SECURITIES & EXCHANGE COMMISSION EDGAR FILING

CEL SCI CORP

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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (date of earliest event reported): December 7, 2020

CEL SCI CORP

(Exact name of Registrant as specified in its charter)

Colorado	001-11889	84-0916344
(State or other jurisdiction of incorporation)	(Commission File No.)	(IRS Employer Identification No.)

8229 Boone Blvd., #802
Vienna, Virginia 22182
(Address of principal executive offices, including Zip Code)

Registrant's telephone number, including area code: (703) 506-9460

N/A
(Former name or former address if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligations of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17CFR 230.425)
☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b)
☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-14c))

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Trading Symbol(s)	Name of Each Exchange on Which Registered
Common Stock	CVM	NYSE American

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§203.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§204.12b-2 of this chapter.

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01 Other Events.

On December 7, 2020, the Company issued a press release, filed as Exhibit 99, concerning the final review stage of the Company's phase 3 clinical trial involving Multikine.

Item 9.01 Financial Statements and Exhibits.

Exhibit Number	Description
99	Press Release re. Phase 3 Cancer Trials

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

CEL-SCI CORPORATION

Date: December 7, 2020

By: /s/ Patricia B. Prichep
Patricia B. Prichep
Senior Vice President of Operations

EXHIBIT 99

NEWS RELEASE

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CEL-SCI Announces Update on Phase 3 Cancer Trial Results

Data lock is complete, final statistical analysis being conducted

Vienna, VA, December 7, 2020 -- CEL-SCI Corporation **(NYSE American: CVM)** announced today that the Phase 3 study is in the final stage of review which involves statistical analysis of all study data. Data lock has already been completed.

Since the required number of events to allow statistical analysis of CEL-SCI's Phase 3 study in head and neck cancer was reached earlier this year, the Clinical Research Organizations (CROs) managing CEL-SCI's Phase 3 study, Ergomed and ICON, had been performing data base lock of the study results. Data base lock is a very important and time intensive process that needs to be completed to ensure any study's data are accurate and as complete as possible before the results of the study can be statistically evaluated and reliable conclusions drawn regarding the study's outcome(s). This process was particularly complicated for CEL-SCI's Phase 3 study because the study was conducted in over 20 countries on three continents, and many of these countries had, and still have, severe shutdowns due to the COVID-19 pandemic.

The statistical analysis of our Phase 3 study data is being performed according to a statistical analysis plan that was approved in advance of data lock. The analysis is being conducted by independent unbiased contractors. CEL-SCI is not involved in this process. Once the analysis has been completed, CEL-SCI will become privy to the study results. At that time, shareholders will be advised of the results through a public announcement. CEL-SCI also plans to publish the results in peer reviewed scientific journals.

"Our goal has been to create a cancer drug that is both non-toxic and works with the body's immune system to increase the 'intent to cure' success rate of the first-line cancer treatment. We believe that immunotherapy should be administered before, not after, surgery, radiation and chemotherapy have damaged the immune system. We further believe that success in head and neck cancer should lead to many new ways of helping cancer patients." said Geert Kersten, CEO of CEL-SCI Corporation. "We are grateful to our shareholders for believing in us and supporting us during the very long Phase 3 study."

About CEL-SCI Corporation

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 study CEL-SCI treated patients who are newly diagnosed with advanced primary squamous cell carcinoma of the head and neck with the investigational product Multikine* first, BEFORE they received surgery, radiation and/or chemotherapy. This approach is unique. Most other cancer immunotherapies are administered only after conventional therapies have been tried and/or failed. Multikine (Leukocyte Interleukin, Injection), has received Orphan Drug designation from the FDA for neoadjuvant therapy in patients with squamous cell carcinoma (cancer) of the head and neck.

CEL-SCI believes that this Phase 3 study is the largest Phase 3 study in the world for the treatment of head and neck cancer. Per the study's protocol, newly diagnosed patients with advanced primary squamous cell carcinoma of the head and neck were treated with the Multikine treatment regimen right after diagnosis and prior to receiving the Standard of Care (SOC), which involves surgery, radiation or concurrent radiochemotherapy. Multikine is designed to help the immune system "see" the tumor at a time when the immune system is still relatively intact and thereby thought to better be able to mount an attack on the tumor. The aim of treatment with Multikine is to boost the body's immune system prior to SOC to attack the cancer. The Phase 3 study is fully enrolled with 928 patients and the last patient was treated in September 2016. To prove an overall survival benefit, the study requires CEL-SCI to wait until 298 events have occurred among the two main comparator groups. This study milestone occurred in late April 2020. The study is currently in the statistical analysis phase.

The Company's LEAPS technology is being developed for rheumatoid arthritis and as a potential treatment for COVID-19 infection. The Company has operations in Vienna, Virginia, and near/in Baltimore, Maryland.

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, including statements with respect to Multikine and the Phase 3 clinical trial of Multikine in patients with advanced primary squamous cell carcinoma of the head and neck. 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 trials or nonclinical 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 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.*

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