CEL SCI CORP
Form 424B5
May 06, 2015
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Filed Pursuant to Rule 424(b)(5)
Registration No. 333-196243

The information in this preliminary prospectus supplement is not complete and may be changed. This preliminary prospectus supplement and the accompanying prospectus are not an offer to sell these securities and we are not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED MAY 6, 2015

PRELIMINARY PROSPECTUS SUPPLEMENT

(To Prospectus dated July 8, 2014)

$35,000,000

Common Stock

CEL-SCI Corporation is selling $35,000,000 of shares of its common stock.

Our common stock is listed on the NYSE MKT under the symbol CVM. On May 5, 2015, the last sale price of our common stock as reported on the NYSE MKT was $1.03 per share.

Investing in our common stock involves a high degree of risk. See Risk Factors beginning on page S-10 of this prospectus supplement and the risks set forth under the caption Item 1A. Risk Factors included in our most recent Annual Report on Form 10-K/A, which is incorporated by reference herein, for certain risks relevant to an investment in shares of our common stock.

	Per Share	Total
Public offering price[(1)]	$	$

Underwriting discounts and commissions[2]	$	$
Proceeds, before expenses, to us	$	$

(1) The underwriter may also exercise its option to purchase up to an additional shares from us, at the public offering price, less the underwriting discount, for 30 days after the date of this prospectus supplement.

(2) Please see Underwriting beginning on page S-50 of this prospectus supplement for additional information regarding the underwriting arrangement.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus supplement is truthful or complete. Any representation to the contrary is a criminal offense.

The underwriter expects to deliver shares of our common stock on or about , 2015.

Sole Book-Running Manager

FBR

Prospectus Supplement dated , 2015

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Prospectus Supplement

PROSPECTUS

You should rely only on the information contained in this prospectus supplement and the accompanying prospectus, any document incorporated or deemed to be incorporated by reference in this prospectus supplement and the accompanying prospectus and any free writing prospectus that we may prepare in connection with this offering. Neither we nor the underwriter has authorized anyone to provide you with any additional or different information. If anyone provides you with any additional or different information, you should not rely on it. Neither this prospectus supplement nor the accompanying prospectus, nor any such free writing prospectus, is an offer to sell or a solicitation of an offer to buy any securities other than the common stock to which it relates, or an offer to sell or the solicitation of an offer to buy securities in any jurisdiction where, or to any person to whom, it is unlawful to make an offer or solicitation. You should not assume that the information contained in this prospectus supplement, the accompanying prospectus, any document incorporated or deemed to be incorporated by reference in this prospectus supplement and the accompanying prospectus, or any free writing prospectus that we may prepare in connection with this offering is correct on any date after their respective dates. Our business, financial condition, liquidity, results of operations and prospects may have changed since those respective dates.

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ABOUT THIS PROSPECTUS SUPPLEMENT

This document forms part of a registration statement that we filed with the Securities and Exchange Commission, or the SEC, using a shelf registration process. This document is in two parts. The first part consists of this prospectus supplement, including the documents incorporated by reference herein, which describes the specific terms of this offering. The second part, the accompanying prospectus, including the documents incorporated by reference therein, provides more general information. We urge you to carefully read this prospectus supplement and the accompanying prospectus, and the documents incorporated herein and therein, before buying any of the securities being offered by this prospectus supplement and the accompanying prospectus. This prospectus supplement may add, update or change information contained in the accompanying prospectus. To the extent that any statement that we make in this prospectus supplement is inconsistent with statements made in the accompanying prospectus or any documents incorporated by reference therein, the statements made in this prospectus supplement will be deemed to modify or supersede those made in the accompanying prospectus and such documents incorporated by reference therein. In addition, any statement in a filing we make with the SEC that adds to, updates or changes information contained in an earlier filing we made with the SEC shall be deemed to modify and supersede such information in the earlier filing.

This prospectus supplement, the accompanying prospectus, and the information incorporated by reference herein and therein, may include trademarks, service marks and trade names owned by us or other companies. All trademarks, service marks and trade names included or incorporated by reference into this prospectus supplement or the accompanying prospectus are the property of their respective owners.

In this prospectus supplement, unless otherwise specified or the context requires otherwise, we use the terms CEL-SCI, the Company, we, us and our to refer to CEL-SCI Corporation. Our fiscal year ends on September 30.

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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 shares of our common stock. 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 this prospectus supplement and the accompanying prospectus, the financial statements and other information incorporated by reference in this prospectus supplement and the accompanying prospectus when making an investment decision.

Our Company

We are dedicated to research and development directed at improving the treatment of cancer and other diseases by using the immune system, the body s natural defense system. We are currently focused on the development of the following product candidates and technologies:

1) Multikine® (Leukocyte Interleukin, Injection), or Multikine, an investigational immunotherapy under development as a potential neoadjuvant therapy in patients with squamous cell carcinoma of the head and neck, or SCCHN, which is a type of head and neck cancer, and anal warts or cervical dysplasia in human immunodeficiency virus, or HIV, and human papillomavirus, or HPV co-infected patients;

2) L.E.A.P.S. (Ligand Epitope Antigen Presentation System) technology, or LEAPS, with two investigational therapies, LEAPS-H1N1-DC, a product candidate under development for the potential treatment of pandemic influenza in hospitalized patients, and CEL-2000, a vaccine product candidate under development for the potential treatment of rheumatoid arthritis.

