CEL SCI CORP
Form 8-K
April 14, 2014

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 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): April 11, 2014

CEL-SCI CORPORATION
(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, VA 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))

Item 8.01 Other Events.

On April 11, 2014, the Company issued a press release announcing the Company's intention to offer, subject to market and other conditions, shares of Company common stock and warrants in an underwritten public offering pursuant to its existing shelf registration statement. Dawson James Securities, Inc. and Laidlaw & Company (UK) Ltd. are the underwriters for the offering. A copy of this press release is attached as Exhibit 99.1.

On April 11, 2014, the Company filed with the Securities and Exchange Commission a preliminary prospectus supplement to its effective shelf registration statement on Form S-3 (the "Preliminary Prospectus Supplement") pursuant to Rule 424 under the Securities Act of 1933, as amended, relating to its proposed public offering of shares of the common stock and warrants. The Preliminary Prospectus Supplement contains certain supplemental and revised disclosure regarding the Company's business in the sections entitled "Prospectus Supplement Summary" and "Risk Factors" which are attached as Exhibit 99.2 and incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press release dated April 11, 2014 regarding the launch of a proposed public offering
99.2	Selected sections the Company's Preliminary Prospectus Supplement dated April 11, 2014.

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.

Date: April 11, 2014

CEL-SCI CORPORATION

By: /s/ Patricia B. Prichep

Patricia B. Prichep
Senior Vice President of Operations

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EXHIBIT 99.1

CEL-SCI CORPORATION

8229 Boone Boulevard, Suite 802
Vienna, VA 22182. USA
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NEWS RELEASE

COMPANY CONTACT:
Gavin de Windt
CEL-SCI Corporation
(703) 506-9460

CEL-SCI CORPORATION ANNOUNCES PROPOSED PUBLIC OFFERING OF COMMON STOCK AND SIX MONTH WARRANTS

Vienna, VA, April 11, 2014 - CEL-SCI Corporation (NYSE MKT: CVM), a late-stage oncology company, today announced that it intends to offer and sell common stock and six month warrants in a "best efforts" underwritten public offering. The offering is subject to market conditions, and there can be no assurance as to whether or when the offering may be completed.

Dawson James Securities, Inc, and Laidlaw & Company (UK) Ltd. are acting as joint book-running managers and underwriters for the proposed offering.

A shelf registration statement and accompanying base prospectus on Form S-3 relating to the securities was filed with the Securities and Exchange Commission and is effective. The offering may be made only by means of a prospectus, copies of which may be obtained, when available, from the offices of Laidlaw & Company (UK) Ltd., 546 Fifth Avenue, 5th Floor, New York, NY, 10036, telephone: 212-953-4900, or from Dawson James Securities, 1 North Federal Highway, Suite 500, Boca Raton, FL 33432, telephone: 561-391-5555.

This press release shall not constitute an offer to sell or the solicitation of an offer to buy these securities, nor shall there be any sale of these securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to the registration or qualification under the securities laws of any such jurisdiction.

About CEL-SCI Corporation

CEL-SCI is dedicated to research and development directed at improving the treatment of cancer and other diseases by utilizing the immune system, the body's natural defense system. Its lead investigational therapy is Multikine (Leukocyte Interleukin, Injection), currently being studied in a pivotal global Phase III clinical trial. CEL-SCI is also investigating an immunotherapy (LEAPS-H1N1-DC) as a possible treatment for H1N1 hospitalized patients and as a

vaccine (CEL-2000) for Rheumatoid Arthritis (currently in preclinical testing) using its LEAPS technology platform. The investigational immunotherapy LEAPS-H1N1-DC treatment involves non-changing regions of H1N1 Pandemic Flu, Avian Flu (H5N1), and the Spanish Flu, as CEL-SCI scientists are very concerned about the possible emergence of a new more virulent hybrid virus through the combination of H1N1 and Avian Flu, or maybe Spanish Flu. The Company has operations in Vienna, Virginia, and in/near Baltimore, Maryland.

*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 its 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 III clinical trial of this investigational therapy that is currently in progress.

