinical trial authorization.

CEL-SCI maintains policies to ensure that its manufacturing facility is in compliance with EU and US standards at all times. As part of the BLA, the FDA will review the plant's process, controls and procedures prior to approval. CEL-SCI has passed all the Qualified Persons inspections for their facility and believes that it is in compliance with FDA and cGMP requirements. Zacks continuously highlights the importance of good practices both internally and with partners who perform manufacturing, testing, packaging, fill and finish and other services. This emphasis is justified given the risk of regulatory agency action highlighting partner oversights and focus on partner compliance in spite of a pharmaceutical product that is safe and effective.

Partners

CEL-SCI originally engaged the services of inVentiv to run its Phase III IT-MATTERS clinical trial. In 2013 CEL-SCI replaced inVentiv with two new CROs, Ergomed Clinical Research Limited and ICON Inc. Ergomed maintains a competency in orphan drug development, is based in the UK and has global coverage in Europe, Asia and the US. Ergomed is in charge of ensuring that sites are accruing and enrolling patients and generating quality data the metrics on patients. ICON is a Dublin, Ireland based contract research organization with a focus on oncology and other therapeutic areas. Ergomed is forwarding the data to ICON, who performs data analysis and control functions. This dual structure creates accountability and data integrity, which CEL-SCI values highly after their difficult experience with inVentiv.

Regarding the funding of clinical trials and eventual commercialization, the company implemented a partnership with other pharmaceutical companies. Teva Pharmaceuticals and Orient Europharma are participating as co-developers and providing funding for the Phase III trial with Multikine. In return for their contributions they will receive development rights in certain markets. If the biologic is approved, Teva has the right to license, market and distribute it for the SCCHN indication in Israel, Turkey, Serbia and Croatia. The original agreement was established in August 2008 and divides net sales equally between CEL-SCI and Teva. In November 2000, CEL-SCI and Orient Europharma obtained rights to market and distribute Multikine in Taiwan, Singapore, Malaysia, Hong Kong, the Philippines, South Korea, Australia and New Zealand for head and neck cancer, naso-pharyngeal cancer and potentially cervical cancer indications. In return for the rights, Orient will fund a portion of the clinical trial cost and

purchase Multikine from CEL-SCI for 35% of its selling price. The company has one other agreement with Byron Biopharma to market and distribute Multikine in South Africa where CEL-SCI will provide product and revenues will be split equally.

Intellectual Property

CEL-SCI has been granted numerous patents worldwide and has other patents pending for the Multikine and LEAPS platforms. Multikine is a biologic and will be granted 12 years of product exclusivity in the United States, ten years in Europe and eight in Japan following approval by the respective regulatory agencies. Given the difficulties that exist in developing biosimilars, and the confidential and unpatented know-how required in the manufacture of Multikine, it will be difficult for a competitor to develop a biosimilar after the expiration of protections. Below we summarize the most important patents owned by CEL-SCI related to composition of matter.

Exhibit X – Key CEL-SCI Patents

Compound	Title	Patent #	Region
Multikine	Method of pre-sensitizing cancer prior to treatment with radiation and/or chemotherapy and a novel cytokine mixture	6,896,879	US, Japan, China
Multikine	A method for altering the CD4/CD8 ratio and the mononuclear cellular infiltrate into a tumor	1,753,452	EU
Multikine	Procede de presensibilisation de cancers avant une radiotherapie et/ou une chimiotherapie, et nouveau melange de cytokines	1,773,368	EU
Multikine	A method for managing cholesterol with a serum-free and mitogen free cytokine mixture	1,773,395	Germany
Multikine	A method for modulating HLA Class II tumor cell surface expression with a cytokine mixture	1,879,618	EU
LEAPS	Method for inducing an immune response and formulations thereof	10,179,174	US
LEAPS	Method for inducing an immune response for treatment of cancer and autoimmune diseases or conditions	10,179,164	US
LEAPS	Peptide constructs for treating autoimmune and related diseases	7,199,216	US
LEAPS	Preparation and composition of peptides useful for treatment of autoimmune and transplant related graft versus host conditions	6,995,237	US
LEAPS	Methods of preparation and composition of peptide constructs useful for treatment of autoimmune and transplant related host versus graft conditions	7,256,254	US
LEAPS	Methods of preparation and composition of peptide constructs useful for treatment of rheumatoid arthritis	2,254,588	EU

Corporate Milestones

CEL-SCI is currently conducting Phase III trials and is expected to complete the [IT-MATTERS](#) trial in the first half of 2019. If results are favorable, we anticipate a biologic license application (BLA) to be filed with the FDA in 2020. Below we list key milestones that have occurred in the last year and anticipated events until the commercialization of Multikine.