The following chart depicts our product candidates, their indications and their current stage of development:

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 1 and Phase 2 clinical trials suggest that Multikine simulates the activities of a healthy person s immune system, enabling it to

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use the body s own anti-tumor immune response. Multikine is the trademark we have registered for this investigational therapy, and this proprietary name is subject to review by the U.S. Food and Drug Administration, or FDA, 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 is an immunotherapy product candidate comprised of a patented defined mixture of 14 human natural cytokines and is manufactured in a proprietary manner in our manufacturing facility. We spent over 10 years and more than $80 million developing and validating the manufacturing process. The pro-inflammatory cytokine mixture includes interleukins, interferons, chemokines and colony-stimulating factors, which contain elements of the body s natural mix of defenses against cancer.

Multikine is designed to be used in a different way than immune therapy is usually used. It is designed to be administered locally to treat local tumors before any other therapy has been administered. For example, in the ongoing Phase 3 clinical trial, Multikine is injected locally at the site of the tumor and near the adjacent draining lymph nodes as a first line of treatment before surgery, radiation and/or chemotherapy because that is when the immune system is thought to be strongest. The goal is to help the intact immune system recognize and kill the micro metastases that usually cause recurrence of the cancer. In short, we believe that local administration and administration before weakening of the immune system by chemotherapy and radiation will result in better anti-tumor response than if Multikine were administered as a second- or later-line therapy. In clinical studies of Multikine, administration of the investigational therapy to head and neck cancer patients has demonstrated the potential for less or limited to no appreciable toxicity.

The first indication we are pursuing for our Multikine product candidate is an indication for neoadjuvant therapy in patients with squamous cell carcinoma of the head and neck, or SCCHN. Multikine investigational immunotherapy was granted Orphan Drug designation for neoadjuvant therapy in patients with SCCHN by the FDA in the United States. SCCHN is a type of head and neck cancer, and we believe that the head and neck cancer market, in the aggregate, represents a large, unmet medical need. The last FDA approval of a therapy for the treatment of advanced primary head and neck cancer was over 50 years ago. In the aggregate, head and neck

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cancer represents about 6% of the world s cancer cases, with over 650,000 patients diagnosed worldwide each year, and nearly 60,000 patients diagnosed annually in the United States.

Current Status of Ongoing Phase 3 Clinical Trial

Regulatory authorities in 21 countries around the world, including the FDA in the United States, have allowed Multikine to be studied in a global Phase 3 clinical trial as a potential neoadjuvant therapy in patients with SCCHN. This trial is currently primarily under the management of two clinical research organizations, or CROs, Aptiv Solutions, Inc., or Aptiv, and Ergomed Clinical Research Limited, or Ergomed, which are adding clinical centers in an effort to increase the speed of patient enrollment.

Pursuant to the co-development agreement we entered into with Ergomed in April 2013, Ergomed is responsible for the majority of the new patient enrollment. Enrollment in 2014 increased approximately 800% over 2013, and the following chart depicts the number of patients enrolled per month since our transfer to the new CROs:

Although we are aiming to enroll 880 patients, our Phase 3 study requires a total of 784 evaluable patients. Ergomed s goal is to reach full enrollment of the targeted number of 880 patients by the end of 2015; however, we are estimating that such enrollment will be completed in March 2016. In order to complete the targeted enrollment of 880 patients by March 2016, we are assuming a 4.3% increase in patients enrolled per month based on our enrolling 31 patients during April 2015, up from 29 patients in March 2015, and based on a total enrollment of 437 patients as of April 30, 2015. Following full enrollment of the study, we have to wait for 298 events (deaths) in the two comparator arms combined to determine if we have met our primary endpoint, which is a 10% increase in overall survival in the Multikine arm over the comparator arm. We estimate that the final data read-out of this Phase 3 clinical trial could occur by the second half of 2017, based on our enrollment projections and estimated survival curves provided in scientific literature.

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Of the 437 patients that have been enrolled in the study, uncertainty remains as to whether up to 117 patients enrolled during our former CRO s tenure as the global manager of the Phase 3 clinical trial will be considered to be evaluable subjects at the close of the study. We are currently engaged in a contract dispute alleging that the former CRO failed to comply with the protocol for the Phase 3 clinical trial and applicable regulatory requirements. We do not believe that we will need to replace all 117 of these patients, but assuming that all of these patients must be replaced, we estimate that it could take an additional two to three months to do so based on our current expectations of enrolling approximately 50 patients per month at the end of the scheduled enrollment period. However, the Phase 3 study design anticipates enrollment of a total of 880 patients, while the statistical analysis requires a total of 784 evaluable patients. Therefore, the actual number of patients enrolled by our former CRO that will need to be replaced and the time needed to do so cannot be determined at this time.

