**CEL-SCI Corporation** 

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# **Company Overview**

CEL-SCI is a Phase 3 cancer immunotherapy company. When it comes to cancer immunotherapy, CEL-SCI believes that boosting a patient's immune system while it is still intact should provide the greatest possible impact on survival. Therefore, in the Phase 3 clinical trial CEL-SCI treats patients who are newly diagnosed with cancer with its lead investigational immunotherapy Multikine right after diagnosis, **before** they have received surgery, radiation and/or chemotherapy. This approach is unique. Most other cancer immunotherapies are used only after conventional therapies have been tried or failed. CEL-SCI finished enrolling 928 patients in its pivotal Phase 3 head and neck cancer study in September 2016. The hope is that Multikine will either increase the cure rate of the patients or delay the time to recurrence. The study will end when 298 events (deaths) have occurred. That was expected to have occurred in 2018, but we are still waiting for the required number of events. Head and neck cancer is a multi-billion dollar global market representing about 6% of all cancers and an unmet medical need. Multikine has received Orphan Drug designation from the FDA for this indication. CEL-SCI is also developing a novel vaccine for the treatment of rheumatoid arthritis using its investigational platform technology LEAPS and received a \$1.5 M grant from the NIH.

#### **RECENT & UPCOMING CATALYSTS**

- Raised \$5.5 M in Public Offering
  606,395 shares of common stock at \$9.07
- Management bought shares recently
  - In Jan. 2020, the CEO invested \$50,000 to purchase CVM shares at \$7.54
  - Between May & Oct. 2019, the CEO and other insiders invested \$307,000 to purchase CVM shares
  - In August 2018, the CEO and other insiders purchased 463,885 CVM shares
- Phase 3 Study Results
  - In October 2019, the IDMC reviewed safety results and efficacy indicators and recommended that the trial continue until the required number of events have occurred
  - The last patients in the Phase 3 study were enrolled in September 2016 and the Phase 3 study is nearing final data
  - Primary end-point is 10% improvement in overall survival; CEL-SCI's prior Phase 2 study had shown a 33% increase in overall survival
  - If the results are positive, CEL-SCI intends to file for marketing approval worldwide

### **HEAD & NECK CANCER MARKET**

- ❖ 6% of all cancers are head & neck
- 650,000 new cases each year globally with 60,000 in the U.S. and 105,000 in Europe
- ❖ 300,000+ deaths per year
- FDA has not approved a new drug for treatment of advanced primary head and neck cancer in 60 years
- Orphan drug status in US

Disclaimer:

Except for historical information contained herein, the statements in this fact sheet are "forward looking" within the meaning of the Private Securities Litigation Act of 1995. A fuller discussion of CEL-SCI Corporation's risks and uncertainties are described in the Company's filings with the Securities and Exchange Commission, which should be reviewed in conjunction with this overview.

Multikine is the trademark that CEL-SCI has registered for this investigational therapy, and this proprietary name is subject to FDA review in connection with our future anticipated regulatory submission for approval. Multikine has not been licensed or approved for sale, barter or exchange by the FDA or any other regulatory agency. Similarly, its safety or efficacy has not been established for any use. Moreover, no definitive conclusions can be drawn from the early-phase, clinical-trials data involving the investigational therapy Multikine (Leukocyte Interleukin, Injection). Further research is required, and early-phase clinical trial results must be confirmed in the well-controlled. Phase 3 clinical trial of this investigational therapy that is currently in progress.

## **Investment Highlights**

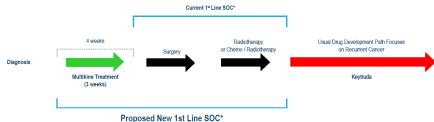
### Multikine Modulates/Mobilizes Intact Immune Response to Kill Cancer

Micrometastases around the tumor and in the lymph nodes are a major cause of cancer recurrence. Cancer treatment today involves aggressive surgery, including the removal of the tongue, because of the fear that tumor micrometastases will survive the first round of cancer treatments and cause tumor recurrence. Radiation or radiochemotherapy are usually given after surgery to kill left over micrometastases, but ... it does not always work. We believe that the patient's own immune system, if activated while it is still strong (before surgery, radiation and chemotherapy), has the capacity to both find and kill these tumor micrometastases. Therefore, the combination of our immunotherapy drug Multikine with surgery plus radiation/chemotherapy should be more successful in eliminating all of the tumor cells than the current standard therapies of surgery plus radiation/chemotherapy, alone.

## Phase 3 Trial's Positive Results Could Lead to Approval

In CEL-SCI's pivotal Phase 3 clinical trial Multikine is given as a first line treatment before surgery, radiation or concurrent radio-chemotherapy because that is when the immune system is thought to be the strongest. The last patient was enrolled in the study in September 2016. There have been 928 patients enrolled who are now being followed for overall survival. The primary endpoint of the study is a 10% improvement in overall survival for patients treated with Multikine treatment regimen plus Standard of Care (SOC) vs. patients treated with SOC alone. A prior Phase 2 study using the same Multikine treatment regimen showed a 33% increase in overall survival as compared to patient survival reported in the scientific literature between 1987 and 2007. To prove an overall survival benefit, the study requires CEL-SCI to wait until 298 events have occurred among the two main comparator groups. That was expected to have occurred in 2018.

#### **Multikine Treatment Regimen Schematic:**



Proposed New 1st Line SOC\* (upon Phase 3 success)

#### **LEAPS Therapeutic Vaccines for Treatment of Rheumatoid Arthritis**

LEAPS is CEL-SCI's second proprietary technology platform. It is a new class of drug that acts early to treat autoimmune and infectious diseases. Research has been funded via collaborations with the U.S. National Institutes of health (NIH), U.S. Army, Navy, and universities. The first indication is rheumatoid arthritis currently being funded by a \$1.5 M grant from the NIH.

### **Robust IP Portfolio and Full-Scale Manufacturing Facility**

CEL-SCI operates its own 73,000 sq. ft. manufacturing facility and produces Multikine for its clinical trials. About \$100 M was spent on the manufacturing plant, development, and validation. CEL-SCI believes Multikine is very difficult to replicate. In addition to the many Multikine manufacturing trade secrets, CEL-SCI has received a number of patents for Multikine from the U.S., EU, China and Japan.