SECURITIES & EXCHANGE COMMISSION EDGAR FILING

CEL SCI CORP

Form: DEFA14A

Date Filed: 2020-03-04

Corporate Issuer CIK: 725363

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
☒ Definitive Additional Materials
☐ Soliciting Material under Rule 14a-12

CEL-SCI CORPORATION
(Name of Registrant as Specified In Its Charter)

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

Payment of Filing Fee (Check the appropriate box):

☒ No fee required

☐ Fee computed on table below per Exchange Act Rules 14a-6(i)(1) and 0-11.

(1) Title of each class of securities to which transaction applies:
(2) Aggregate number of securities to which transaction applies:
(3) Per unit price or other underlying value of transaction computed pursuant to Exchange Act Rule 0-11 (set forth the amount on which the filing fee is calculated and state how it was determined):
(4) Proposed maximum aggregate value of transaction:
(5) Total fee paid:

☐ Fee paid previously with preliminary materials.

☐ Check box if any part of the fee is offset as provided by Exchange Act Rule 0-11(a)(2) and identify the filing for which the offsetting fee was paid previously. Identify the previous filing by registration statement number, or the form or schedule and the date of its filing.

(1) Amount Previously Paid:
(2) Form, Schedule or Registration Statement No.:
(3) Filing Party:
(4) Date Filed:

CEL-SCI CORPORATION
8229 Boone Blvd., Suite 802
Vienna, Virginia 22l82
(703) 506-9460

CEL-SCI
Empowering Immune Defenses

February 2020

Dear Fellow Shareholders:

A long time ago we set out to create a cancer drug that addresses the following concerns:

- has little to no toxicity,
- extends life, or better yet, aims to cure cancer patients and
- is not prohibitively expensive.

Even in those days, when the so-called experts ridiculed our efforts and goals saying ‘it could not be done’, we believed that the immune system held the key to

our health and ability to effectively fight cancer. The challenge we faced was how to develop a medicine that can harness the immune system's power to fight cancer. Now the application of immunotherapy in the treatment of cancer has gone from "it can/will not work" to "this is the future." Today's cancer immunotherapies are generally being developed for patients who have already had surgery, radiation and/or chemotherapy or for patients for whom surgery is not an option. These patients usually also have compromised immune systems. The Phase 3 trial of our investigational cancer immunotherapy, Multikine* (Leukocyte Interleukin Injection) is designed to demonstrate that we can be even more successful in increasing the overall survival (OS) of cancer patients when we stimulate their immune systems before they are ravaged by the effects of surgery, radiation, and/or chemotherapy.

The global pivotal Phase 3 clinical trial, which we started nine years ago for our Multikine immunotherapy in advanced primary head and neck cancer patients, tests the hypothesis that giving the Multikine treatment regimen right after cancer diagnosis, BEFORE surgery, radiation or radiochemotherapy, will increase the OS of patients beyond the OS achieved with the current "intent to cure" standard of care (SOC) therapies. In short, we seek to make the current "intent to cure" SOC treatment more successful. And we hope to do so with little to no toxicity added by our Multikine immunotherapy. Our first goal is to prove this concept in the treatment of newly diagnosed patients with advanced primary head and neck cancer, about 4% of all cancers. This is an indication in dire need of a new and effective treatment because the last drug approved by the U.S. FDA for this indication was about 60 years ago, and just about everyone agrees that the current treatments are horrible and fail to properly address this unmet medical need. We hope to extend this concept to other solid tumors as well should our Phase 3 trial be successful.

We started accruing patients to our Phase 3 study in early 2011 and completed enrollment of 928 cancer patients in September 2016. Per the study protocol, 298 deaths (events) will have to occur in the two comparator groups (Multikine treatment regimen plus SOC vs. SOC alone) in order to determine whether the study's primary endpoint, a 10% increase in overall survival in favor of the Multikine regimen treatment group, has been achieved.

