CEL SCI CORP
Form DEFA14A
August 08, 2018

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

SCHEDULE 14A INFORMATION

Proxy Statement Pursuant to Section 14(a) of the Securities Exchange Act of 1934

Filed by the Registrant
Filed by a Party other than the Registrant

Check the appropriate box:

- Preliminary Proxy Statement
- Confidential, For Use of the Commission Only (As Permitted by Rule 14a-6(e)(2))
- Definitive Proxy Statement
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CEL-SCI CORPORATION
(Name of Registrant as Specified In Its Charter)

(Name of Person(s) Filing Proxy Statement, if other than the Registrant)

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August 2018

Dear CEL-SCI Shareholders:

Our singular goal right now is to reach the final data readout of the Phase 3 trial to establish the utility of our investigational immunotherapy Multikine* (Leukocyte Interleukin, Injection) in the treatment of head and neck cancer. Enrollment was completed in September of 2016. Based on published survival data, we believe top line results may be available as soon as early 2019.

The results of the Phase 3 study, if positive, will form the basis of our regulatory submissions for marketing applications worldwide to commercially market and distribute Multikine. The U.S. FDA has not approved a new drug for advanced primary squamous cell carcinoma (cancer) of the head and neck in about 60 years, a clear unmet medical need. The FDA has granted Multikine Orphan Drug status in this indication.

If we receive FDA approval, we believe that Multikine should become part of the standard of care (SOC) because the study endpoint of “improvement in overall survival” is the gold standard for cancer drug approval. Since our Phase 3 head and neck cancer study is the largest head and neck cancer study ever conducted, we expect data from it should be sufficiently robust and highly regarded to support our belief. Multikine should then become the recommended first treatment to be administered following diagnosis of cancer and before SOC is administered, for a cancer that affects about 650,000 patients per year.

This key inflection point is on the near term horizon. CEL-SCI is a cancer immunotherapy company that has a market cap of about $20 million. That makes little sense. We think that this is in large part due to the fact that we have all been waiting for Phase 3 data for 8.5 years. That is a long time. But, the last patients were enrolled almost two years ago and the final read out of the Phase 3 study is near. In the past 18 months, several successful Phase 3 cancer immunotherapy companies were sold for $7 billion to almost $12 billion. They had positive survival data from their pivotal studies, but had not yet received FDA approval. In addition, recently one cancer immunotherapy company with Phase 3 studies that were not yet complete was sold for about $1.6 billion.

CEL-SCI’s Multikine Phase 2 open label “Proof of Concept” study used the same three week Multikine treatment regimen prior to SOC that is being used in the current Phase 3 study. The effects of a 3 week Multikine treatment regimen on the tumors that were removed at surgery (per SOC) following the Multikine treatment regimen was examined and evaluated by pathology. The findings were published in the Journal of Clinical Oncology and presented at American Society of Clinical Oncology. The pathologists found that about 10% of patients had no tumor cells remaining after a three week Multikine treatment, and the remaining patients had only about 50% of their tumor cells remaining. In a survival follow-up study of patients from the same Phase 2 study, it was determined that there was a 33% overall survival benefit compared to results obtained in 55 clinical trials reported in the scientific literature between 1987 and 2007 in the same patient population (Advanced Primary Squamous Cell Carcinoma of the Head and Neck). Our pivotal Phase 3 study is designed to prove a 10% overall survival benefit in a prospectively controlled study in a statistically significant manner.

Our idea and aim is to help cancer patients by boosting their immune system BEFORE the ravages of surgery, radiation and chemotherapy. We believe that boosting a cancer patient's immune system while it is still intact, before surgery and/or radiation/chemotherapy, should provide the greatest possible impact on survival. Our Phase 3 study is meant to prove this. This is a logical concept and one that made sense to 24 regulatory agencies, including the FDA, when we applied to them to conduct this global Phase 3 study. This idea is now gaining traction among oncologists. If we are successful in head and neck cancer, we hope to expand this concept to other cancers.

-- more --

We recently completed and won the arbitration against the clinical research organization (CRO) that ran our Phase 3 head and neck cancer study from 2011-2013. The arbitrator ruled that the CRO materially breached its contract with CEL-SCI. The arbitrator's decision has vindicated us. Many investment funds and analysts did not like the legal risk of this arbitration and now that the arbitration has been resolved in our favor, this should no longer be an impediment to investors and should result in renewed investment interest in CEL-SCI. With the arbitration behind us, we move forward with a clean slate.

Investors, new and old, can now focus on the achievements that establish the true value of our Company: 1) a fully enrolled cancer Phase 3 clinical trial awaiting final top line data readout; and 2) a very promising rheumatoid arthritis treatment vaccine candidate, based on our LEAPS technology, funded by a large U.S. government grant.

Moving forward to a promising future, we plan to meet with and provide an update to interested investors, many of whom will be looking at CEL-SCI for the first time.

Sincerely,

Geert Kersten
Chief Executive Officer

Forward-Looking Statements

This shareholder letter contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. When used in this press release, the words "intends," "believes," "anticipated," "plans" and "expects," and similar expressions, are intended to identify forward-looking statements. Such statements are subject to risks and uncertainties that could cause actual results to differ materially from those projected. Factors that could cause or contribute to such differences include, an inability to duplicate the clinical results demonstrated in clinical studies, timely development of any potential products that can be shown to be safe and effective, receiving necessary regulatory approvals, difficulties in manufacturing any of the Company's potential products, inability to raise the necessary capital and the risk factors set forth from time to time in CEL-SCI's filings with the Securities and Exchange Commission, including but not limited to its report on Form 10-K for the year ended September 30, 2017. The Company undertakes no obligation to publicly release the result of any revision to these forward-looking statements which may be made to reflect the events or circumstances after the date hereof or to reflect the occurrence of unanticipated events.

* Multikine (Leukocyte Interleukin, Injection) is the trademark that CEL-SCI has registered for this investigational therapy, and this proprietary name is subject to FDA review in connection with the Company's 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. Further research is required, and early-phase clinical trial results must be confirmed in the Phase 3 clinical trial of this investigational therapy that is in progress.