

CEL SCI CORP  
Form 424B5  
May 06, 2015  
Table of Contents

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 <sup>(1)</sup>	\$	\$

Edgar Filing: CEL SCI CORP - Form 424B5

Underwriting discounts and commissions <sup>(2)</sup>	\$	\$
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

**Table of Contents****TABLE OF CONTENTS****Prospectus Supplement**

<u>About this Prospectus Supplement</u>	S-ii
<u>Prospectus Supplement Summary</u>	S-1
<u>Risk Factors</u>	S-10
<u>Forward-Looking Statements</u>	S-30
<u>Use of Proceeds</u>	S-32
<u>Capitalization</u>	S-33
<u>Price Range of Common Stock</u>	S-35
<u>Dilution</u>	S-36
<u>Government Regulation</u>	S-37
<u>Material U.S. Federal Income Tax Consequences to Non-U.S. Holders</u>	S-43
<u>Description of Securities</u>	S-47
<u>Underwriting</u>	S-50
<u>Legal Matters</u>	S-55
<u>Experts</u>	S-55
<u>Where You Can Find More Information</u>	S-55
<u>Incorporation by Reference</u>	S-56

**PROSPECTUS**

<u>Prospectus Summary</u>	1
<u>Forward-Looking Statements</u>	9
<u>Risk Factors</u>	10
<u>Comparative Share Data</u>	17
<u>Market for CEL-SCI's Common Stock</u>	20
<u>Plan of Distribution</u>	22
<u>Description of Securities</u>	24
<u>Experts</u>	25
<u>Indemnification</u>	25
<u>Additional Information</u>	25

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.

**Table of Contents**

**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.

**Table of Contents**

**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

**Table of Contents**

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

**Table of Contents**

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.

## **Table of Contents**

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.



---

**Table of Contents*****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).

**Table of Contents**

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.

## **Table of Contents**

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.

## **Table of Contents**

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 Musculoskeletal 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](http://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.

**Table of Contents**

**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 <sup>(1)</sup>	shares ( shares if the underwriter exercises its option to purchase additional shares in full).
Use of proceeds	<p>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.</p> <p>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.</p>
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.



---

**Table of Contents**

**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





## Table of Contents

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;

## Edgar Filing: CEL SCI CORP - Form 424B5

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.

S-11

---

## **Table of Contents**

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

---

**Table of Contents**

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.

## **Table of Contents**

*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

## Edgar Filing: CEL SCI CORP - Form 424B5

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.

S-14

## **Table of Contents**

*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;

relative convenience and ease of administration;

the prevalence and severity of adverse side effects; and

the effectiveness of our sales and marketing efforts.

If our product candidates are approved but fail to achieve an adequate level of acceptance by physicians, healthcare payors and patients, we will not be able to generate significant revenues, and we may not become or remain profitable.

## **Risks Related to Government Approvals**

*Our product candidates must undergo rigorous preclinical and clinical testing and regulatory approvals, which could be costly and time-consuming and subject us to unanticipated delays or prevent us from marketing any products.*

## Edgar Filing: CEL SCI CORP - Form 424B5

Our product candidates are subject to premarket approval from the FDA in the United States, the EMA in the European Union, and by comparable agencies in most foreign countries before they can be sold. Before obtaining marketing approval, these product candidates must undergo costly and time consuming preclinical and clinical testing which could subject us to unanticipated delays and may prevent us from marketing our product candidates. There can be no assurance that such approvals will be granted on a timely basis, if at all.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Our current and future clinical trials may not be successful.

S-15



## Table of Contents

Although we have a Phase 3 clinical trial ongoing for Multikine, we may experience delays in our ongoing clinical trials and we do not know whether planned clinical trials will begin on time, need to be redesigned, enroll patients on time or be completed on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including delays related to:

the availability of financial resources needed to commence and complete our planned trials;

obtaining regulatory approval to commence a trial;

reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;

obtaining Institutional Review Board, or IRB, approval at each clinical trial site;

recruiting suitable patients to participate in a trial;

having patients complete a trial or return for post-treatment follow-up;

clinical trial sites deviating from trial protocol or dropping out of a trial;

adding new clinical trial sites; or

manufacturing sufficient quantities of our product candidate for use in clinical trials.

Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating. Furthermore, we rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials and while we have agreements governing their committed activities, we have limited influence over their actual performance.

For example, we are currently involved in a dispute with our former CRO relating to the conduct of our Phase 3 study where we allege (i) breach of contract, (ii) fraud in the inducement, (iii) fraud, and (iv) professional malpractice. In connection with this dispute, we have alleged that our CRO failed to properly select, monitor and supervise the study sites and principal investigators, ensure proper enrollment of subjects, and ensure strict compliance with the Phase 3 trial protocol and Good Clinical Practices, or GCP, and other applicable regulatory requirements. If we or regulatory authorities determine that our former CRO did not comply with GCP or other applicable regulatory requirements, data collected by that former CRO may be rendered unusable in support of our marketing applications, and we may be required to enroll additional subjects in our Phase 3 study beyond our current plans, which could cause additional delays in our clinical testing and development program.

We could also encounter delays if physicians encounter unresolved ethical issues associated with enrolling patients in clinical trials of our product candidates in lieu of prescribing existing treatments that have established safety and efficacy profiles. Further, a clinical trial may be suspended or terminated by us, the IRBs for the institutions in which such trials are being conducted, the Independent Data Monitoring Committee, or IDMC, for such trial, or by the FDA or other regulatory authorities due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions or lack of adequate funding

to continue the clinical trial.

If we experience termination of, or delays in the completion of, any clinical trial of our product candidates, the commercial prospects for our product candidates will be harmed, and our ability to generate product revenues will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow our product development and approval process and jeopardize our ability to commence product sales and generate revenues.