- Multikine Phase III (IT-MATTERS) trial fully enrolled – September 2016
- Clinical hold lifted on IT-MATTERS trial – August 2017
- Arbitrator rules in favor of CEL-SCI against former CRO inVentiv – June 2018
- Anticipated completion of IT-MATTERS trial – 1H:19
- Topline readout for IT-MATTERS trial – 2H:19
- Submission of BLA to FDA – 2020
- PDUFA date for BLA submission – 2H:20
- Commercialization of Multikine - 2021

CEL-SCI History

Early Days

CEL-SCI was incubated by Maximilian de Clara at the Max Planck Institute in Germany in the 1970s. His goal was to advance the theory that the immune system could fight cancer. In 1978, de Clara began early research for Multikine and in 1983 founded the company, naming it Interleukin 2, Inc. The company was later named CEL-SCI. It went public soon after, and de Clara crossed the Atlantic to Washington D.C., close to the office of his patent attorney. Clinical trials for Multikine began in the late 1980s and England while the company operated on a shoestring budget. Manufacturing technologies advanced sufficiently by 1993 making it possible to produce the biologic in sufficient quantities to support commercialization. At this point, the company became committed to full commercial development of Multikine. It began clinical trials in 1994 and completed validation of the manufacturing process in 2001. Following an extensive period of data review and publication, Phase III trials were cleared by the FDA to begin in the United States in 2007. An orphan designation was concurrently granted and plans to begin construction on a manufacturing facility were initiated the same year. In September 2016, the FDA put the IT-MATTERS trial on clinical hold which was removed in August 2017, following a review of all 928 patients. No changes were made to the study protocol and the trial was fully enrolled by the time of the hold, minimizing the disruption to the study's progress.

Dispute with CRO and Arbitration

CEL-SCI hired Pharmanet in 2010 to manage the IT-MATTERS trial and in 2011 Pharmanet was acquired by inVentiv. Rapid enrollment was initially expected; however, as months passed, it fell far behind initial projections and the CRO was not able to achieve what it had promised over the 2011 to 2013 period. CEL-SCI subsequently replaced the CRO with two new clinical development companies, ICON and Ergomed to complete the study and filed an arbitration suit against their former CRO. In June 2018, an arbitrator made a final ruling that the former CRO had materially breached its contract with CEL-SCI and awarded CEL-SCI \$2.9 million in damages.

Recent Events

Since the resumption of the trial after the clinical hold and the resolution of the arbitration with inVentiv Health, CEL-SCI has raised additional capital to through share issuances and warrant exercises to prepare for the anticipated readout of the pivotal Phase III Multikine trial. We anticipate the trial will reach its target event objective in 1H:19.

RISKS

All investments contain an element of risk which reflects the uncertainty of the business and what it will ultimately achieve. Some investments exhibit higher predictability, with current cash flows and established sales. These enterprises will have a lower level of perceived risk while other companies that are developing an undefined, new technology have a much higher level of perceived risk.

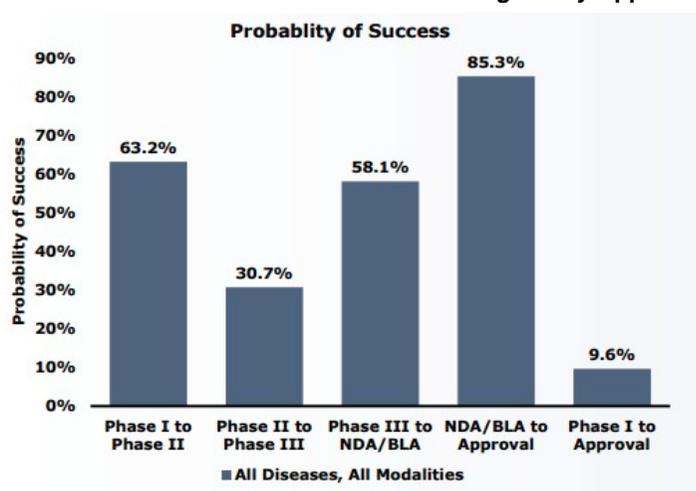
The biotechnology space includes companies at both ends of the spectrum, from mega-cap pharmaceutical powerhouses that have multiple products currently generating revenues, to small operations with a handful of employees conducting pre-clinical studies. Many of the risks faced by the large pharmaceutical companies and smaller biotechnology-focused firms are similar; however, there are some hazards that are particular to smaller companies that have not yet established themselves or their products.

For smaller early-stage companies, investing in drug development is an extended process. The timeframe for conducting pre-clinical research to eventually commercializing a drug can take from 12 to 15 years or even longer given market and company-specific conditions. And with, on average, only one in one thousand compounds eventually making it to the market from the preclinical stage, the risks are substantial.

Even if a company has a strong, experienced team that is developing a therapy with a high likelihood of success and a large addressable market, securing funding may pose a substantial risk. Access to financing comes and goes in cycles. During periods of improving confidence, capital may be easy to obtain; however, during a liquidity crisis or a period of heightened risk perception, even companies with bright prospects may be in trouble if they are dependent on the financial markets to fund their work. If capital is needed to sustain operations and it is not readily available, the company may be forced to suspend research and development, sell equity at a substantial discount to previous valuations and dilute earlier shareholders. A lack of funding may leave potentially promising therapies without a viable route to progress or force a company to accept onerous terms.