We estimate that the total remaining cost of the Phase 3 trial, excluding any costs that will be paid by our partners, will be approximately $24.4 million after March 31, 2015. This is in addition to the approximately $20.2 million that we have spent on the trial as of March 31, 2015. This estimate is based on information currently available under our contracts with the CROs responsible for managing the Phase 3 trial. This number may be affected by the rate of patient enrollment, foreign currency exchange rates and many other factors, some of which cannot be foreseen today. It is therefore possible that the cost of the Phase 3 trial will be higher than currently estimated.

The current standard of care, or SOC, treatment regimen for advanced primary head and neck cancer patients consists of surgical resection of the tumor and involved lymph nodes, followed by either radiotherapy alone or radiotherapy and concurrent chemotherapy. Our ongoing Phase 3 trial is testing the hypothesis that Multikine treatment, administered prior to such SOC treatment regimen, will extend overall survival, enhance the local/regional control of the disease and reduce the rate of disease progression in patients with squamous cell carcinoma of the head and neck.

The primary clinical endpoint in our ongoing Phase 3 clinical trial is the achievement of a 10% improvement in overall survival in the Multikine plus SOC treatment arm over that which is achieved in the SOC treatment arm alone (all subjects in the Phase 3 study will receive SOC). Based on what is presently known about the current survival statistics for this population, we believe that achievement of this endpoint should enable us, subject to further consultations with the FDA, to move forward, prepare and submit a Biologic License Application, or BLA, to the FDA for Multikine as neoadjuvant therapy in patients with SCCHN.

In our Phase 3 clinical trial, Multikine is administered 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 3 clinical trial.

Throughout the course of the Phase 3 study thus far, an Independent Data Monitoring Committee, or IDMC, has met periodically to review safety data from the Phase 3 study, and the IDMC is expected to continue doing so throughout the remainder of the Phase 3 study. At the various points in the study thus far at which the IDMC has completed review of the safety data it has indicated that safety signals have not been identified thus far in the Phase 3 study that would call into question the benefit/risk of continuing the study and has recommended that the Phase 3 study may continue. Ultimately, the decision as to whether a drug is safe (and whether it is effective) is made by the FDA and other regulatory authorities based upon an assessment of all of the data from an entire drug development program submitted in an application for marketing approval.

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Follow-Up Analysis of Overall Survival in Phase 2 Patients

The following is a summary of results from our last Phase 2 study conducted with Multikine. This study employed the same treatment protocol as is being followed in our Phase 3 study:

In a follow-up analysis of the Phase 2 clinical study population, which used the same dosage and treatment regimen as is being used in the Phase 3 study, head and neck cancer patients with locally advanced primary disease who received our investigational therapy Multikine as first-line investigational therapy, followed by surgery and radiotherapy, or surgery and chemoradiotherapy, were reported by the clinical investigators to have had a 63.2% overall survival, or OS, rate at a median of 3.3 years from surgery. This percentage of OS was arrived at as follows: of the 21 subjects enrolled in the Phase 2 study, the consent for the survival follow-up portion of the study was received from 19 subjects. OS was calculated using the entire treatment population that consented to the follow-up portion of the study (19 subjects), including two subjects who, as later determined by three pathologists blinded to the study, did not have oral squamous cell carcinoma, or OSCC, which is a type of SCCHN. These two subjects were thus not evaluable per the protocol and were not included in the pathology portion of the study for purposes of calculating complete response rate, as described below, but were included in the OS calculation. The overall survival rate of subjects receiving the investigational therapy in this study was compared to the overall survival rate that was calculated based upon a review of 55 clinical trials conducted in the same cancer population (with a total of 7,294 patients studied), and reported in the peer reviewed scientific literature between 1987 and 2007. Review of this literature showed an approximate survival rate of 47.5% at 3.5 years from treatment. Therefore, the results of our final Phase 2 study were considered to be potentially favorable in terms of overall survival, recognizing the limitations of this early-phase study. It should be noted that an earlier investigational therapy Multikine study appears to lend support to the overall survival findings described above Feinmesser et al Arch Otolaryngol. Surg. 2003. However, no definitive conclusions can be drawn from these data about the potential efficacy or safety profile of this investigational therapy. Moreover, further research is required, and these results must be confirmed in the Phase 3 clinical trial of this investigational therapy that is currently in progress. Subject to completion of that Phase 3 trial, and the FDA s review and acceptance of our entire data set on this investigational therapy, we believe that these early-stage clinical trial results indicate the potential for our Multikine product candidate to become a neoadjuvant therapy in patients with SCCHN, if approved.

Reported average of 50% reduction in tumor cells in Phase 2 trials (based on 19 patients evaluable by pathology, having OSCC): The clinical investigators who administered the three-week Multikine treatment regimen used in the Phase 2 study reported that, as was determined in a controlled pathology study, Multikine administration appeared to have caused, on average, the disappearance of about half of the cancer cells present at surgery (as determined by histopathology assessing the area of Stroma/Tumor (Mean+/- Standard Error of the Mean of the number of cells counted per filed)) even before the start of standard therapy, which normally includes surgery, radiation and chemotherapy (Timar et al JCO 2005).