S-16

## **Table of Contents**

Any of these occurrences may harm our business, prospects, financial condition and results of operations significantly. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval for our product candidates.

We cannot be certain when or under what conditions we will undertake future clinical trials. A variety of issues may delay our Phase 3 clinical trial for Multikine or preclinical and early clinical trials for our other product candidates. For example, early trials, or the plans for later trials, may not satisfy the requirements of regulatory authorities, such as the FDA. We may fail to find subjects willing to enroll in our trials. We manufacture Multikine in our own manufacturing facility, but rely on third-party vendors to manage the trial process and other activities, and these vendors may fail to meet appropriate standards. Accordingly, the clinical trials relating to our product candidates may not be completed on schedule, the FDA or foreign regulatory agencies may order us to stop or modify our research, or these agencies may not ultimately approve any of our product candidates for commercial sale. Varying interpretations of the data obtained from pre-clinical and clinical testing could delay, limit or prevent regulatory approval of our product candidates. The data collected from our clinical trials may not be sufficient to support regulatory approval of our various product candidates, including Multikine. Our failure to adequately demonstrate the safety and efficacy of any of our product candidates would delay or prevent regulatory approval of our product candidates in the United States, which could prevent us from achieving profitability. Although we had positive results in our Phase 2 trials for Multikine, those results were for a very small sample set, and we will not know how Multikine will perform in a larger set of subjects until we are well into, or complete, our Phase 3 clinical trial.

The development and testing of product candidates and the process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant to administrative or judicial sanctions. FDA sanctions could include, among other actions, refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning letters, product recalls or withdrawals from the market, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

The requirements governing the conduct of clinical trials, manufacturing and marketing of our product candidates, including Multikine, outside the United States vary from country to country. Foreign approvals may take longer to obtain than FDA approvals and can require, among other things, additional testing and different trial designs. Foreign regulatory approval processes include all of the risks associated with the FDA approval process. Some of those agencies also must approve prices for products approved for marketing. Approval of a product by the FDA or the EMA does not ensure approval of the same product by the health authorities of other countries. In addition, changes in regulatory requirements for product approval in any country during the clinical trial process and regulatory agency review of each submitted new application may cause delays or rejections.

We have only limited experience in filing and pursuing applications necessary to gain regulatory approvals. Our lack of experience may impede our ability to obtain timely approvals from regulatory agencies, if at all. We will not be able to commercialize Multikine and other product candidates until we have obtained regulatory approval. In addition, regulatory authorities may also limit the types of patients to which we or our third-party partners may market Multikine or our other product candidates. Any failure to obtain or any delay in obtaining required regulatory approvals may adversely affect our or our third-party partners' ability to successfully market our product candidates.

***Even if we obtain regulatory approval for our product candidates, we will be subject to stringent, ongoing government regulation.***

If our products receive regulatory approval, either in the United States or internationally, those products will be subject to limitations on the approved indicated uses for which the product may be marketed or to the

**Table of Contents**

conditions of approval, and may contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance of the safety and efficacy of the product candidate. We will continue to be subject to extensive regulatory requirements. These regulations are wide-ranging and govern, among other things:

product design, development and manufacture;

product application and use

adverse drug experience;

product advertising and promotion;

product manufacturing, including good manufacturing practices

record keeping requirements;

registration and listing of our establishments and products with the FDA, EMA and other state and national agencies;

product storage and shipping;

drug sampling and distribution requirements;

electronic record and signature requirements; and

labeling changes or modifications.

We and any of our third-party manufacturers or suppliers must continually adhere to federal regulations setting forth requirements, known as cGMPs, and their foreign equivalents, which are enforced by the FDA, the EMA and other national regulatory bodies through their facilities inspection programs. If our facilities, or the facilities of our contract manufacturers or suppliers, cannot pass a pre-approval plant inspection or fail such inspections in the future, the FDA, EMA or other national regulators will not approve our marketing applications for our product candidates, or may withdraw any prior approval. In complying with cGMP and foreign regulatory requirements, we and any of our potential third-party manufacturers or suppliers will be obligated to expend time, money and effort in production, record-keeping and quality control to ensure that our product candidates meet applicable specifications and other requirements.

If we do not comply with regulatory requirements at any stage, whether before or after marketing approval is obtained, we may be subject to, among other things, license suspension or revocation, criminal prosecution, seizure, injunction, fines, be forced to remove a product from the market or experience other adverse consequences, including restrictions or delays in obtaining regulatory marketing approval for such products or for other product candidates for which we seek approval. This could materially harm our financial results, reputation and stock price. Additionally, we may not be able to obtain the labeling claims necessary or desirable for product promotion. If we or other parties identify adverse effects after any of our products are on the market, or if manufacturing problems occur, regulatory approval may be suspended or withdrawn. We may be required to reformulate our products, conduct additional clinical trials, make changes in product labeling or indications of use, or submit additional marketing applications to support any changes. If we encounter any of the foregoing problems, our business and

## Edgar Filing: CEL SCI CORP - Form 424B5

results of operations will be harmed and the market price of our common stock may decline.

FDA and other governmental authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability. We cannot predict the extent of adverse government regulations which might arise from future legislative or administrative action. Without government approval, we will be unable to sell any of our product candidates.

S-18

---

**Table of Contents**

***Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.***

Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign authorities. Results of our clinical trials could reveal a high and unacceptable severity and/or prevalence of these or other side effects. In such an event, our trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of, or deny approval of, our product candidates for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

Additionally if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including:

regulatory authorities may withdraw approvals of such product;

regulatory authorities may require additional warnings on the label;

we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;

we could be sued and held liable for harm caused to patients; and

our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, results of operations and prospects.