All drugs must navigate the regulatory approval process in the US, EU and other countries before commercialization in those regions. This effort is a material uncertainty which may take years depending upon the needs and desires of the determining authority. Substantial expense is undertaken to bring a molecule or compound through clinical trials and address all of the regulatory agencies' concerns. Isolating companies that have a long history of research success in drug development, with opinion leaders and experts in the field are important fundamentals that can help mitigate this risk. Companies that have had previous success with the FDA or other regulatory agencies also are more attractive than those who may be new to the process. Some accelerated pathways to approval have been put forth such as the Orphan Drug Act, however, changes in sentiment or perceived safety for pharmaceuticals drugs could change the regulatory environment to demand a more thorough process and these pathways may be extended or additional requirements may be put in place.

Exhibit XI – Success of Phased Trials and Regulatory Approval²⁵



²⁵Clinical Development Success Rates 2006-2015. David Thomas, Justin Burns, John Audette, Adam Carroll, Corey Dow-Hygelund, Michael Hay.

CEL-SCI has traversed many of the pitfalls of the drug development process and is now in the late stages of a Phase III trial for its lead candidate. The company plans to submit a BLA to the FDA following the generation of favorable data from its trial. Despite success in a Phase III trial, approval is not guaranteed and complete response letters (CRLs) and delays to originally anticipated timelines and issued PDUFA dates are common. CEL-SCI may also commercialize Multikine which will require the hiring and training of a salesforce to market the biologic to appropriate audiences. These are all high risk endeavors and many precedents of failures exist despite the best efforts of management teams and their employees.

In recent years, contract research organizations (CROs) have taken on a larger role in the development of drug candidates as the complexity and cost of trials has increased. Finding appropriate populations to participate in clinical trials has become increasingly difficult due to the shift to personalized medicine and orphan indications that address only a small group of patients. This shift has increased the dependence on these specialized CROs for project management and clinical monitoring services which add additional risks and dependence on third parties.

CEL-SCI relies on two CROs to conduct its clinical trials. CROs may have multiple competing projects that are vying for limited resources which can limit their success compared to initial expectations. Small drug development companies are extremely reliant on the hard work and professionalism of their CRO partners and many times a sponsor's success or failure can rest on the efforts of this partner.

CEL-SCI maintains its own manufacturing facility and will require FDA approval of its processes and adherence to cGMP. Risks of poor manufacturing processes, quality control issues and product delays may postpone ultimate production of a drug if facilities are out of compliance with regulatory agency requirements. CEL-SCI has developed an internal system to ensure good practices and conformance to guidelines. Despite these efforts, regulatory agencies may identify discrepancies and as a result delay or halt production of a product in the approval process or one that has already been approved.

Drug price inflation has gained increased attention over the last several years and has contributed materially to the increase in health care costs over the last decades. As new therapies have been approved, drug prices have set new records and increased at a substantial rate. For example, in 1996, new cancer drugs cost roughly \$54,000 for each additional year of life they provided. However, by 2013, this amount increased to over \$200,000. The inflation rate for established drugs has also been very high. In a Forbes article, an author highlighted Novartis' leukemia drug Gleevec. This drug cost \$24,000 in 2001 when it was first approved; and 14 years later, in 2015, had risen to a cost of \$90,000. This represents a 10% compound annual growth rate over that period. Other price moves such as the 5,000% price hike for Turing Pharmaceutical's Daraprim and Valeant Pharmaceuticals 500% and 200% price increase for Isuprel and Nitropress combined with similar moves by other companies may create a situation where further increases are unsustainable. We also cite the broad response to Mylan's (NASDAQ: MYL) EpiPen price increases which have pressured the company to offer lower priced alternatives and brought a number of competitors into the market.

We highlight several risks that come from these pricing increases. Health care may become unaffordable for a broad segment of the population, reducing the market size to a level below current expectations. Pharmacy benefit managers and other third party payers may continue to remove drugs from their formularies due to price concerns and sharp price increases will attract the attention of elected officials and regulators who may create legislation and implement regulations that limit drug profitability. Additionally, the government may impose additional non-price related regulation and disclosure requirements that can increase costs for the industry.

While we have discussed a broad variety of risks above, we believe that our forecast parameters, discount rates, success probabilities and valuation metrics address these eventualities and our target price reflects an assumption of these risks faced by all biotechnology companies.

COMPETITORS AND COMPETING THERAPIES

There are many participants in the cancer immunotherapy space with a variety of approaches to IO from all over the globe including checkpoint inhibitors, CAR-T, oncolytic viruses, antibody drug conjugates and cancer vaccines to name a few. None of these other treatments can be used in the advanced primary disease patient population that is destined for the “intent to cure” treatment, having surgical resection of the tumor and any associated lymph nodes as the initial segment of the current SOC. The neo-adjuvant administration of IO presents a narrow three week window for treatment, which can only be addressed by CEL-SCI’s Multikine.

Below, we highlight several of the key companies that are developing cancer immunotherapies in adjacent spaces to CEL-SCI. This list is not exhaustive and only represents a cross section of the immunotherapy companies contributing to the space.