Safe Harbor Statement

When used in this release, the words "intends," "believes," "anticipated" and "expects" and similar expressions are intended to identify forward-looking statements. Forward-looking statements include, without limitation, the company's ability to complete the proposed public offering of its common stock and warrants described above. Such statements are subject to risks and uncertainties which could cause actual results to differ materially from those projected. 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.

EXHIBIT 99.2

PROSPECTUS SUPPLEMENT SUMMARY

This summary highlights certain information about us, this offering and information appearing elsewhere in this prospectus supplement, in the accompanying prospectus and in the documents we incorporate by reference. This summary is not complete and does not contain all of the information that you should consider before investing in our securities. To fully understand this offering and its consequences to you, you should read this entire prospectus supplement and the accompanying prospectus carefully, including the information referred to under the heading "Risk Factors" in the accompanying prospectus and set forth herein, the financial statements and other information incorporated by reference in this prospectus supplement and the accompanying prospectus when

making an investment decision.

About CEL-SCI Corporation

We were formed as a Colorado corporation in 1983. Our principal office is located at 8229 Boone Boulevard, Suite 802, Vienna, VA 22182. Our telephone number is 703-506-9460 and our web site is www.cel-sci.com. The information on our website is not part of this prospectus.

Our business consists of the following:

1) Multikine(R) (Leukocyte Interleukin, Injection) investigational immunotherapy against cancer and Human Papilloma Virus (HPV);

2) LEAPS technology, with two investigational therapies, LEAPS-H1N1-DC pandemic flu treatment for hospitalized patients and CEL-2000, a rheumatoid arthritis treatment vaccine.

MULTIKINE

Our lead investigational therapy, Multikine, is currently being developed as a potential therapeutic agent directed at using the immune system to produce an anti-tumor immune response. Data from Phase I and Phase II clinical trials suggest that Multikine simulates the activities of a healthy person's immune system, enabling it to use the body's own anti-tumor immune response. Multikine (Leukocyte Interleukin, Injection) is the full name of this investigational therapy, which, for simplicity, is referred to in the remainder of this document as Multikine. Multikine is the trademark that we have 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. Neither has its safety or efficacy been established for any use.

Multikine has been cleared by the regulators in twelve countries around the world, including the U.S. FDA, for a global Phase III clinical trial in advanced primary (not yet treated) head and neck cancer patients. The trial is currently under the management of two new clinical research organizations (CROs) who are adding approximately 60 clinical centers in existing and new countries to increase the speed of patient enrollment.

The trial will test the hypothesis that Multikine treatment administered prior to the current standard therapy for head and neck cancer patients (surgical resection of the tumor and involved lymph nodes followed by radiotherapy or radiotherapy and concurrent chemotherapy) will extend the overall survival, enhance the local/regional control of the disease and reduce the rate of disease progression in patients with advanced oral squamous cell carcinoma.

The primary clinical endpoint in CEL-SCI's ongoing Phase III clinical trial is that a 10% improvement in overall survival in the Multikine treatment arm, plus the current standard of care (SOC - consisting of surgery + radiotherapy or surgery + radiochemotherapy), over that which can be achieved in the SOC arm alone (in the well-controlled Phase III clinical trial currently ongoing) must be achieved. Based on what is presently known about the current survival statistics for this population, CEL-SCI believes that achievement of this endpoint should enable CEL-SCI, subject to further consultations with FDA, to move forward, prepare and submit a Biologic License Application to FDA for

Multikine.

The clinical trial involves giving Multikine to cancer patients prior to their receiving any conventional treatment for cancer, including surgery, radiation and/or chemotherapy. This could be shown to be important because conventional therapy may weaken the immune system, and may compromise the potential effect of immunotherapy. Because Multikine is given before conventional cancer therapy, when the immune system may be more intact, we believe the possibility exists for it to have a greater likelihood of activating an anti-tumor immune response under these conditions. This likelihood is one of the clinical aspects being evaluated in the ongoing global Phase III clinical trial.

Multikine is a different kind of investigational therapy in the fight against cancer. Multikine is a defined mixture of cytokines. It is a combination immunotherapy, possessing both active and passive properties.