Based on the known survival statistics available for the patient population in our study when we initiated our Phase 3 trial, we had expected to have reached the required 298 events some time ago. Clearly, it is a good thing when these very sick stage 3 and 4 cancer patients live longer and/or do not die. In fact, that is the goal of the study. Since we are blinded to the details of the study results, we cannot know definitively whether it is our investigational immunotherapy Multikine treatment regimen or something else that is responsible for patients living longer. Nevertheless, it would not come as a surprise for us to see a survival benefit from our Multikine treatment regimen in the Phase 3 trial because we saw an approximate 33% survival benefit in our final Phase 2 study. In that final Phase 2 study, the Multikine treatment regimen was administered to patients just as it is in the Phase 3 study. Also, the final Phase 2 study showed, by pathology, that in just three weeks of administering our Multikine treatment regimen, 100% of the tumor was eliminated in some patients and approximately 50% of the tumor was eliminated in many of the other patients. Twenty-four regulators, including the U.S. FDA, gave us permission to run our pivotal Phase 3 clinical trial based on these clinical results and other data.

We have discussed at great length, internally and with outside experts, what factors, other than the Multikine treatment regimen, might be contributing to what appears to be a better than expected survival in this Phase 3 study. The most obvious factors to consider are 1) the treatments that patients are receiving, either as the first line treatment (SOC) for newly diagnosed cancer or as treatment of a tumor that has recurred, have improved during our Phase 3 trial or 2) the apparent increased survival of the patients in our study is related to the dropout rate of patients since that would reduce the sample size from which events can be collected.

To help us evaluate these factors we engaged an independent statistical group and asked them to determine if the survival of patients with squamous cell carcinoma (cancer) of the oral cavity and soft palate (the same patient population as we enrolled in our Phase 3 study) treated in the U.S. presumably with the same SOC and in the same manner as the patients in our Phase 3 study, had changed during the time patients were enrolled and treated in our Phase 3 study. The statistical group analyzed the most recently available data from the U.S. Government National Cancer Registry called SEER. The Cancer Registry contains data about, among other things, cancer patients' disease diagnosis, staging at diagnosis, treatments administered, and survival of specific cancer populations in the U.S. The survival data in the U.S. available from the SEER Cancer Registry for the types of patients treated in our Phase 3 study during the same time our study was conducted indicated that these patients had only a 47% survival at three (3) years and a 37% survival at five (5) years, establishing that the survival in treating those patients who had been receiving the best SOC treatments available in the U.S. did not improve during our long Phase 3 study. That means that the SOC treatment and any follow-up treatments once the cancer recurred do not look to be responsible for the patients apparently living longer in our Phase 3 study.

After treatment with Multikine and the SOC, the patients enrolled in our study can take any medicine if their tumor recurs. We therefore considered the possibility that the introduction in late 2016 of Keytruda and Opdivo, two new cancer immunotherapy drugs for recurrent head and neck cancer, might be responsible for the lower than expected death rate in our study. We do not think that this is the case based on the following: 1) The use of Keytruda and Opdivo as a treatment should already be accounted for in the SEER database results which were evaluated since these drugs were used in the U.S. for patients with recurring disease. 2) Our study was enrolled in 20+ countries and these drugs were not available in many of those countries during the time patients were enrolled and treated in our study. In most of those countries Keytruda and Opdivo are still not available, even today. 3) Keytruda and Opdivo show a survival benefit of about 3 months in head and neck cancer once the initial treatment has failed and the tumor recurs. Any patient who received a 3-month survival benefit from Keytruda or Opdivo would already have passed on since the patients in the Phase 3 study entered/completed treatment between 3.5 and 9 years ago. Therefore, the delay in reaching 298 events in the Multikine Phase 3 study should not be due to Keytruda and Opdivo.