There are no other companies that we have come across that are developing a first line treatment for SCCHN that can complement SOC, making CEL-SCI unique. Some IO agents, such as checkpoints are approved or in clinical trials for second line treatment and therapy for recurrent or metastatic head and neck cancer patients, or those who are not candidates for surgery. These IOs cannot be used in the first line, “intent to cure” population. We also highlight the importance of not delaying SOC,²⁶ which makes it difficult to conduct clinical trials using alternative therapy that would defer or replace SOC.

Exhibit XII – Peers and Competitors²⁷

Ticker	Company	Price	MktCap (MM)	EV (MM)	Therapeutic Area
NVS	Novartis AG	\$85.67	\$198,377	\$217,340	IO: PD1/PDL1,CRISPR,Ab drug conjugates (ADC)
MRK	Merck & Co	\$73.37	\$190,790	\$204,110	IO: PD1/PDL1
GILD	Gilead Sciences	\$69.83	\$90,330	\$86,830	IO: CAR-T, anti-BCMA, BTK Inhibit, PI3K inhibitor
BMY	Bristol-Myers	\$48.86	\$79,760	\$79,450	IO: CTLA4,PD1/PDL1, LAG3, PEG-IL2, IDO Inhibit
AZN	AstraZeneca	\$35.95	\$90,330	\$108,910	IO: PD1/L1,CTLA4,CD22,BTK,EGFR,PARP&MET Inhibit
SGEN	Seattle Genetics	\$75.13	\$12,030	\$11,190	Ab drug conjugate (ADC),sugar engineered Ab (SEA)
BLUE	Bluebird Bio	\$130.16	\$7,120	\$5,210	IO: CAR-T
NKTR	Nektar Therapeutics	\$43.10	\$7,460	\$6,180	IO: Topo I inhibitor, CD122 agonist, PEGPH20.
ADRO	Aduro Biotech	\$2.72	\$216	(\$70)	IO: STING, APRIL (Checkpoint inhibit), anti-CD27
AGEN	Agenus Inc	\$3.48	\$456	\$386	IO: vaccine, checkpoints, bi-specifics
IMV	Immunovaccine Inc	\$5.78	\$260	\$252	IO: T-cell therapy
NLNK	NewLink Genetics	\$1.45	\$54	(\$71)	IDO Inhibitor
ADXS	Advaxis	\$0.34	\$24	(\$18)	IO: Lm delivery platform
CLDX	Celldex Therapeutics	\$0.41	\$71	(\$46)	IO: anti-CD27, Flt3L, CD135, ErbB3
BAVA	Barvarian Nordic A/S	DKK 149	DKK 4,800	DKK 3,000	IO: Ab targeting CEA & MUC1, vaccines
OXB.L	Oxford Biomedica plc.	£6.83	£451	£439	Cancer IO
INO	Inovio Pharmaceuticals	\$5.04	\$481	\$401	Cancer IO/Infectious Disease
CLRB	Cellectar Biosciences	\$2.02	\$10	(\$3)	Oncology: phospholipid drug conjugate
TROV	TrovaGene Oncology	\$0.70	\$16	(\$2)	Oncology: PLK1 Inhibitor
HTBX	Heat Biologics	\$1.41	\$46	\$9	Oncology: T cell activation/stimulation
SNGX	Soligenix	\$0.90	\$16	\$5	Various cancer indications & vaccine platform
TNG.PA	Transgene	€ 2.83	€ 176	€ 204	Cancer IO, Oncolytic Viruses
pvt	INmuneBIO				Oncology: NK Cell/MDSC Inhibition
pvt	Checkmate Pharma				Cancer IO - TLR9 agonist
CVM	CEL-SCI Corporation	\$2.85	\$83.4	\$81.1	IO: Multikine/cytokines

²⁶ Delaying treatment for SCCHN by six to eight weeks is associated with an increased risk of death. The analysis showed that delaying treatment by 60 days was “most consistently detrimental.” Murphy, C. et al. Survival Impact of Increasing Time to Treatment Initiation for Patients With Head and Neck Cancer in the United States. Journal of Clinical Oncology, Volume 34, no. 2. January 10, 2016.

²⁷ Price and market capitalization data is as of January 30, 2019.

MANAGEMENT PROFILES

Geert Kersten, Director and Chief Executive Officer

Mr. Kersten has served in his current leadership role at CEL-SCI since 1995. Mr. Kersten joined CEL-SCI in 1987 as head of investor relations and advanced through the ranks in successive years. He has been involved in the pioneering field of cancer immunotherapy for almost two decades and has successfully navigated CEL-SCI through many challenging cycles in the biotechnology industry.

Mr. Kersten also provides CEL-SCI with significant expertise in the fields of finance and law and has a unique vision of how the company's Multikine product will change the way cancer is treated. Prior to CEL-SCI, Mr. Kersten worked at the law firm of Finley & Kumble and worked at Source Capital, an investment banking firm located in McLean, VA. He is a native of Germany and completed his studies in the US. Mr. Kersten completed his Undergraduate Degree in Accounting, received an M.B.A. from George Washington University, and a law degree (J.D.) from American University in Washington, DC. Mr. Kersten is also the inventor of a patent on the potential use of Multikine in managing cholesterol.