Reported 10.5% complete response in the Phase 2 trial (based on 19 patients evaluable by pathology, having OSCC): The clinical investigators who administered the three-week Multikine investigational treatment regimen used in the Phase 2 study reported that, as was determined in a controlled pathology study, the tumor apparently was no longer present (as determined by histopathology) in approximately 10.5% of evaluable patients with OSCC. In the original study, 21 subjects received Multikine, two of which were later excluded, as subsequent analysis by three pathologists blinded to the study revealed that these two patients did not have OSCC. Two subjects in this study had a complete response, leaving a reported complete response rate of two out of 19 assessable subjects with OSCC (or 10.5%) (Timar et al, JCO 2005).

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Subsequently, an analysis on the 21 subjects originally treated with Multikine in the study to evaluate overall survival was conducted, as described above. In connection with the follow-up portion of the study for overall survival, we also conducted an unreported post-hoc analysis of complete response rate in the study population, which included subjects who provided consent for the follow-up and who also had OSCC. Two out of the 21 subjects did not re-consent for follow-up, and two of the remaining 19 subjects were excluded from the post-hoc complete response rate analysis as they had previously been determined by pathology analysis to not have OSCC. The two complete responders with OSCC both consented to the follow-up study. Therefore, the post-hoc analysis of complete response was based on a calculation of the two complete responders out of 17 evaluable subjects who consented to the follow-up analysis and who also had OSCC (or 11.8%).

Furthermore, we reported an overall response rate of 42.1% based on the number of evaluable patients who experienced a favorable response to the treatment, including those who experienced minor, major and complete responses. Out of the 19 evaluable patients, two experienced a complete response, two experienced a major response, and four experienced a minor response to treatment. Thus, we calculated the number of patients experiencing a favorable response as eight patients out of 19 (or 42.1%) (Timar et al, JCO 2005).

Peri-Anal Warts and Cervical Dysplasia in HIV/HPV Co-Infected Patients

HPV is a very common sexually transmitted disease in the United States and also other parts of the world. It can lead to cancer of the cervix, penis, anus, esophagus and head and neck. Our focus in HPV, however, is not on developing an antiviral for the potential treatment or prevention of HPV in the general population. Instead, our focus is on developing an immunotherapy product candidate designed to be administered to patients who are immune-suppressed by other diseases, such as HIV, and who are therefore less able or unable to control HPV and its resultant or co-morbid diseases. Such patients have limited treatment options available to them.

One condition that is commonly associated with both HIV and HPV is the occurrence of anal intraepithelial dysplasia, or AIN, and anal and genital warts. The incidence of AIN in HIV-infected people is estimated to be about 25%. The incidence of anal HPV infection in HIV-infected men who have sex with men, or MSM, is estimated to be as high as 95%. In the aggregate, the United States and Europe have about 875,000 HIV-infected patients with AIN (assuming AIN prevalence of approximately 25% of the aggregate HIV-infected population). Persistent HPV infection in the anal region is thought to be responsible for up to 80% of anal cancers, and men and women who are HIV positive have a 30-fold increase in their risk of anal cancer. Persistent HPV infection can also be a precursor to cervical cancer, as well as certain head and neck cancers.

On October 7, 2013, we announced a cooperative research and development agreement, or CRADA, with the U.S. Naval Medical Center, San Diego, or the USNMC. Pursuant to this agreement, the USNMC will conduct a Phase 1 study, approved by the Human Subjects Institutional Review Board, of our investigational immunotherapy, Multikine, in HIV/HPV co-infected men and women with peri-anal warts. The purpose of this study is to evaluate the safety and clinical impact of Multikine as a potential treatment of peri-anal warts and assess its effect on AIN in HIV/HPV co-infected men and women.

Pursuant to the CRADA, we are contributing the investigational study drug Multikine for use in this Phase 1 study, and we will retain all rights to any currently-owned technology and will have the right to exclusively license any new technology developed from the collaboration. In October 2013, we also entered into a co-development and profit sharing agreement with Ergomed for development of Multikine as a potential treatment of HIV/HPV co-infected men and women with peri-anal warts. This agreement will initially be in support of the development with the USNMC.

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On September 29, 2014, we announced that the first volunteer patient had been enrolled and administered Multikine in this Phase 1 study, which is currently ongoing. If we are able to add an additional Key Opinion Leader, or KOL, we believe that we will complete patient enrollment by the second half of 2015, and that the Phase 1 results will occur in the first half of 2016.

The treatment regimen for this Phase 1 study of up to 15 HIV/HPV co-infected patient volunteers with peri-anal warts, being conducted by the USNMC, is identical to the regimen that was used in an earlier Institutional Review Board-approved Multikine Phase 1 study in HIV/HPV co-infected patients, which was conducted at the University of Maryland. In that study, our Multikine investigational therapy was administered to HIV/HPV co-infected women with cervical dysplasia, resulting in visual and histological evidence of clearance of lesions in three out of the eight subjects.

Furthermore, in this earlier Phase 1 study, the number of HPV viral sub-types in three volunteer subjects tested were reduced post-treatment with Multikine, as opposed to pre-treatment, as determined by in situ polymerase chain reaction 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.

In October 2013, we entered into a co-development and profit sharing agreement with Ergomed for Multikine in HIV/HPV co-infected women with cervical dysplasia.