In October 2012 and again in November 2013, in an interim review of the safety data from the Phase III study, an Independent Data Monitoring Committee (IDMC) raised no safety concerns. The IDMC also indicated that no safety signals were found that would call into question the benefit/risk of continuing the study. CEL-SCI considers the results of the IDMC review to be important since studies have shown that up to 30% of Phase III trials fail due to safety considerations and the IDMC's safety findings from this interim review were similar to those reported by investigators during CEL-SCI's Phase I-II trials. Ultimately, the decision as to whether a drug is safe is made by the FDA based on an assessment of all of the data from a trial.

On October 7, 2013, CEL-SCI announced a Cooperative Research and Development Agreement with the U.S. Naval Medical Center, San Diego. Pursuant to this agreement, the Naval Medical Center will conduct Human Subjects Institutional Review Board approved Phase I study of CEL-SCI's investigational immunotherapy, Multikine, in HIV/HPV co-infected men and women with peri-anal warts. Anal and genital warts are commonly associated with the Human Papilloma Virus, the most common sexually transmitted disease. Men and women with a history of anogenital warts have a 30 fold increased risk of anal cancer. Persistent HPV infection in the anal region is thought to be responsible for up

to 80% of anal cancers. HPV is a significant health problem in the HIV infected population as individuals are living longer as a result of greatly improved HIV medications.

The purpose of this study is to evaluate the safety and clinical impact of Multikine as a treatment of peri-anal warts and assess its effect on anal intraepithelial dysplasia (AIN) in HIV/HPV co-infected men and women.

CEL-SCI will contribute the investigational study drug Multikine, will retain all rights to any currently owned technology, and will have the right to exclusively license any new technology developed from the collaboration.

Multikine is being given to the HIV/HPV co-infected patients with peri-anal warts since promising early results were seen in another Institutional Review Board approved Multikine Phase I study conducted at the University of Maryland. In this study, investigational therapy Multikine was given to HIV/HPV co-infected women with cervical dysplasia resulting in visual and histological evidence of clearance of lesions. Furthermore, elimination of a number of HPV strains was determined by in situ polymerase chain reaction (PCR) performed on tissue biopsy collected before and after Multikine treatment. As reported by the

investigators in the earlier study, the study volunteers all appeared to tolerate the treatment with no reported serious adverse events.

The treatment regimen for the study of up to 15 HIV/HPV co-infected patient volunteers with peri-anal warts to be conducted by the Naval Medical Center will be identical to the regimen that was used in the earlier Multikine cervical study in HIV/HPV co-infected patients.

In October 2013, CEL-SCI entered into a co-development and profit sharing agreement with Ergomed for Multikine in HIV/HPV co-infected men and women with peri-anal warts. This agreement will initially be in support of the development with the US Navy. Ergomed will assume up to $3 million in clinical and regulatory costs.

Also in October 2013, CEL-SCI entered into a co-development and profit sharing agreement with Ergomed for Multikine in HIV/HPV co-infected women with cervical dysplasia. Human Papilloma Virus (HPV) is the most common sexually transmitted disease. HPV is a significant health problem in the HIV infected population as individuals are living longer as a result of greatly improved HIV medications. People living with HIV and others with compromised immunity are more at risk for HPV-related complications. Persistent HPV infection can also be a precursor to cervical cancer. Ergomed will assume up to $3 million in clinical and regulatory costs.

CEL-SCI's focus in HPV is not the development of an antiviral against HPV in the general population. Instead it is the development of an immunotherapy to be used in patients who are immune suppressed by diseases such as HIV and are therefore less able or unable to control HPV and its resultant diseases. This group of patients has no good treatments available to them and there are, to the Company's knowledge, no competitors at the current time. HPV is also relevant to

the head and neck cancer Phase III study since it is now known that HPV is a cause of head and neck cancer. Multikine was shown to kill HPV in an earlier study of HIV infected women with cervical dysplasia.

LEAPS

CEL-SCI's patented T-cell Modulation Process, referred to as LEAPS (Ligand Epitope Antigen Presentation System), uses "heteroconjugates" to direct the body to choose a specific immune response. LEAPS is designed to stimulate the human immune system to more effectively fight bacterial, viral and parasitic infections as well as autoimmune, allergies, transplantation rejection and cancer, when it cannot do so on its own. Administered like a vaccine, LEAPS combines T-cell binding ligands with small, disease associated, peptide antigens and may provide a new method to treat and prevent certain diseases.