Eyal Talor, Ph.D., Chief Scientific Officer

Dr. Talor joined CEL-SCI in October 1993. In October 2009, Dr. Talor was promoted to Chief Scientific Officer. Prior to this promotion, Dr. Talor was the Senior Vice President of Research and Manufacturing. He is a clinical immunologist with over 25 years of hands-on management of clinical research and drug development for immunotherapy application; pre-clinical to Phase III, in the biopharmaceutical industry. His expertise includes; biopharmaceutical R&D and Biologics product development, GMP (Good Manufacturing Practices) manufacture, Quality Control testing, and the design and building of GMP manufacturing and testing facilities. He served as Director of Clinical Laboratories (certified by the State of Maryland) and has experience in the design of clinical trials (Phase I - III) and GCP (Good Clinical Practices) requirements. He also has broad experience in the different aspects of biological assay development, analytical methods validation, raw material specifications, and QC (Quality Control) tests development under FDA/GMP, USP, and ICH guidelines. He has extensive experience in the preparation of documentation for IND and other regulatory submissions. His scientific area of expertise encompasses immune response assessment. He is the author of over 29 publications and has published a number of reviews on immune regulations in relation to clinical immunology. Before coming to CEL-SCI, he was Director of R&D and Clinical Development at CBL, Inc., Principal Scientist - Project Director, and Clinical Laboratory Director at SRA Technologies, Inc. Prior to that he was a full-time faculty member at The Johns Hopkins University, Medical Institutions; School of Public Health. He has invented technologies which are covered by four US patents; one on Multikine's composition of matter and method of use in cancer, and one on a platform Peptide technology ('Adapt') for the treatment of autoimmune diseases, asthma, allergy, and transplantation rejection and 2 on LEAPS technology. He also has 4 other issued patents relating to Multikine for a combined total of 10 patents (from the US, EU, China and Japan). He also is responsible for numerous product and process inventions as well as a number of pending US and PCT patent applications. He received his Ph.D. in Microbiology and Immunology from the University of Ottawa, Ottawa, Ontario, Canada, and had post-doctoral training in clinical and cellular immunology at The Johns Hopkins University, Baltimore, Maryland, USA. He holds an Adjunct Associate teaching position at the Johns Hopkins University Medical Institutions.

Patricia B. Prichep, Senior Vice President of Operations

Ms. Prichep has over 30 years' experience in business operations and administration. She joined CEL-SCI in 1992 and has been CEL-SCI's Senior Vice President of Operations since March 1994. Between December 1992 and March 1994, Ms. Prichep was CEL-SCI's Director of Operations. Ms. Prichep became CEL-SCI's Corporate Secretary in May 2000. She is responsible for all day-to-day operations of the Company, including human resources and is the liaison with the auditing firm for financial reporting. June 1990 to December 1992, Ms. Prichep was the Manager of Quality and Productivity for the NASD's Management, Systems and Support Department. She was responsible for the internal auditing and work flow analysis of operations. Between 1982 and 1990, Ms. Prichep was Vice President and Operations Manager for Source Capital, Ltd. She handled all operations and compliance for the company and was licensed as a securities broker. Ms. Prichep received her B.A. from the University of Bridgeport in Connecticut.

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

Dr. Zimmerman is the head of the LEAPS technology program. He has invented technologies which are covered by over a dozen US patents as well as many foreign equivalent patents. He is the author of over 40 scientific publications in the area of immunology and infectious diseases. He has been awarded numerous grants from NIH and DOD. From 1969-1973, Dr. Zimmerman was a Senior Staff Fellow at NIH. For the following 25 years, he continued on at NIH as a guest worker. Dr Zimmerman received a Ph.D. in Biochemistry in 1969, a Masters in Zoology in 1966 from the University of Florida and a B.S. in Biology from Emory and Henry College in 1963.

John Cipriano, Senior Vice President of Regulatory Affairs

Mr. Cipriano brings to CEL-SCI over 30 years of experience in both biotech and pharmaceutical companies. In addition, he held positions at the United States Food and Drug Administration (FDA) as Deputy Director, Division of Biologics Investigational New Drugs, Office of Biologics Research and Review and was the Deputy Director, IND Branch, Division of Biologics Evaluation, Office of Biologics for 17 years, prior to his industry experience. Mr. Cipriano completed his B.S. in Pharmacy from the Massachusetts College of Pharmacy in Boston, Massachusetts. He received his M.S. in Pharmaceutical Chemistry from Purdue University in West Lafayette, Indiana, and holds a Registered Pharmacist license.

William "Brooke" Jones, Vice President of Quality Assurance

Mr. Jones has been with CEL-SCI since 1999 and has overall responsibility for Quality Assurance. Mr. Jones began his career in biotechnology in 1978 at the Fort Detrick, NCI-Frederick Cancer Research Center where he was responsible for GMP compliance of fermentation-based, clinical trial drug products used by the National Cancer Institute. With nearly 30 years of management experience in biotechnology at companies such as Biogen and Novartis, Mr. Jones brings significant American and European experience in the areas of Quality, Regulatory and Validation. In addition to his responsibilities at Novartis in the US, Mr. Jones was also the Director of Quality Control and Quality Assurance at the Systemix facility in Lyon, France, where he was involved in developing cell therapy-based clinical trial products derived from the hematopoietic stem cell. Mr. Jones completed his Undergraduate degree in Biology at George Mason University and his Graduate Degree course work in Environmental Biology at Hood College.