MANUFACTURING FACILITY

Before starting the Phase 3 trial, we needed a dedicated manufacturing facility to produce Multikine. In 2007, the build out of a facility near Baltimore, Maryland commenced in accordance with our specifications. We took delivery of this facility in the fall of 2008 and validated it in 2009 and 2010. The aggregate construction cost was approximately $25 million, of which we funded approximately $10 million. The facility has been subject to inspection by a European Union Qualified Person on two different occasions with no major observations, and we have produced multiple clinical lots for the Phase 3 clinical trial at this facility. In addition to using this facility to manufacture Multikine, we may, but only if the facility is not being used to manufacture Multikine, offer the use of the facility as a service to pharmaceutical companies and others, particularly those that need to fill and finish their drugs in a cold environment (4 degrees Celsius, or approximately 39 degrees Fahrenheit). However, we intend to give priority to Multikine as management considers the Multikine supply to the clinical studies and preparation for a marketing approval application to be more important than offering fill and finish services. Fill and finish is the process of filling injectable drugs in a sterile manner and is a key part of the manufacturing process for many medicines. Our lease on the manufacturing facility expires on October 31, 2028, and we may, at our election, extend the lease for two ten-year periods or purchase the building at the end of the initial lease term.

LEAPS

Our patented T-cell Modulation Process, referred to as LEAPS (Ligand Epitope Antigen Presentation System), is designed to use 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. Designed to be administered like a vaccine, LEAPS combines T-cell binding ligands with small, disease-associated peptide antigens, and has the potential to 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.

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Using the LEAPS technology, we are developing LEAPS-H1N1-DC, a potential peptide treatment for H1N1 influenza in hospitalized patients. This LEAPS influenza product candidate is designed to focus on the conserved, non-changing epitopes of the different strains of Type A influenza viruses in order to minimize the chance of viral escape by mutations from immune recognition. Type A influenza viruses include strains such as H1N1, H5N1 and H3N1, which are also known as swine influenza, avian or bird influenza, and Spanish influenza, respectively. Therefore, we think of this product candidate as targeting not only an H1N1 indication, but also a pandemic influenza indication. Our LEAPS influenza product candidate contains epitopes known to be associated with immune protection against influenza in animal models.

Additional work on this product candidate for the potential treatment of pandemic influenza is being pursued in collaboration with the National Institute of Allergy and Infectious Diseases, or 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 studies in mice of LEAPS. Infection with the H1N1 virus activated dendritic cells, or 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 the NIAID s Division of Intramural Research, part of the U.S. National Institutes of Health, or NIH.

In July 2013, we announced the publication of the results of additional influenza studies by researchers from the NIAID in the Journal of Clinical Investigation. The studies described in the publication demonstrate that when investigational LEAPS candidate was used in vitro to activate immune cells called dendritic cells, or 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 vaccine product candidate under development for rheumatoid arthritis. In animal studies of rheumatoid arthritis, CEL-2000 therapy demonstrated both a reduction in several parameters of tissue damage and destruction upon histological examination and joint swelling (investigational parameter in this animal study) with fewer administrations than those required by currently-marketed anti-rheumatoid arthritis treatments, including Enbrel®. We believe that CEL-2000 has the potential to be a more disease type-specific therapy, and we plan to price it so that, if successfully developed and approved, it is significantly less expensive than currently marketed rheumatoid arthritis treatments. Further, we believe it has the potential for use in patients unable to tolerate or who may not be responsive to existing anti-arthritis therapies.

In July 2014, we were awarded a Phase 1 Small Business Innovation Research, or SBIR, grant from the National Institute of Arthritis Muscoskeletal and Skin Disease, which is part of the NIH, in the amount of $225,000, of which we have received approximately $90,000 to date. The grant is to fund the further development of vaccines for rheumatoid arthritis and the work is being conducted in collaboration with scientists at Rush University Medical Center in Chicago, Illinois.

Corporate Information

We were formed as a Colorado corporation in 1983. Our principal office is located at 8229 Boone Boulevard, Suite 802, Vienna, Virginia 22182. Our telephone number is 703-506-9460 and our web site is *www.cel-sci.com*. The information contained in, and that which can be accessed through, our website is not incorporated into and does not form a part of this prospectus supplement.

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The Offering

Issuer	CEL-SCI Corporation
Securities offered by us	shares of commons stock, $0.01 par value per share. We have granted the underwriter an option to purchase up to additional shares for 30 days after the date of this prospectus supplement.
Common stock to be outstanding immediately after this offering[(1)]	shares (shares if the underwriter exercises its option to purchase additional shares in full).
Use of proceeds	We estimate that the net proceeds from this offering will be approximately $32.6 million (or $37.5 million if the underwriter exercises its option to purchase additional shares in full) after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. We intend to use the net proceeds from this offering primarily to complete patient enrollment in our Phase 3 clinical trial of Multikine as a neoadjuvant therapy for patients with squamous cell carcinoma of the head and neck, to fund the Phase 1 trial of Multikine in HIV/HPV co-infected patients with anal warts, to repay a $1.1 million note upon maturity in July 2015 and for general corporate purposes. See Use of Proceeds.
Dividend policy	We have not declared or paid any cash or other dividends on our common stock and do not expect to declare or pay any cash or other dividends in the foreseeable future.
Risk factors	Investing in our common stock involves a high degree of risk, and the purchasers of our common stock may lose all or part of their investment. Before deciding to invest in our common stock, please carefully read the section entitled Risk Factors, including the risks incorporated therein from our most recent Annual Report on Form 10-K/A for the year ended September 30, 2014 and our other periodic reports filed with the SEC and incorporated by reference herein.
NYSE MKT trading symbol	CVM