The ability to generate a specific immune response is important because many diseases are often not combated effectively due to the body's selection of the "inappropriate" immune response. The capability to specifically reprogram an immune response may offer a more effective approach than existing vaccines and drugs in attacking an underlying disease.

Using the LEAPS technology, we have created a potential peptide treatment for H1N1 (swine flu) hospitalized patients. This LEAPS flu treatment is designed to focus on the conserved, non-changing epitopes of the different strains of Type A Influenza viruses (H1N1, H5N1, H3N1, etc.), including "swine", "avian or

bird", and "Spanish Influenza", in order to minimize the chance of viral "escape by mutations" from immune recognition. Therefore one should think of this treatment not really as an H1N1 treatment, but as a pandemic flu treatment. CEL-SCI's LEAPS flu treatment contains epitopes known to be associated with immune protection against influenza in animal models.

Additional work on this treatment for the pandemic flu work is being pursued in collaboration with the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health, USA. In May 2011 NIAID scientists presented data at the Keystone Conference on "Pathogenesis of Influenza: Virus-Host Interactions" in Hong Kong, China, showing the positive results of efficacy studies in mice of L.E.A.P.S. H1N1 activated dendritic cells (DCs) to treat the H1N1 virus. Scientists at the NIAID found that H1N1-infected mice treated with LEAPS-H1N1 DCs showed a survival advantage over mice treated with control DCs. The work was performed in collaboration with scientists led by Kanta Subbarao, M.D., Chief of the Emerging Respiratory Diseases Section in NIAID's Division of Intramural Research, part of the National Institutes of Health, USA.

In July 2013, CEL-SCI announced the publication of the results of additional influenza studies by researchers from the NIAID in the Journal of Clinical Investigation (www.jci.org/articles/view/67550). The studies described in the publication show that when CEL-SCI's investigational J-LEAPS Influenza Virus treatments were used "in vitro" to activate immune cells called dendritic cells (DCs), these activated dendritic cells, when injected into influenza infected mice, arrested the progression of lethal influenza virus infection in these mice. The work was performed in the laboratory of Dr. Subbarao.

With our LEAPS technology, we have also developed a second peptide named CEL-2000, a potential rheumatoid arthritis vaccine. The data from animal studies of rheumatoid arthritis using the CEL-2000 treatment vaccine demonstrated that CEL-2000 is an effective treatment against arthritis with fewer administrations than those required by other anti-rheumatoid arthritis treatments, including Enbrel(R). CEL-2000 is also potentially a more disease type-specific therapy, is calculated to be significantly less expensive, and may be useful in patients unable to tolerate or who may not be responsive to existing anti-arthritis therapies.

RISK FACTORS

Investing in our common stock and warrants involves significant risks. You should carefully consider the "Risk Factors" included and incorporated by reference in the accompanying prospectus, this prospectus supplement and any other applicable prospectus supplement, including the risk factors incorporated by reference from our most recent Annual Report on Form 10-K for the fiscal year ended September 30, 2013, as updated by our Quarterly Report on Form 10-Q for the period ended December 31, 2013 and our other filings with the SEC, filed after the Annual Report. The risks and uncertainties we described are not the only ones facing us. Additional risks not presently known to us, or that we currently deem immaterial, may also impair our business operations. If any of these risks were to occur, our business, financial condition, or result of operations would likely suffer. In that event, the trading price of our common stock would decline, and you could lose all or part of your investment.

Management will have broad discretion as to the use of the proceeds of this offering.

We currently intend to use the net proceeds from this offering for our

Phase III clinical trial, other research and development, and general and administrative expenses. See "Use of Proceeds" on page 12. We have not designated the amount of net proceeds we will receive from this offering for any particular purpose. Accordingly, our management will have broad discretion as to the application of these net proceeds and could use them for purposes other than those contemplated at the time of this offering. You will be relying on the judgment of our management with regard to the use of these net proceeds, and you will not have the opportunity, as part of your investment decision, to assess whether the net proceeds are being used appropriately. It is possible that the net proceeds will be invested in a way that does not yield a favorable, or any, return for us. The failure of our management to use such funds effectively could have a material adverse effect on our business, financial condition, operating results and cash flow.

You will experience immediate and substantial dilution.