***We rely on third parties to conduct our preclinical and clinical trials. If these third parties do not successfully carry out their contractual duties and meet regulatory requirements, or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.***

We have relied upon and plan to continue to rely upon third-party CROs to prepare for, conduct, monitor and manage data for our ongoing preclinical and clinical programs. We rely on these parties for all aspects of the execution of our preclinical and clinical trials, and although we diligently oversee and carefully manage our CROs, we directly control only certain aspects of their activities and rely upon them to provide timely, complete, and accurate reports on their conduct of our studies. Although such third parties stand in our shoes for regulatory purposes in the context of our clinical trials, ultimately we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory, and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities. We and our CROs acting on our behalf as well as principal investigators and trial sites are required to comply with GCP and other applicable requirements, which are implemented through regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area, or EEA, and comparable foreign regulatory authorities for all of our products in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators, and trial sites. If we or any of our CROs fail to comply with applicable GCPs or other applicable regulations, the clinical data generated in our clinical trials may be determined to be unreliable and we may therefore need to enroll additional subjects in our clinical trials, or the FDA, EMA or comparable foreign regulatory authorities may require us to perform an additional clinical trial or trials before approving our marketing applications. Moreover, if we or any of our CROs, principal investigators, or trial sites, fail to comply with applicable regulatory and GCP requirements, then we, our CROs, principal

---

**Table of Contents**

investigators, or trial sites may be subject to enforcement actions, such as fines, warning letters, untitled letters, clinical holds, civil or criminal penalties, injunction, and/or disbarment. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with product produced under GMP regulations. Our failure to comply with these regulations may require us to delay or repeat clinical trials, which would delay the regulatory approval process.

For example, we are currently involved in a dispute with our former CRO relating to the conduct of our Phase 3 study where we allege (i) breach of contract, (ii) fraud in the inducement, (iii) fraud, and (iv) professional malpractice. In connection with this dispute, we have alleged that our CRO failed to properly select, monitor and supervise the study sites and principal investigators, ensure proper enrollment of subjects, and ensure strict compliance with the Phase 3 trial protocol and GCP and other applicable regulatory requirements. If we or regulatory authorities determine that our former CRO did not comply with GCP or other applicable regulatory requirements, the data collected by that former CRO may be rendered unusable in support of our marketing applications, and we may be required to enroll additional subjects in our Phase 3 study beyond our current plans, which could cause additional delays in our clinical testing and development program.

If any of our relationships with our third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. In addition, our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our on-going clinical, nonclinical and preclinical programs. If CROs do not successfully fulfill their regulatory obligations, carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed.

Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we diligently oversee and carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in our clinical development in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

***We have obtained orphan drug designation from the FDA for Multikine for neoadjuvant, or primary, therapy in patients with squamous cell carcinoma of the head and neck, but we may be unable to maintain the benefits associated with orphan drug designation, including the potential for market exclusivity.***

Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug or biologic intended to treat a rare disease or condition, which is defined as one occurring in a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug or biologic will be recovered from sales in the United States. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. In addition, if a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications, including a full Biologics License Application, or BLA, to market the same biologic for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or where the manufacturer is unable to assure sufficient product quantity.

**Table of Contents**

Even though we have received orphan drug designation for Multikine for the treatment of squamous cell carcinoma of the head and neck, we may not be the first to obtain marketing approval of a product for the orphan-designated indication due to the uncertainties associated with developing pharmaceutical products. In addition, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan-designated indication, or may be lost if the FDA later determines that the request for designation was materially defective or if we are unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Further, even if we obtain orphan drug exclusivity for a product candidate, that exclusivity may not effectively protect the product candidate from competition because different drugs with different active moieties can be approved for the same condition. Even after an orphan product is approved, the FDA can subsequently approve another drug with the same active moiety for the same condition if the FDA concludes that the later drug is safer, more effective, or makes a major contribution to patient care. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process.

***Our current and future relationships with healthcare professionals, principal investigators, consultants, customers (actual and potential) and third-party payors in the United States and elsewhere may be subject, directly or indirectly, to applicable healthcare laws and regulations.***

Healthcare providers, physicians and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any drug candidates for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, principal investigators, consultants, customers (actual and potential) and third-party payors may expose us to broadly applicable fraud and abuse and other healthcare laws, including, without limitation:

the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation. In addition, the Affordable Care Act provided that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;

federal civil and criminal false claims laws, including the federal False Claims Act, which impose criminal and civil penalties, including civil qui tam actions, in which whistleblowers may share in any amounts paid to the government in fines and settlement payments, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

the civil monetary penalties statute, which imposes penalties against any person or entity who, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent;

the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private), knowingly and willfully embezzling or stealing from a health care benefit program, willfully obstructing a criminal investigation of a healthcare offense and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the



---

**Table of Contents**

delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose obligations on covered entities, including healthcare providers, health plans, and healthcare clearinghouses, as well as their respective business associates that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

the federal Physician Payments Sunshine Act and its implementing regulations, which imposes annual reporting requirements for certain manufacturers of drugs, devices, biologicals and medical supplies for payments and transfers of value provided to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; and

analogous state and foreign laws, such as state anti-kickback and false claims laws, which may be broader in scope and may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our future business arrangements with third parties will comply with applicable healthcare laws and regulations may involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, including, without limitation, damages, fines, imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations, all of which could significantly harm our business. If any of the physicians or other healthcare providers or entities with whom we expect to do business, including our current and future collaborators, are found not to be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from participation in government healthcare programs, which could also adversely affect our business.

***Failure to obtain or maintain adequate coverage and reimbursement for our product candidates, if approved, could limit our ability to market those products and decrease our ability to generate revenue.***

Sales of our product candidates will depend substantially, both domestically and abroad, on the extent to which the costs of our product candidates will be paid by health maintenance, managed care, pharmacy benefit, and similar healthcare management organizations, or reimbursed by government authorities, private health insurers and other third-party payors. We anticipate that government authorities and other third-party payors will continue efforts to contain healthcare costs by limiting the coverage and reimbursement levels for new drugs. If coverage and reimbursement are not available, or are available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a return on our investment. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our product candidates.