Todd Burkhart, Vice President of Manufacturing

Mr. Burkhart joined CEL-SCI Corporation as Vice President of Manufacturing/Facilities and Commercial Operations in January 2010. Mr. Burkhart has over 30 years of experience in the manufacture and process development of biologicals, medical devices and other active pharmaceutical ingredients (APIs). During his career in the pharmaceutical and biopharmaceutical industry and prior to joining CEL-SCI, Mr. Burkhart has been responsible for all aspects of GMP manufacturing and operations including production, materials controls and facilities maintenance. In addition he has extensive experience in the design of manufacturing facilities meeting FDA GMP requirements. Mr. Burkhart has also been involved in the building and/or running a number of major pharmaceutical facilities at companies such as Cephalon, Human Genome Sciences and Univax Biologics. Mr. Burkhart received his B.S. in Biology from Tusculum College, Greeneville, TN.

Financial Results

CEL-SCI announced full year fiscal 2018 results on December 20, 2018 following the filing of their Form 10-K the day before. The company entered the year with its IT-MATTERS trial fully enrolled with 928 patients, and the recent receipt of a \$1.5 million grant to develop LEAPS for rheumatoid arthritis. The company had also recently concluded the testimony phase of the arbitration with their former CRO. As 2018 progressed, CEL-SCI reported a patent award for LEAPS in the EU, participated in various investor conferences and raised additional capital as the Multikine trial reaches the final stretch.

The most important news of the year arrived in July, when the arbitrator announced a ruling favorable to CEL-SCI and awarded them \$2.9 million in damages. The settlement removed an overhang on the company and cleared the way for management to focus on completing the IT-MATTERS trial for Multikine.

Total revenue, which represented grants related to LEAPS development, was \$476 thousand for the year, compared to nothing in the prior year. Total operating expenses were \$17.2 million, representing a 19% decline vs. the prior year. Research and development fell 40% to \$9.4 million. The decline stemmed from the maturation of the IT-MATTERS trial as clinical trial costs tend to be lower following the enrollment phase and during the last stages of the study. General and administrative costs were up 35% to \$7.8 million, primarily due to higher employee compensation costs related to milestone achievement and greater public relations costs.

The balance sheet held \$10.3 million in cash and equivalents and no debt as of September 30, reflecting a capital raise from share issuance and warrant exercise in the fourth quarter. Cash burn for fiscal year 2018 was (\$13.4) million compared to (\$13.8) million in FY:17. Cash generated from financing was \$21.4 million for the year increasing from \$13.3 million in FY:17.

VALUATION

CEL-SCI's lead candidate, Multikine, is a cancer immunotherapy developed using collection of cytokines sourced from normal human donor leukocytes. The therapy is used prior to and in conjunction with SOC. It appears that the unique cytokine mixture in Multikine may signal the immune system to produce an anti-tumor response. In numerous Phase II trials, Multikine + SOC has shown improved OS compared to SOC alone.

Multikine's lead indication is for advanced primary SCCHN, which can pursue a market of near 60,000 persons per year in the United States and 650,000 globally. CEL-SCI's pipeline is also augmented by a second Multikine indication in Phase I and the LEAPS platform, which is in the preclinical stage. We anticipate a read out of the SCCHN trial in 1H:19, at which time we will update our valuation based on the strength of the data. Our valuation is exclusively focused on the SCCHN indication and will add other pipeline candidates as they move closer towards approval.

CEL-SCI has not provided guidance on timing for the completion of the IT-MATTERS trial, nor have they given an indication of when topline might be available. However, based on historical event rates, we anticipate a first half 2019 completion and a second half 2019 topline readout after which we anticipate CEL-SCI will efficiently prepare and file a BLA with the FDA. We anticipate a favorable response in late 2020, assuming no CRL is issued, and an early 2021 US launch of Multikine. While CEL-SCI has accumulated a few partners that cover a very small geography, it has made no commitment to either develop its own salesforce or work with a partner to commercialize the approved product.

For simplicity, we assume that CEL-SCI assigns the rights to commercialization to a global partner who will commercialize Multikine in the US and Europe. Our model assumes a 2021 launch in the United States and a 2022 launch in the EU, following EMA approval. We forecast conservative pricing of \$120,000 per treatment in the US. While many IO treatments now are listed well above \$150,000 per treatment, we anticipate pushback from payors against expensive cancer treatments as they become more common. Pricing will also depend on Multikine's results for OS and its safety profile, which could propel reasonable pricing higher than our estimate. We assume a 50% discount to the realized price assumption in the EU.