Since the offering price of the securities offered pursuant to this prospectus supplement and the accompanying prospectus is higher than the net tangible book value per share of our common stock, you will suffer substantial dilution in the net tangible book value of the common stock you purchase in this offering. After giving effect to the sale of _____ shares of common stock and _____ warrants in this offering at the public offering price shown on the cover page of this prospectus, and after deducting estimated underwriting

commissions and estimated offering expenses payable by us, if you purchase securities in this offering, you will suffer immediate and substantial dilution of approximately $___ per share in the net tangible book value of the common stock you acquire. See the "Dilution" section of this prospectus supplement for a more detailed discussion of the dilution you will incur if you purchase securities in this offering.

You may experience future dilution as a result of future equity offerings or other equity issuances.

We expect that significant additional capital will be needed in the future to continue our planned operations. To raise additional capital, we may in the future offer additional shares of our common stock or other securities convertible into or exchangeable for our common stock. We cannot assure you that we will be able to sell shares or other securities in any other offering at a price per share that is equal to or greater than the price per share paid by investors in this offering. The price per share at which we sell additional shares of our common stock or other securities convertible into or exchangeable for our common stock in future transactions may be higher or lower than the price per share in this offering. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. If we sell common stock, convertible securities or other equity securities, your investment in our common stock will be diluted. These sales may also result in material dilution to our existing shareholders, and new investors could gain rights superior to our existing shareholders.

Our outstanding options and warrants may adversely affect the trading price of our common stock.

As of March 31, 2014, there were outstanding options which allows the holders to purchase approximately 6,000,000 shares of our common stock, at prices ranging between $0.85 and $20.00 per share, outstanding warrants which allow the holders to purchase approximately 35,132,000 shares of our common stock, at prices ranging between $0.53 and $17.50 per share, and a convertible

note which allows the holder to acquire approximately 276,000 shares of our common stock at a conversion price of $4.00. The outstanding options and warrants could adversely affect our ability to obtain future financing or engage in certain mergers or other transactions, since the holders of options and warrants can be expected to exercise them at a time when we may be able to obtain additional capital through a new offering of securities on terms more favorable to us than the terms of the outstanding options and warrants. For the life of the options, warrants and the convertible note, the holders have the opportunity to profit from a rise in the market price of our common stock without assuming the risk of ownership. The issuance of shares upon the exercise of outstanding options and warrants, or the conversion of the note, will also dilute the ownership interests of our existing stockholders.

We may have exposure for certain securities we sold in October 2013.

In September 2012, we filed a shelf registration statement covering the sale of $50,000,000 of securities (the "2012 Registration Statement"), and in January 2013 we filed another shelf registration statement covering the sale of an additional $50,000,000 of securities (the "2013 Registration Statement"). In October 2013, we filed a prospectus supplement to the 2012 Registration

Statement for the sale in an underwritten public offering of 17,826,087 shares of our common stock, 20,475,000 Series S Warrants, as well as up to 20,475,000 shares of common stock issuable upon the exercise of the Series S warrants (the "October Prospectus"). Collectively, we offered approximately $43.4 million of securities pursuant to the October Prospectus. This amount includes approximately $17.8 million for the sale of the common stock and Series S warrants and $25.6 million upon the exercise of the Series S Warrants. We subsequently realized that at the time of the October 2013 offering we had approximately $28.9 million available for issuance under the 2012 Registration Statement. As a result, we issued securities that were not registered with the SEC, and that may not have been eligible for an exemption from registration under the federal or state securities laws. We had securities available under the 2013 Registration Statement to register all of the securities not covered by the 2012 Registration Statement. In December 2013, we filed a prospectus supplement to the 2013 Registration Statement registering the offer and sale of all of the shares of common stock issuable upon exercise of the Series S Warrants included in the October 2013 offering to assure that the offering and sale of all of the shares issuable upon exercise of the Series S Warrants were registered (the "December Prospectus"). Prior to the filing of the December Prospectus, no Series S Warrants issued in the October offering had been exercised. Notwithstanding the above, the actions we have taken to mitigate our possible non-compliance with securities laws will not prevent regulators from asserting that we violated the law, from imposing penalties and fines against us with respect to any potential violations of securities laws, and may subject us to possible claims for damages from certain investors.