---

**Table of Contents*****Healthcare legislative reform measures may have a material adverse effect on our business and results of operations.***

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs that may result in more limited coverage or downward pressure on the price we may otherwise receive for our product candidates. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the Affordable Care Act, was passed, which substantially changes the way health care is financed by both governmental and private insurers, and significantly impacts the U.S. pharmaceutical industry. The Affordable Care Act, among other things, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations, established annual fees and taxes on manufacturers of certain branded prescription drugs, and established the Center for Medicare and Medicaid Innovation with broad authority to test and implement new payment models under Medicare and Medicaid, which are designed to reduce expenditures while preserving and enhancing quality of care.

In addition, other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. On August 2, 2011, the Budget Control Act of 2011 among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect in April 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2024 unless additional Congressional action is taken. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers. On April 16, 2015, President Obama signed into law the Medicare Access and CHIP Reauthorization Act of 2015, or MACRA. Among other things, MACRA creates incentives for physicians to participate in alternative payment models under Medicare that emphasize quality and value in place of the traditional, volume-based fee-for-service program. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

***Foreign governments often impose strict price controls, which may adversely affect our future profitability.***

We intend to seek approval to market Multikine in both the United States and foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions, we will be subject to rules and regulations in those jurisdictions relating to Multikine. In some foreign countries, particularly in the European Union, prescription drug pricing is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a drug candidate. Coverage and reimbursement decisions in one foreign jurisdiction may impact decisions in other countries. To obtain reimbursement or pricing approval in some countries, we may be required to conduct clinical trials that demonstrate our product candidate is more effective than current treatments and that compare the cost-effectiveness of Multikine to other available therapies. If reimbursement of Multikine is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, we may be unable to achieve or sustain profitability.

**Risks Related to Intellectual Property**

***We may not be able to achieve or maintain a competitive position, and other technological developments may result in our proprietary technologies becoming uneconomical or obsolete.***

We are involved in a biomedical field that is undergoing rapid and significant technological change. The pace of change continues to accelerate. The successful development of product candidates from our compounds,

---

**Table of Contents**

compositions and processes, through research financed by us, or as a result of possible third-party licensing arrangements with pharmaceutical or other companies, is not assured. We may fail to apply for patents on important technologies or product candidates in a timely fashion, or at all.

Many companies are working on drugs designed to cure or treat cancer or cure and treat viruses, such as HPV or H1N1. Many of these companies have financial, research and development, and marketing resource, which are much greater than ours, and are capable of providing significant long-term competition either by establishing in-house research groups or by forming collaborative ventures with other entities. In addition, smaller companies and non-profit institutions are active in research relating to cancer and infectious diseases. The future market share of Multikine or our other product candidates, if approved, will be reduced or eliminated if our competitors develop and obtain approval for products that are safer or more effective than our product candidates. Moreover, the patent positions of pharmaceutical companies are highly uncertain and involve complex legal and factual questions for which important legal principles are often evolving and remain unresolved. As a result, the validity and enforceability of patents cannot be predicted with certainty. In addition, we do not know whether:

we were the first to make the inventions covered by each of our issued patents and pending patent applications;

we were the first to file patent applications for these inventions;

others will independently develop similar or alternative technologies or duplicate any of our technologies;

any of our pending patent applications will result in issued patents;

any of our patents will be valid or enforceable;

any patents issued to us or our collaboration partners will provide us with any competitive advantages, or will be challenged by third parties;

we will be able to develop additional proprietary technologies that are patentable;

the U.S. government will exercise any of its statutory rights to our intellectual property that was developed with government funding;  
or

our business may infringe the patents or other proprietary rights of others.

***Our patents might not protect our technology from competitors, in which case we may not have any advantage over competitors in selling any products that we may develop.***

Our commercial success will depend in part on our ability to obtain additional patents and protect our existing patent position, as well as our ability to maintain adequate intellectual property protection for our technologies, product candidates, and any future products in the United States and other countries. If we do not adequately protect our technology, product candidates and future products, competitors may be able to use or practice them and erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability. The laws of some foreign countries do not protect our proprietary rights to the same extent or in the same manner as U.S. laws, and we may encounter significant problems in protecting and defending our proprietary rights in these countries. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary technologies, product candidates and any future products are covered by valid and enforceable patents or are effectively maintained as trade secrets.

## Edgar Filing: CEL SCI CORP - Form 424B5

Certain aspects of our technologies are covered by U.S. and foreign patents. In addition, we have a number of new patent applications pending. There is no assurance that the applications still pending or which may be filed in the future will result in the issuance of any patents. Furthermore, there is no assurance as to the breadth and degree of protection any issued patents might afford us. Disputes may arise between us and others as to the scope and validity of these or other patents. Any defense of the patents could prove costly and time consuming and there can be no assurance that we will be in a position, or will deem it advisable, to carry on such a defense. A suit for patent infringement could result in increasing costs, delaying or halting development, or even forcing

S-24

## **Table of Contents**

us to abandon a product candidate. Other private and public concerns, including universities, may have filed applications for, may have been issued, or may obtain additional patents and other proprietary rights to technology potentially useful or necessary to us. We are not currently aware of any such patents, but the scope and validity of such patents, if any, and the cost and availability of such rights are impossible to predict.

*Much of our intellectual property is protected as trade secrets or confidential know-how, not as a patent.*

We consider proprietary trade secrets and/or confidential know-how and unpatented know-how to be important to our business. Much of our intellectual property pertains to our manufacturing system, certain aspects of which may not be suitable for patent filings and must be protected as trade secrets and/or confidential know-how. This type of information must be protected diligently by us to protect its disclosure to competitors, since legal protections after disclosure may be minimal or non-existent. Accordingly, much of our value is dependent upon our ability to keep our trade secrets and know-how confidential.