In 2019, the American Cancer Society forecasts 53,000 cases of head and neck cancer per in the US. 90% of these cases will be squamous cell and two thirds of these cases will be advanced primary disease yielding an addressable market of approximately 32,000 persons per year. Our model anticipates 10% penetration into this addressable market in the first full year of commercialization, increasing to 40% over the next five years. After 2030, we anticipate increased competition and a decline in market share over the succeeding years. We also assume modest population growth and inflation in treatment cost, which yields a peak of near \$2.2 billion in Multikine revenues by 2030 in the US.

Based on head and neck incidence rates in the US applied to the population of the EU we anticipate about 83,000 cases to occur in the European Union per year in 2019. Assuming the same 90% rate of squamous cell carcinoma and 67% rate of advanced primary disease, we anticipate an addressable market of about 50,000 in the EU. We follow a similar penetration and growth rate in the EU as we do in the US, anticipating 10% share in the first full year of commercialization, rising to 40% by 2028. Using these assumptions we achieve peak sales of \$1.75 billion in 2031.

CEL-SCI is keeping its options open with respect to further partnerships and it is not clear whether or not they will commercialize using an internally developed team or enter into a global partnership with an established pharmaceutical company. We see many strong arguments in favor of working with a partner that has an established salesforce, durable relationships and a well-functioning distribution system already in place. We build our revenue model assuming that an approved Phase III asset will be able to secure a 30% royalty from the commercializing entity to CEL-SCI. We see the ownership of an approved manufacturing facility dedicated to Multikine as a valuable asset that provides additional negotiating strength. While we anticipate the normal licensing structure of upfront payment, royalty and milestones, for simplicity we have assumed all value from the arrangement is represented by the royalty payment.

R&D and administrative expenses are anticipated to be ~\$14.5 million in 2019 and fall slightly to \$13.4 million in 2020, as the FDA considers Multikine for approval. After the launch in the US and EU, we reduce R&D expenses to zero and G&A to \$5 million per year. These numbers will be updated when CEL-SCI announces a new program and increases in R&D will be associated with related revenues. Taxes, which will be paid after the company works

through its NOLs, are anticipated to be 30%, in a mix of US federal and state rates. This includes a 21% rate for federal taxes, a 5% rate for state taxes and an additional 4% to reflect tax increases that reflect reversals to deficit spending or shift of tax burden to states.

Our target price is generated using forecasts over the next 20 years after which we assume a terminal growth rate of 2%. We anticipate that some as yet unidentified alternate therapy will begin to compete with Multikine after 10 years on the market due to the substantial amount of research that is being done in this space and the accelerating pace at which new therapies are being proven. Therefore we begin to reduce penetration rates for Multikine in 2030. Assuming a 2020 approval by the FDA, biologic exclusivity for Multikine will expire in 2032, however, due to innovation and the difficulties in creating biosimilars, we do not anticipate a material impact from this expiration. We use a discount rate of 15% in our NPV model and apply a 50% probability of FDA approval and ultimate commercialization based on the guidance provided in the Biomedtracker analysis.²⁸

Despite the conservative stance of our assumptions, margins can potentially be very high if Multikine is developed internally. We estimate that gross margins can be approximately 90% and that in the United States, CEL-SCI could potentially commercialize the biologic with an internal salesforce of 30 individuals. We believe that a salesforce of this size would be sufficient to address the 1,600 surgeons that CEL-SCI has identified as the market for Multikine and could cost about \$10 million, plus a few million more for sales-based bonuses. Fixed G&A to support this operation could reasonably be \$16 million or less resulting in operating margins of over 80% for sales above \$500 million. While we believe a global pharma could achieve higher penetration than CEL-SCI, there is substantial potential if developed internally. This leverage also gives CEL-SCI a strong negotiating position if the company finds an interested buyer.

We also examine recent merger and acquisition activity to identify transaction prices that have been paid for companies with promising oncology drugs and platforms. The selection below includes a small sampling of companies acquired with a variety of products and platforms of different stages of development and commercialization in their portfolio. Despite the lack of precise comparability, if Multikine is approved and LEAPS is able to enter the clinic, we think CEL-SCI could be acquired at values in the range of the oncology companies below.

Exhibit XIII – Comparable Transactions in Oncology Space

Target	Buyer	Date	EV (MM)	Drug/Platform
Loxo Oncology	Eli Lilly	7-Jan-19	\$6,550	Viktravi/RET, TRK & BTK Inhibitors
Stemcentrix	AbbVie	28-Apr-16	\$5,800	Antibody Drug Conjugate
Medivation	Pfizer	22-Aug-16	\$14,000	Xtandi, talazoparib, pidilizumab
Pharmacyclics	AbbVie	4-Mar-15	\$21,000	ibrutinib
Celator Pharma	Jazz Pharma	31-May-16	\$1,500	Liposome for injection
Tesaro	GlaxoSmithKline	3-Dec-17	\$5,100	Zejula, PARP Inhibitor

We note that the determinant for many of the variables in our model will be the ultimate safety and efficacy profile as demonstrated in the IT-MATTERS trial. If OS is substantially better than the 10% hurdle identified in the primary endpoint, this argues for greater pricing power, higher penetration and greater demand from a potential acquirer. We will update our model accordingly when data from the trial is made available.

