

SECURITIES & EXCHANGE COMMISSION EDGAR FILING

CEL SCI CORP

Form: 8-K

Date Filed: 2015-05-13

Corporate Issuer CIK: 725363

**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): May 13, 2015

CEL-SCI CORPORATION

(Exact name of registrant as specified in its charter)

| | | |
|--|---|--|
| <u>Colorado</u> (State or other jurisdiction of incorporation) | <u>001-11889</u> (Commission File No.) | <u>84-0916344</u> (I.R.S. Employer Identification No.) |
|--|---|--|

8229 Boone Boulevard, Suite
802
Vienna, Virginia 22182
(Address of principal executive
offices, including Zip Code)

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

Not Applicable
(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 obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 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-4(c))
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Item. 8.01 Other Events.

On May 13, 2015, CEL-SCI Corporation (“CEL SCI” or the “Company”) issued a press release announcing that the Italian Medicines Agency (AIFA) has authorized the Company to commence patient enrollment for its ongoing Phase 3 trial of its investigational immunotherapy Multikine (Leukocyte Interleukin, Injection) in patients with advanced primary squamous cell carcinoma of the oral cavity/soft palate, a type of head and neck cancer. Italy is the 23rd country to authorize CEL-SCI’s Phase 3 trial for patient enrollment.

Having surpassed its originally planned milestone of receiving authorization to conduct the Phase 3 study from 21 countries, CEL-SCI is now aiming to expand the trial into a total of approximately 100 clinical centers in about 25 countries. As of April 30, 2015, 437 patients had been enrolled in the global Phase 3 study.

A copy of the press release is furnished herewith as Exhibit 99.1.

Forward-Looking Statements

This report 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 Corporation’s filings with the Securities and Exchange Commission, including but not limited to its report on Form 10-K and 10-K/A for the year ended September 30, 2014. 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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

| Exhibit No. | Description |
|--------------------|--------------------|
|--------------------|--------------------|

| | |
|------|----------------------------------|
| 99.1 | Press release dated May 13, 2015 |
|------|----------------------------------|

SIGNATURE

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: May 13, 2015

By: /s/ Patricia B. Prichep

Patricia B. Prichep

Senior Vice President of Operations



NEWS RELEASE

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CEL-SCI Corporation
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CEL-SCI RECEIVES AUTHORIZATION TO CONDUCT ITS PHASE 3 MULTIKINE TRIAL IN ITALY

Italy is 23rd country to authorize CEL-SCI's trial for patient enrollment

Vienna, VA, May 13, 2015 -- CEL-SCI Corporation (**NYSE MKT: CVM**) ("CEL SCI" or the "Company") today announced that the Italian Medicines Agency (AIFA) has authorized the Company to commence patient enrollment for its ongoing Phase 3 trial of its investigational immunotherapy Multikine* (Leukocyte Interleukin, Injection) in patients with advanced primary squamous cell carcinoma of the oral cavity/soft palate, a type of head and neck cancer. Italy is the 23rd country to authorize CEL-SCI's Phase 3 trial for patient enrollment.

Having surpassed its originally planned milestone of receiving authorization to conduct the Phase 3 study from 21 countries, CEL-SCI is now aiming to expand the trial into a total of approximately 100 clinical centers in about 25 countries. As of April 30, 2015, 437 patients had been enrolled in the global Phase 3 study.

About the Multikine Phase 3 Study

The Multikine Phase 3 study is enrolling patients with advanced primary squamous cell carcinoma of the head and neck. The objective of the study is to demonstrate a statistically significant improvement in the overall survival of enrolled patients who are treated with the Multikine treatment regimen plus standard of care ("SOC") vs. subjects who are treated with SOC only.

About Multikine

Multikine (Leukocyte Interleukin, Injection) is an investigational immunotherapeutic agent that is being tested in an open-label, randomized, controlled, global pivotal Phase 3 clinical trial as a potential first-line treatment for advanced primary squamous cell carcinoma of the head and neck. Multikine is designed to be a different type of therapy in the fight against cancer: one that appears to have the potential to work with the body's natural immune system in the fight against tumors.

Multikine is also being tested in a Phase 1 study under a Cooperative Research and Development Agreement ("CRADA") with the U.S. Naval Medical Center, San Diego, as a potential treatment for peri-anal warts in HIV/HPV co-infected men and women. CEL-SCI has also entered into two co-development agreements with Ergomed Clinical Research Limited to further the development of Multikine for cervical dysplasia/neoplasia in women who are co-infected with HIV and HPV and for peri-anal warts in men and women who are co-infected with HIV and HPV.

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About CEL-SCI Corporation

CEL-SCI's work is focused on finding the best way to activate the immune system to fight cancer and infectious diseases. Its lead investigational therapy, Multikine (Leukocyte Interleukin, Injection), is currently being studied in a pivotal Phase 3 clinical trial as a potential neoadjuvant treatment for patients with squamous cell carcinoma of the head and neck. If the study endpoint, which is a 10% improvement in overall survival of the subjects treated with the Multikine treatment regimen plus the current SOC as compared to subjects treated with the current SOC only, is satisfied, the study results will be used to support applications that the Company plans to submit to regulatory agencies in order to seek commercial marketing approvals for Multikine in major markets around the world. Additional clinical indications for Multikine that are being investigated include the treatment of cervical dysplasia in HIV/HPV co-infected women, and the treatment of peri-anal warts in HIV/HPV co-infected men and women. A Phase 1 trial of the former indication has been completed at the University of Maryland. The latter indication is now in a Phase 1 trial in conjunction with the U.S. Naval Medical Center, San Diego, under a CRADA.

CEL-SCI is also developing its pre-clinical L.E.A.P.S. (Ligand Epitope Antigen Presentation System) technology for the potential treatment of pandemic influenza in hospitalized patients and as a potential vaccine for the treatment of rheumatoid arthritis.

The Company has operations in Vienna, Virginia, and in/near Baltimore, Maryland. For more information, please visit www.cel-sci.com.

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, 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 Corporation's filings with the Securities and Exchange Commission, including but not limited to its report on Form 10-K and 10-K/A for the year ended September 30, 2014. 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 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 have 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 Phase 3 clinical trial of this investigational therapy that is currently in progress.*

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