To protect this type of information against disclosure or appropriation by competitors, our policy is to require our employees, consultants, contractors and advisors to enter into confidentiality agreements with us. However, current or former employees, consultants, contractors and advisers may unintentionally or willfully disclose our confidential information to competitors, and confidentiality agreements may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. Enforcing a claim that a third party obtained illegally, and is using trade, secrets and/or confidential know-how is expensive, time consuming and unpredictable. The enforceability of confidentiality agreements may vary from jurisdiction to jurisdiction.

In addition, in some cases a regulator considering our application for product candidate approval may require the disclosure of some or all of our proprietary information. In such a case, we must decide whether to disclose the information or forego approval in a particular country. If we are unable to market our product candidates in key countries, our opportunities and value may suffer.

Failure to obtain or maintain trade secrets and/or confidential know-how trade protection could adversely affect our competitive position. Moreover, our competitors may independently develop substantially equivalent proprietary information and may even apply for patent protection in respect of the same. If successful in obtaining such patent protection, our competitors could limit our use of such trade secrets and/or confidential know-how.

*We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.*

We may also be subject to claims that former employees, collaborators or other third parties have an ownership interest in our patents or other intellectual property. We may be subject to ownership disputes in the future arising, for example, from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

### **Risks related to this Offering**

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

We currently intend to use the net proceeds from this offering to complete patient enrollment in our Phase 3 clinical trial of Multikine for neoadjuvant therapy in patients with SCCHN, 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 and administrative expenses. See "Use of Proceeds" on page S-32 of this prospectus supplement. We

---

**Table of Contents**

have not designated the specific amount of net proceeds to us from this offering that will be used for these purposes. Accordingly, our management will have broad discretion as to the allocation 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.

In addition, the net proceeds from this offering will not be sufficient to complete clinical trials and other studies required for the approval of any product candidate, including the Phase 3 clinical trial of Multikine, by the FDA or any other regulatory authority, and we will need significant additional funds in order to complete the Phase 3 Multikine study.

***You will experience immediate and substantial dilution in the net tangible book value of the common stock you purchase in this offering.***

Since the assumed public 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 33,980,583 shares of common stock based on an assumed public offering price of \$1.03 per share, which was the last reported sale price of our common stock on the NYSE MKT on May 5, 2015, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, if you purchase securities in this offering, you will suffer immediate and substantial dilution of approximately \$0.68 per share in the net tangible book value of the common stock you acquire (based on our net tangible book value as of December 31, 2014). Furthermore, in the past, we issued options and warrants to acquire common stock at prices significantly below the public offering price. To the extent these outstanding options and warrants are ultimately exercised, investors purchasing common stock in this offering may sustain further dilution.

The dilution information discussed above is illustrative only and will change based on the actual public offering price and other terms of this offering determined at pricing. Assuming an issuance of 33,980,583 shares of common stock in this offering, based on an assumed public offering price of \$1.03 per share, which was the last reported sale price of our common stock on the NYSE MKT on May 5, 2015, a \$0.10 increase (decrease) in the assumed public offering price per share would increase (decrease) the as adjusted net tangible book value by approximately \$3.2 million, or approximately \$0.03 per share, and increase (decrease) the dilution per share to new investors by approximately \$0.07 per share, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. An increase (decrease) of 2,000,000 shares in the number of shares offered by us would increase (decrease) the as adjusted net tangible book value by approximately \$1.9 million, or \$0.02 per share, and would decrease (increase) the dilution per share to new investors by approximately \$0.01 per share, assuming that the assumed public offering price of \$1.03 per share, as set forth above, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

***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

---

**Table of Contents**

securities, your investment in our common stock will be diluted. These sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders.

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

As of May 5, 2015, there were outstanding options which allow the holders to purchase approximately 6,744,000 shares of our common stock, at prices ranging between \$0.55 and \$20.00 per share, with a weighted average exercise price of \$3.00 per share; outstanding warrants which allow the holders to purchase approximately 34,833,000 shares of our common stock, at prices ranging between \$0.53 and \$5.00 per share, 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; and a convertible loan, 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 loan, 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 loan, will also dilute the ownership interests of our existing stockholders.

***Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.***

Under Section 382 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an ownership change (generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period), the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income may be limited. Taking into account our initial public offering and other transactions, we may have triggered an ownership change limitation. In addition, we may experience ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which are outside our control. As a result, our ability to use our pre-change net operating loss carryforwards and other pre-change tax attributes to offset U.S. federal taxable income may be subject to limitations, which could result in increased tax liability to the Company.

***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 only 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

## **Table of Contents**

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.

*Since we do not intend to pay dividends on our common stock, any potential return to investors will result only from any increases in the price of our common stock.*

At the present time, we intend to use available funds to finance our operations. Accordingly, while payment of dividends rests within the discretion of our board of directors, no common stock dividends have been declared or paid by us and we have no intention of paying any common stock dividends in the foreseeable future. Additionally, any future debt financing arrangement may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. Any return to our investors will therefore be limited to appreciation in the price of our common stock, which may never occur. If our stock price does not increase, our investors are unlikely to receive any return on their investments in our common stock.

*The price of our common stock has been volatile and is likely to continue to be volatile, which could result in substantial losses for purchasers of our common stock.*

Our stock price has been, and is likely to continue to be, volatile. The stock market in general has experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, you may not be able to sell your shares of our common stock at or above its current market price. The market price for our common stock may be influenced by many factors, including:

actual or anticipated fluctuations in our financial condition and operating results;

actual or anticipated changes in our growth rate relative to our competitors;

competition from existing products or new products or product candidates that may emerge;

development of new technologies that may address our markets and may make our technology less attractive;

changes in physician, hospital or healthcare provider practices that may make our product candidates less useful;

announcements by us, our partners or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;

developments or disputes concerning patent applications, issued patents or other proprietary rights;

the recruitment or departure of key personnel;

failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public;

actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;



## Edgar Filing: CEL SCI CORP - Form 424B5

variations in our financial results or those of companies that are perceived to be similar to us;

changes to coverage and reimbursement levels by commercial third-party payors and government payors, including Medicare, and any announcements relating to reimbursement levels;

general economic, industry and market conditions; and

the other factors described in this Risk Factors section.