Based on the assumptions identified in our discounted cash flow model above and after adjusting for anticipated share issuance, restricted stock and options outstanding, we generate a target price of \$14.00.

²⁸ Clinical Development Success Rates 2006-2015. David W. Thomas, Justin Burns, John Audette, Adam Carroll, Corey Dow-Hygelund, Michael Hay.

CONCLUSION

Multikine has shown efficacy and impressive safety in a number of clinical trials including several Phase II studies. The cytokine mixture has shown early efficacy helping the immune system recognize tumor cells and improve the body's immune profile before the patient receives SOC. In contrast to other immunotherapies in development, Multikine does not require the delay of SOC and is complementary to it. With a substantial unmet need in a debilitating and disfiguring indication and a product that has a strong record of safety in over 200 patients that have been treated in completed trials, Multikine maintains an enviable position for market entry. Despite a number of other IO products in the clinic, none of them are targeting the advanced primary "intent-to-cure" population, which comprises two-thirds of initially diagnosed SCCHN patients. Based on historical event rates in SCCHN and the timing of enrollments, we anticipate the end of the Phase III trial to occur in 1H:19, following by a topline readout and subsequent filing of a BLA. SCCHN is the seventh most common cancer in the United States and Multikine has potential efficacy in additional indications as well, providing a material and potentially large market to penetrate. Based on the lack of alternative therapies and the unmet need, Multikine is in a strong position with physicians to become part of a new standard of care and with payors to be properly reimbursed.

Key reasons to own CEL-SCI shares:

- **Compelling preclinical and clinical data supportive of Multikine's effective mechanism of action**
- **Multikine is complementary to first line "intent to cure" SOC, in contrast to other monotherapies**
- **Multikine is administered prior to SOC, synchronizing with the preparation period prior to surgery**
- **Differentiated approach that employs multiple proteins for cancer cell identification & destruction**
- **Proprietary manufacturing process, patent protection and anticipated biologics exclusivity**
- **CEL-SCI maintains operation and control of its Multikine manufacturing facility**
- **Multikine source material is abundant human PBMCs**
- **Favorable drug safety profile with no reported drug-related adverse events**
- **Biologic eligible for 12 years of exclusivity in United States**
- **Global rights to intellectual property**
- **Pipeline includes LEAPS platform with additional indications**
 - **Rheumatoid Arthritis**
 - **Pandemic Flu**
 - **Breast Cancer**

In summary, we believe that if Multikine is able to achieve its primary endpoint of 10% improvement in overall survival, the shares are undervalued relative to their potential. While our valuation only accounts for sales of Multikine for an indication in advanced primary SCCHN, the biologic may address other cancer and immunodeficient diseases as well. CEL-SCI also is developing its LEAPS technology which provides another platform for creating value which we expect will enter the clinic following initial commercialization of Multikine. Based on our analysis and forecasts, we initiate CEL-SCI with a target price of \$14.00.

PROJECTED FINANCIALS

CEL-SCI Corporation - Income Statement

CELSCI Corporation	2017 A	Q1 A	Q2 A	Q3 A	Q4 A	2018 A	2019 E	2020 E
Total Revenues	\$0.1	\$0.1	\$0.1	\$0.1	\$0.1	\$0.5	\$0.4	\$0.4
<i>YOY Growth</i>		560%	668%	499%	636%	590%	-16%	0%
Research & Development	\$15.6	\$2.3	\$3.0	\$2.4	\$1.7	\$9.4	\$7.1	\$6.0
General & Administrative	\$5.8	\$2.7	\$1.4	\$1.7	\$2.0	\$7.8	\$7.8	\$7.8
Income from operations	(\$21.3)	(\$4.9)	(\$4.2)	(\$4.1)	(\$3.6)	(\$16.8)	(\$14.5)	(\$13.4)
Other Income	\$11.0	(\$1.0)	\$1.2	(\$0.0)	(\$8.8)	(\$8.6)	\$0.0	\$0.0
Interest Expense	(\$4.0)	(\$0.3)	(\$1.7)	(\$1.9)	(\$2.6)	(\$6.5)	\$0.0	\$0.0
Pre-Tax Income	(\$14.4)	(\$6.2)	(\$4.7)	(\$6.0)	(\$14.9)	(\$31.8)	(\$14.5)	(\$13.4)
Provision for Income Tax	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
<i>Tax Rate</i>	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Net Income	(\$14.4)	(\$6.2)	(\$4.7)	(\$6.0)	(\$14.9)	(\$31.8)	(\$14.5)	(\$13.4)
<i>Net Margin</i>								
Reported EPS	(\$1.82)	(\$0.53)	(\$0.31)	(\$0.36)	(\$0.61)	(\$1.87)	(\$0.42)	(\$0.27)
<i>YOY Growth</i>								
Basic Shares Outstanding	7.90	11.64	15.21	16.65	24.52	17.00	34.50	50.00

Source: Company Filing // Zacks Investment Research, Inc. Estimates

HISTORICAL STOCK PRICE

CEL-SCI Corporation – Share Price Chart



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