(1) This number is based on 91,608,295 shares outstanding as of May 5, 2015, which excludes (i) 34,833,152 shares that may be issued upon the exercise of outstanding warrants, with a weighted average exercise price of $1.72 per share (including 25,928,010 shares at an exercise price of $1.25 per share), (ii) 276,014 shares that may be issued upon the conversion of an outstanding convertible loan and (iii) 6,743,900 shares that may be issued upon the exercise of outstanding options, with a weighted average exercise price of $3.00 per share. Unless otherwise indicated, the information in this prospectus supplement assumes that the underwriter will not exercise its option to purchase additional shares.

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RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the following risks, the risks described in our Annual Report on Form 10-K/A for the year ended September 30, 2014, as well as the other information and data set forth in this prospectus supplement, the accompanying prospectus and the documents incorporated by reference herein and therein before making an investment decision with respect to our common stock. 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, result of operations and liquidity 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. Some statements in this prospectus supplement, including statements in the following risk factors, constitute forward-looking statements. See Forward-Looking Statements.

Risks Related to CEL-SCI

We have incurred significant losses since inception, and we anticipate that we will continue to incur significant losses for the foreseeable future and may never achieve or maintain profitability.

We have a history of net losses and expect to incur substantial losses and have negative operating cash flow for the foreseeable future, and may never achieve or maintain profitability. Since the date of our formation and through December 31, 2014, we incurred net losses of approximately $247 million. We have relied principally upon the proceeds of the public and private sales of our securities to finance our activities to date. To date, we have not commercialized any products or generated any revenue from the sale of products, and we do not expect to generate any product revenue for the foreseeable future. We do not know whether or when we will generate product revenue or become profitable.

We are heavily dependent on the success of Multikine which is under clinical development. We cannot be certain that Multikine will receive regulatory approval or be successfully commercialized even if we receive regulatory approval. Multikine is our only product candidate in late-stage clinical development, and our business currently depends heavily on its successful development, regulatory approval and commercialization. We have no drug products for sale currently and may never be able to develop approved and marketable drug products.

Even if we succeed in developing and commercializing one or more of our product candidates, we expect to incur substantial losses for the foreseeable future and may never become profitable. We also expect to continue to incur significant operating and capital expenditures and anticipate that our expenses will increase substantially in the foreseeable future as we:

- continue to undertake preclinical development and clinical trials for product candidates;
- seek regulatory approvals for product candidates;
- implement additional internal systems and infrastructure; and
- hire additional personnel.

To become and remain profitable, we must succeed in developing and commercializing our product candidates, which must generate significant revenue. This will require us to be successful in a range of challenging activities, including completing preclinical testing and clinical trials of our product candidates, discovering or acquiring additional product candidates, obtaining regulatory approval for these product candidates and manufacturing, marketing and selling any products for which we may obtain regulatory approval. We are only in the preliminary stages of most of these activities. We may never succeed in these activities and, even if we do, may never generate revenue that is significant enough to achieve profitability.

Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable could depress the value of our company and could

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impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product offerings or even continue our operations. A decline in the value of our company could cause our stockholders to lose all or part of their investment.

We will require substantial additional capital to remain in operation. A failure to obtain this necessary capital when needed could force us to delay, limit, reduce or terminate our product candidates development or commercialization efforts.

As of March 31, 2015, we had cash and cash equivalents of $2.6 million. After giving effect to this offering, we would have had cash and cash equivalents of $35.2 million (or $40.1 million if the underwriter exercises its option to purchase additional shares in full) as of March 31, 2015. We believe that we will continue to expend substantial resources for the foreseeable future developing Multikine, LEAPS and any other product candidates or technologies that we may develop or acquire. These expenditures will include costs associated with research and development, potentially obtaining regulatory approvals and having our products manufactured, as well as marketing and selling products approved for sale, if any. In addition, other unanticipated costs may arise. Because the outcome of our current and anticipated clinical trials is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidates.

Our future capital requirements depend on many factors, including:

- the rate of progress of, results of and cost of completing Phase 3 clinical development of Multikine for the treatment of certain head and neck cancers;
- the results of our applications to and meetings with the FDA, the EMA and other regulatory authorities and the consequential effect on our operating costs;
- assuming favorable Phase 3 clinical results, the cost, timing and outcome of our efforts to obtain marketing approval for Multikine in the United States, Europe and in other jurisdictions, including the preparation and filing of regulatory submissions for Multikine with the FDA, the EMA and other regulatory authorities;
- the scope, progress, results and costs of additional preclinical, clinical, or other studies for additional indications for Multikine, LEAPS and other product candidates and technologies that we may develop or acquire;
- the timing of, and the costs involved in, obtaining regulatory approvals for LEAPS if clinical studies are successful;
- the cost and timing of future commercialization activities for our products, if any of our product candidates are approved for marketing, including product manufacturing, marketing, sales and distribution costs;
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- the cost of having our product candidates manufactured for clinical trials and in preparation for commercialization;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of such agreements;

the costs involved in preparing, filing and prosecuting patent applications and maintaining, defending and enforcing our intellectual property rights, including litigation costs, and the outcome of such litigation; and

the extent to which we acquire or in-license other products or technologies.