***Under our amended bylaws, stockholders that initiate certain proceedings may be obligated to reimburse us and our officers and directors for all fees, costs and expenses incurred in connection with such proceedings if the claim proves unsuccessful.***

On February 18, 2015, we adopted new bylaws which include a fee-shifting provision in Article X for stockholder claims. Article X provides that in the event that any stockholder initiates or asserts a claim against

S-28

---

**Table of Contents**

us, or any of our officers or directors, including any derivative claim or claim purportedly filed on our behalf, and the stockholder does not obtain a judgment on the merits that substantially achieves, in substance and amount, the full remedy sought, then the stockholder will be obligated to reimburse us and any of our officers or directors named in the action, for all fees, costs and expenses of every kind and description that we or our officers or directors may incur in connection with the claim. In adopting Article X, it is our intent that:

All actions, including federal securities law claims, would be subject to Article X;

The phrase a judgment on the merits means the determination by a court of competent jurisdiction on the matters submitted to the court;

The phrase substantially achieves, in both substance and amount means the plaintiffs in the action would be awarded at least 90% of the relief sought;

Only persons who were stockholders at the time an action was brought would be subject to Article X; and

Only the directors or officers named in the action would be allowed to recover.

The fee-shifting bylaw contained in Article X of our bylaws is not limited to specific types of actions, but is rather potentially applicable to the fullest extent permitted by law. Fee-shifting bylaws are relatively new and untested. The case law and potential legislative action on fee-shifting bylaws are evolving and there exists considerable uncertainty regarding the validity of, and potential judicial and legislative responses to, such bylaws. For example, it is unclear whether our ability to invoke our fee-shifting bylaw in connection with claims under the federal securities laws, including any claims related to this offering, would be pre-empted by federal law. Similarly, it is unclear how courts might apply the standard that a claiming stockholder must obtain a judgment that substantially achieves, in substance and amount, the full remedy sought. The application of our fee-shifting bylaw in connection with such claims, if any, will depend in part on future developments of the law. We cannot assure you that we will or will not invoke our fee-shifting bylaw in any particular dispute, including any claims related to this offering. In addition, given the unsettled state of the law related to fee-shifting bylaws, such as ours, we may incur significant additional costs associated with resolving disputes with respect to such bylaw, which could adversely affect our business and financial condition.

If a stockholder that brings any such claim, suit, action or proceeding is unable to obtain the required judgment, the attorneys' fees and other litigation expenses that might be shifted to a claiming stockholder are potentially significant. This fee-shifting bylaw, therefore, may dissuade or discourage stockholders (and their attorneys) from initiating lawsuits or claims against us or our directors and officers. In addition, it may impact the fees, contingency or otherwise, required by potential plaintiffs' attorneys to represent our stockholders or otherwise discourage plaintiffs' attorneys from representing our stockholders at all. As a result, this bylaw may limit the ability of stockholders to affect the management and direction of CEL-SCI, particularly through litigation or the threat of litigation.

***The provision of our amended bylaws requiring exclusive venue in the U.S. District Court for Delaware for certain types of lawsuits may have the effect of discouraging lawsuits against us and our directors and officers.***

Article X of our amended bylaws provides that stockholder claims brought against us, or our officers or directors, including any derivative claim or claim purportedly filed on our behalf, must be brought in the U.S. District Court for the district of Delaware and that with respect to any such claim, the laws of Delaware will apply.

The exclusive forum provision may limit a stockholder's ability to bring a claim in a judicial forum the stockholder finds favorable for disputes with us or our directors or officers, and may have the effect of discouraging lawsuits with respect to claims that may benefit us or our stockholders.

**Table of Contents**

**FORWARD-LOOKING STATEMENTS**

This prospectus supplement, the accompanying prospectus and the documents that are incorporated or deemed to be incorporated by reference into this prospectus supplement and the accompanying prospectus, contain or incorporate by reference forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. You can generally identify these forward-looking statements by forward-looking words such as anticipates, believes, expects, intends, future, could, estimates, plans, would, should, potential, continues and similar words, as well as other words or expressions referencing future events, conditions or circumstances). These forward-looking statements involve risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements, including, but not limited to:

the progress and timing of, and the amount of expenses associated with, our research, development and commercialization activities for our product candidates, including Multikine;

the expected progress, rate, timing and success of patient enrollment in our ongoing Phase 3 clinical trial of Multikine;

our expectations regarding the timing, costs and outcome of any pending or future litigation matters, lawsuits or arbitration proceedings, including but not limited to the pending arbitration proceeding we initiated against our former clinical research organization, or CRO;

the success of our clinical studies for our product candidates;

our ability to obtain U.S. and foreign regulatory approval for our product candidates and the ability of our product candidates to meet existing or future regulatory standards;

our expectations regarding federal, state and foreign regulatory requirements;

the therapeutic benefits and effectiveness of our product candidates;

the safety profile and related adverse events of our product candidates;

our ability to manufacture sufficient amounts of Multikine or our other product candidates for use in our clinical studies or, if approved, for commercialization activities following such regulatory approvals;

our plans with respect to collaborations and licenses related to the development, manufacture or sale of our product candidates;

our expectations as to future financial performance, expense levels and liquidity sources;

our ability to compete with other companies that are or may be developing or selling products that are competitive with our product candidates;

anticipated trends and challenges in our potential markets; and

our ability to attract, retain and motivate key personnel.