We do not think the increased survival of the patients in our study is related to the dropout rate of patients either. While we are blinded to the study results, we have never heard from the CROs who run the study that the dropout rate is a problem. In addition, the actions by the Independent Data Monitoring Committee (IDMC) speak against that as well. The IDMC, which meets periodically to review the study and data in an unblinded manner (i.e., they see everything) is tasked with focusing on the following areas:

- Efficacy: to assess the primary efficacy measure as well as the conditional power and sample size
- Safety: to assess the magnitude of adverse events and monitor for safety concerns

In reviewing the conditional power and sample size the IDMC would be considering the dropout rate. If there was a problem with the dropout rate, then per the Charter the IDMC is required to tell us to enroll more patients. They have not done so. As recently as October 2019, the IDMC recommended "…to continue the trial until the appropriate number of events has occurred". In their letter to us they said that they reviewed "…progression free and overall survival and limited demographic and safety data available for the aforementioned protocol." This language tells us that they are following the guidelines outlined in their charter.

We are treating newly diagnosed cancer patients, hoping to improve the "intent to cure" treatment, and our Phase 3 trial is a very large event driven overall survival study, the 'gold standard' of studies for approval of cancer drugs. Patients have already been in our Phase 3 study between 3.5 and 9 years, and some people are asking how much longer our study will have to last. We knew from the start that since the study is event driven it might take longer to complete than we had estimated, however, it is taking even longer to complete than we thought. Many of our shareholders think that simply because it looks as if things are going well, the study should end before 298 events are reached so the product can be made available to help patients. This thinking is incorrect for our situation due to the event-driven study design.

It is now established that patients treated with cancer immunotherapy, in contrast to cancer patients treated with other modalities (surgery, radiation and chemotherapy) may receive a delayed survival benefit. Bristol Myers Squib's (BMS) event driven overall survival study of their blockbuster immunotherapy drug, Yervoy, which was developed for the treatment of metastatic melanoma, proved this concept. At 5 years follow up of patients in a 3 year study of Yervoy they observed a significant separation in the survival curves between the immunotherapy treatment regimen and SOC groups indicating great survival benefit from Yervoy. Had BMS not continued to follow up with the patients in their study beyond three years, this valuable information would have been missed. Since the statistical power to prove the clinical benefit in our Multikine study is derived from the number of events, regardless of cause or when they may occur, if our study is ended prematurely we could miss valuable data and not have sufficient statistical power to prove Multikine's benefit. Yervoy went on to become a huge success helping many melanoma patients. We hope that, as with Yervoy, the delay we are experiencing in reaching the required 298 events in the 2 comparator groups in our study will be an indication that patients who were treated with the Multikine treatment regimen are receiving a delayed survival benefit.

We are blinded to the Phase 3 study results. However, it is clear that there is something occurring in our study that is keeping patients alive longer than expected. By eliminating the factors other than Multikine that could contribute to this observed delay in reaching the required events, and because it is now established that cancer immunotherapy can produce a delayed survival benefit, we believe that Multikine is likely producing some kind of a survival benefit, just as it did in the final Phase 2 study. We are treating advanced (stages 3 and 4) primary (just diagnosed and not yet treated) head and neck cancer patients who have cancer in the worst anatomical regions with regard to survival outcome. They simply do not get better on their own. In its annual reports published in January 2019 and January 2020 the American Cancer Society indicated that deaths in oral cancer patients have increased during the past 10 years. This report confirms that the current SOC treatment or treatments that patients are receiving if their tumor recurs have not improved in the nine years since we started our Phase 3 study and validates that an extreme unmet medical need still exists for these patients.

We believe that we are nearing the end of this long Phase 3 study, and we hope the results will prove that stimulating the immune systems of cancer patients with Multikine to fight cancer BEFORE they are ravaged by the effects of surgery, radiation, and chemotherapy will help these patients to survive longer.

And if we can do so with little to no toxicity as we did in our earlier Multikine studies, then we will have made a huge contribution to the cancer armamentarium.

We thank you for your support. We believe!

Sincerely,

Geert Kersten
Chief Executive Officer

Forward-Looking Statements

This press release 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, areintended to identify forward-looking statements. Such statements are subject to risks and uncertainties that could cause actual results to differ materially from those projected. Such statements include, but are not limited to, statements about the terms,expected proceeds, use of proceeds and closing of the offering. 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/A for the year ended September 30, 2019. 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 otherregulatory 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.*