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Based on our current operating plan, and absent any future financings or strategic partnerships, we believe that the net proceeds we receive from this offering (assuming the underwriter does not exercise its option to purchase additional shares) and our existing cash and cash equivalents and investments will be sufficient to fund our projected operating expenses and capital expenditure requirements through the second quarter of 2016. However, our operating plan may change as a result of many factors currently unknown to us, and we may need additional funds sooner than planned. Additional funds may not be available when we need them on terms that are acceptable to us, or at all. If adequate funds are not available to us on a timely basis, we may be required to delay, limit, reduce or terminate preclinical studies, clinical trials or other development activities for Multikine, LEAPS, or any other product candidates or technologies that we develop or acquire, or delay, limit, reduce or terminate our establishment of sales and marketing capabilities or other activities that may be necessary to commercialize our product candidates.

The costs of our product candidate development and clinical trials are difficult to estimate and will be very high for many years, preventing us from making a profit for the foreseeable future, if ever.

Clinical and other studies necessary to obtain approval of a new drug can be time consuming and costly, especially in the United States, but also in foreign countries. Our estimates of the costs associated with future clinical trials and research may be substantially lower than what we actually experience. It is impossible to predict what we will face in the development of a product candidate, such as Multikine. The purpose of clinical trials is to provide both us and regulatory authorities with safety and efficacy data in humans. It is relatively common to revise a trial or add subjects to a trial in progress. These examples of common variances in product development and clinical investigations demonstrate how predicted costs may exceed reasonable expectations. The difficult and often complex steps necessary to obtain regulatory approval, especially that of the FDA, and the European Union s European Medicine s Agency, or EMA, involve significant costs and may require several years to complete. We expect that we will need substantial additional financing over an extended period of time in order to fund the costs of future clinical trials, related research, and general and administrative expenses.

The extent of our clinical trials and research programs are primarily based upon the amount of capital available to us and the extent to which we receives regulatory approvals for clinical trials. We have established estimates of the future costs of the Phase 3 clinical trial for Multikine, but, as explained above, that estimate may not prove correct.

An adverse determination in any current or future lawsuits or arbitration proceedings to which we are a party could have a material adverse effect on us.

We are currently involved in a pending arbitration proceeding, *CEL-SCI Corporation v. inVentiv Health Clinical, LLC (f/k/a PharmaNet LLC) and PharmaNet GmbH (f/k/a PharmaNet AG)*. We initiated the proceedings against inVentiv Health Clinical, LLC, or inVentiv, our former third-party CRO, seeking at least $50 million in damages related to inVentiv s prior involvement in our ongoing Phase 3 clinical trial of Multikine. In connection with the pending arbitration proceedings, inVentiv has asserted counterclaims against us for (i) breach of contract, seeking at least $2 million in damages for services allegedly performed by inVentiv; (ii) breach of contract, seeking at least $1 million in damages for our alleged use of inVentiv s name in connection with publications and promotions in violation of the parties contract; (iii) opportunistic breach, restitution and unjust enrichment, seeking at least $20 million in disgorgement of alleged unjust profits allegedly made by us as a result of the purported breaches referenced in subsection (ii); and (iv) defamation, seeking at least $1 million in damages for allegedly defamatory statements made about inVentiv. We believe inVentiv s counterclaims are meritless and intend to vigorously defend against them. However, if such defense is unsuccessful, and inVentiv successfully asserts any of its counterclaims, such an adverse determination could have a material adverse effect on our business, results, financial condition and liquidity. The arbitration hearing on the merits has been tentatively rescheduled for October 27, 2015 through November 17, 2015.

Additionally, we may also be the target of claims asserting violations of securities and fraud and abuse laws and derivative actions, or other litigation or arbitration proceedings in the future. Any future litigation could

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result in substantial costs and divert our management s attention and resources. These lawsuits or arbitration proceedings may result in large judgments or settlements against us, any of which could have a material adverse effect on our business, operating results, financial condition and liquidity.

Compliance with changing regulations concerning corporate governance and public disclosure may result in additional expenses.

Changing laws, regulations and standards relating to corporate governance and public disclosure may create uncertainty regarding compliance matters. New or changed laws, regulations and standards are subject to varying interpretations in many cases. As a result, their application in practice may evolve over time. We are committed to maintaining high standards of corporate governance and public disclosure. Complying with evolving interpretations of new or changing legal requirements may cause us to incur higher costs as we revises current practices, policies and procedures, and may divert management time and attention from potential revenue-generating activities to compliance matters. If our efforts to comply with new or changed laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to practice, our reputation may also be harmed. Further, our board members, chief executive officer, president and other executive officers could face an increased risk of personal liability in connection with the performance of their duties. As a result, we may have difficulty attracting and retaining qualified board members and executive officers, which could harm our business.