All forward-looking statements contained herein are expressly qualified in their entirety by this cautionary statement, the risk factors set forth under the heading "Risk Factors" and elsewhere in this prospectus supplement, in the accompanying prospectus and in the documents incorporated or deemed to be incorporated by reference into this prospectus supplement and the accompanying prospectus. The forward-looking statements contained in this prospectus supplement, the accompanying prospectus and any document incorporated or deemed to be incorporated by reference in this prospectus supplement and the accompanying prospectus, speak only as of their respective dates. Except to the extent required by applicable laws and regulations, we undertake no obligation to update these forward-looking statements to reflect new information, events or circumstances

S-30

**Table of Contents**

after the date of this prospectus supplement or to reflect the occurrence of unanticipated events. In light of these risks and uncertainties, the forward-looking events and circumstances described in this prospectus supplement, the accompanying prospectus and the documents that are incorporated by reference into this prospectus supplement and the accompanying prospectus may not occur and actual results could differ materially from those anticipated or implied in such forward-looking statements. Accordingly, you are cautioned not to place undue reliance on these forward-looking statements.

S-31

**Table of Contents**

**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 to complete patient enrollment in our ongoing Phase 3 clinical trial of Multikine for neoadjuvant therapy in patients with SCCHN, to fund the Phase 1 trial 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. We have not yet determined the amount of net proceeds to be used specifically for these purposes. The net proceeds from this offering will not be sufficient to complete clinical trials and other studies required for the approval of any product candidate, including the Phase 3 clinical trial of Multikine, by the FDA or any other regulatory authority, and we will need significant additional funds in order to complete the Phase 3 Multikine study.

Our management will have broad discretion in the application of the net proceeds from this offering, and investors will be relying on the judgment of our management with regard to the use of the net proceeds. Pending the use of the net proceeds from this offering as described above, we intend to invest the net proceeds in short-term, investment-grade, interest-bearing instruments.

S-32

**Table of Contents****CAPITALIZATION**

The following table sets forth (i) our actual cash and cash equivalents and consolidated capitalization as of December 31, 2014, (ii) our cash and cash equivalents and consolidated capitalization as of December 31, 2014, adjusted to give effect to this offering and (iii) our cash and cash equivalents and consolidated capitalization as of December 31, 2014, adjusted to give effect to this offering and on a pro forma basis to give effect to the use of the net proceeds as set forth in Use of Proceeds. No adjustments have been made to reflect normal operations by us or other developments with our business after December 31, 2014. As a result, the as adjusted information provided below is not indicative of our actual cash and cash equivalents position or consolidated capitalization as of any date. You should read this table in conjunction with Use of Proceeds in this prospectus supplement and the consolidated financial statements and related notes and Management's Discussion and Analysis of Financial Condition and Results of Operations in our Quarterly Report on Form 10-Q for the quarter ended December 31, 2014, which is incorporated by reference in this prospectus supplement.

	As of December 31, 2014		
	Actual	As Adjusted	As Adjusted Pro Forma
Cash and cash equivalents <sup>(1)</sup>	\$ 9,461,235	\$ 42,061,235	\$ 40,957,178
Debt:			
Related party loan <sup>(2)</sup>	\$ 1,104,057	\$ 1,104,057	
Capital lease	15,448	15,448	15,448
Total debt	1,119,505	1,119,505	15,448
Stockholders' equity:			
Preferred stock, par value \$0.01; 200,000 shares authorized; -0- shares issued and outstanding, actual and as adjusted			
Common stock, par value \$0.01; 600,000,000 shares authorized; 91,483,252 shares issued and outstanding, actual <sup>(3)</sup> ; 125,463,835 shares issued and outstanding, as adjusted <sup>(3)(4)</sup>	914,833	1,254,639	1,254,639
Additional paid-in capital	258,296,260	290,556,454	290,556,454
Accumulated deficit	(247,372,151)	(247,372,151)	(247,372,151)
Total stockholders' equity	11,838,942	44,438,942	44,438,942
Total capitalization	\$ 12,958,447	\$ 45,558,447	\$ 44,454,390

- (1) As of March 31, 2015, we had approximately \$2.6 million of cash and cash equivalents. 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.
- (2) Represents a convertible loan payable to a trust for which Mr. Kersten, our Chief Executive Officer and a member of our board of directors, is the trustee and a beneficiary. The trust, or any subsequent holder, has the right, upon the conversion of the loan, to acquire approximately 276,000 shares of our common stock at a conversion price of \$4.00. See noted (3) below.
- (3) Excludes shares that may be issued upon the exercise of outstanding warrants or options, or the conversion of a loan, as shown in the following table.

Security	Shares Issuable Upon Exercise/Conversion	Exercise/Conversion Price	Expiration Date
Series H warrants	1,200,000	\$ 5.00	August 1, 2015
Series P warrants	590,001	\$ 4.50	March 6, 2017
Series Q warrants	1,200,000	\$ 5.00	December 22, 2015
Series R warrants	2,625,000	\$ 4.00	December 6, 2016

Edgar Filing: CEL SCI CORP - Form 424B5

Series S warrants <sup>(a)</sup>	25,928,010	\$	1.25	October 11, 2018
Series U warrants	445,514	\$	1.75	October 17, 2017
Related party warrants	2,844,627	\$	0.53	August 18, 2015
Related party loan	276,014	\$	4.00	July 6, 2015

S-33



**Table of Contents**

<b>Security</b>	<b>Shares Issuable Upon Exercise/ Conversion</b>	<b>Exercise/ Conversion Price</b>	<b>Expiration Date</b>
Incentive stock options	1,708,331	\$ 3.05 <sup>(c)</sup>	September 9, 2015 August 5, 2024
Non-qualified stock options <sup>(b)</sup>	5,027,569	\$ 2.96 <sup>(c)</sup>	August 15, 2015 January 31, 2025
Other options <sup>(b)</sup>	8,000	\$ 20.00	October 14, 2015
Total	41,853,066		

(a) Series S warrants are publicly traded on the NYSE MKT under the symbol CVM WS.