We have not established a definite plan for the marketing of Multikine, if approved.

We have not established a definitive plan for marketing nor have we established a price structure for any of our product candidates, if approved. However, we intend, if we are in a position to do so, to sell Multikine ourselves in certain markets where it is approved, and or to enter into written marketing agreements with various third parties with established sales forces in such markets. The sales forces in turn would, we believe, focus on selling Multikine to targeted cancer centers, physicians and clinics involved in the treatment of head and neck cancer. We have already licensed future sales of Multikine, if approved, to three companies: Teva Pharmaceuticals in Israel, Turkey, Serbia and Croatia; Orient Europharma in Taiwan, Singapore, Hong Kong, Malaysia, South Korea, the Philippines, Australia and New Zealand; and Byron BioPharma, LLC in South Africa. We believe that these companies will have the resources to market Multikine appropriately in their respective territories, if approved, but there is no guarantee that they will. There is no assurance that we will be able to find qualified third-party partners to market our product in other areas, on terms that are favorable to us, or at all.

We may encounter problems, delays and additional expenses in developing marketing plans with third parties. In addition, even if Multikine, if approved, is cost-effective and demonstrated to increase overall patient survival, we may experience other limitations involving the proposed sale of Multikine, such as uncertainty of third-party coverage and reimbursement. There is no assurance that we can successfully market Multikine, if approved, or any other product candidates we may develop.

We hope to expand our clinical development capabilities in the future, and any difficulties hiring or retaining key personnel or managing this growth could disrupt our operations.

We are highly dependent on the principal members of our management and development staff. If the ongoing Phase 3 Multikine clinical trial is successful, we expect to expand our clinical development and manufacturing capabilities, which will involve hiring additional employees. Future growth will require us to continue to implement and improve our managerial, operational and financial systems and to continue to retain, recruit and train additional qualified personnel, which may impose a strain on our administrative and operational infrastructure. The competition for qualified personnel in the biopharmaceutical field is intense. We are highly dependent on our ability to attract, retain and motivate highly qualified management and specialized personnel required for clinical development. Due to our limited resources, we may not be able to manage effectively the expansion of our operations or recruit and train additional qualified personnel. If we are unable to retain key personnel or manage our future growth effectively, we may not be able to implement our business plan.

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If product liability or patient injury lawsuits are brought against us, we may incur substantial liabilities and may be required to limit clinical testing or future commercialization of Multikine or our other product candidates.

We face an inherent risk of product liability as a result of the ongoing clinical testing of Multikine and other product candidates, and will face an even greater risk if we commercialize any of our product candidates. For example, we may be sued if our Multikine or LEAPS product candidates, or any other future product candidates, allegedly cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing or, if approved, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product candidate, negligence, strict liability and a breach of warranties. Claims could also be asserted under state consumer protection acts.

Furthermore, Multikine is made, in part, from components of human blood. There are inherent risks associated with products that involve human blood such as possible contamination with viruses, including hepatitis or HIV. Any possible contamination could cause injuries to patients who receive such contaminated Multikine, or could require us to destroy batches of Multikine, thereby subjecting us to possible financial losses, lawsuits and harm to our business.

If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit or cease the clinical testing or commercialization of our product candidates, if approved. Even a successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for Multikine or our other product candidates, if approved;
- injury to our reputation;
- withdrawal of existing, or failure to enroll additional, clinical trial participants;
- costs to defend any related litigation;
- a diversion of management s time and our resources;
- substantial monetary awards to trial participants or patients;
- product candidate recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- inability to commercialize Multikine or our other product candidates; and
- a decline in the price of our common stock.

Although we have product liability insurance for Multikine in the amount of $5.0 million, the successful prosecution of a product liability case against us could have a materially adverse effect upon our business if the amount of any judgment exceeds our insurance coverage. Any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions, and we may be subject

to a claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. We commenced the Phase 3 clinical trial for Multikine in December 2010. Although no claims have been brought to date, participants in our clinical trials could bring civil actions against us for any unanticipated harmful effects allegedly arising from the use of Multikine or any other product candidate that we may attempt to develop.

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Our commercial success depends, in part, upon attaining significant market acceptance of our product candidates, if approved, among physicians, patients, healthcare payors and major operators of cancer clinics.

Even if we obtain regulatory approval for our product candidates, any resulting product may not gain market acceptance among physicians, healthcare payors, patients and the medical community, which are critical to commercial success. Market acceptance of any product candidate for which we receive approval depends on a number of factors, including:

- the efficacy and safety as demonstrated in clinical trials;
- the timing of market introduction of such product candidate as well as competitive products;
- the clinical indications for which the drug is approved;
- the approval, availability, market acceptance and reimbursement for the companion diagnostic;
- acceptance by physicians, major operators of cancer clinics and patients of the drug as a safe and effective treatment;
- the potential and perceived advantages of such product candidate over alternative treatments, especially with respect to patient subsets that are targeted with such product candidate;
- the safety of such product candidate seen in a broader patient group, including its use outside the approved indications;
- the cost of treatment in relation to alternative treatments;
- the availability of adequate reimbursement and pricing by third-party payors and government authorities;