(b) Represents options issued to consultants.

(c) Reflects weighted average exercise price.

(4) Represents the sale of 33,980,583 shares of our common stock in this offering based on an assumed public offering price of \$1.03 per share, which was the last reported sale price of our common stock on the NYSE MKT on May 5, 2015.

**Table of Contents****PRICE RANGE OF COMMON STOCK**

Our common stock is publicly traded on the NYSE MKT under the symbol CVM . The following table sets forth, for the periods indicated, the high and low intraday sale prices of our common stock as reported by the NYSE MKT.

	<b>HIGH</b>	<b>LOW</b>
<b>FY 2015</b>		
Third Quarter (through May 5, 2015)	\$ 1.09	\$ 0.78
Second Quarter (through March 31, 2015)	\$ 1.23	\$ 0.59
First Quarter (through December 31, 2014)	\$ 0.91	\$ 0.54
<b>FY 2014</b>		
Fourth Quarter (through September 30, 2014)	\$ 1.30	\$ 0.75
Third Quarter (through June 30, 2014)	\$ 1.72	\$ 0.98
Second Quarter (through March 31, 2014)	\$ 1.90	\$ 0.59
First Quarter (through December 31, 2013)	\$ 1.80	\$ 0.53
<b>FY 2013<sup>(1)</sup></b>		
Fourth Quarter (through September 30, 2013)	\$ 2.70	\$ 1.60
Third Quarter (through June 30, 2013)	\$ 3.10	\$ 2.00
Second Quarter (through March 31, 2013)	\$ 2.90	\$ 2.10
First Quarter (through December 31, 2012)	\$ 3.90	\$ 2.60

(1) The numbers shown for FY 2013 are adjusted for a 1-for-10 reverse stock split effected on September 25, 2013.

On May 5, 2015, the last reported sale price of our common stock on the NYSE MKT was \$1.03 per share. As of May 5, 2015, there were 91,608,295 shares of our common stock outstanding held by approximately 1,300 holders of record.

**Table of Contents****DILUTION**

If you invest in our common stock in this offering, your interest will be immediately diluted to the extent of the difference between the public offering price per share of our common stock in this offering and the net tangible book value per share of our common stock after this offering. As of December 31, 2014, we had a historical net tangible book value of \$11.5 million, or \$0.13 per share of common stock. Our net tangible book value represents total tangible assets less total liabilities, all divided by the number of shares of common stock outstanding on December 31, 2014.

After giving effect to the sale of 33,980,583 shares of common stock in this offering, based on an assumed public offering price per share equal to the last reported sale price of our common stock on the NYSE MKT on May 5, 2015, or \$1.03 per share, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses, our as adjusted net tangible book value at December 31, 2014 would have been approximately \$44.1 million, or \$0.35 per share. This represents an immediate increase in as adjusted net tangible book value of \$0.22 per share to existing stockholders and an immediate dilution of \$0.68 per share to new investors. The following table illustrates this per share dilution:

Assumed public offering price per share	\$ 1.03
Net tangible book value per share as of December 31, 2014	\$ 0.13
Increase in net tangible book value per share attributable to this offering	0.22
As adjusted net tangible book value per share after this offering	0.35
Dilution per share to new investors participating in this offering	\$ 0.68

If the underwriter fully exercises its option to purchase additional shares, as adjusted net tangible book value after this offering would increase to approximately \$0.38 per share, and there would be an immediate dilution of approximately \$0.65 per share to new investors.

Assuming that the assumed number of shares of common stock offered by us in this offering, as set forth above, remains the same, a \$0.10 increase (decrease) in the assumed public offering price of \$1.03 per share would increase (decrease) the as adjusted net tangible book value by approximately \$3.2 million, or approximately \$0.03 per share, and increase (decrease) the dilution per share to new investors by approximately \$0.07 per share, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. An increase (decrease) of 2,000,000 shares in the number of shares offered by us would increase (decrease) the as adjusted net tangible book value by approximately \$1.9 million, or \$0.02 per share, and would decrease (increase) the dilution per share to new investors by approximately \$0.01 per share, assuming that the assumed public offering price of \$1.03 per share remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. The as adjusted information discussed above is illustrative only and will adjust based on the actual public offering price and other terms of this offering determined at pricing.

**Table of Contents**

**GOVERNMENT REGULATION**

The FDA and other regulatory authorities at federal, state and local levels and in foreign countries extensively regulate, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, record keeping, approval, advertising, promotion, marketing and post-approval monitoring and reporting of biologics such as those we are developing. We, along with third party contractors, will be required to navigate the various preclinical, clinical and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval or licensure of our product candidates. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local, and foreign statutes and regulations require the expenditure of substantial time and financial resources.

**U.S. Food and Drug Administration Approval**

The process required by the FDA before biologic product candidates may be marketed in the United States generally involves the following:

completion of preclinical laboratory tests and animal studies performed in accordance with the FDA's Good Laboratory Practice, or GLP, regulations;

submission to the FDA of an investigational new drug application, or IND, which must become effective before clinical trials may begin and must be updated annually;

approval by an independent Institutional Review Board, or IRB, or ethics committee at each clinical site before the trial is initiated;

performance of adequate and well-controlled human clinical trials in compliance with Good Clinical Practice, or GCP, regulations to establish the safety, purity and potency of the proposed biologic product candidate for its intended purpose;

preparation of and submission to the FDA of a Biologics License Application, or BLA, after completion of clinical trials;

satisfactory completion of an FDA Advisory Committee review, if applicable;

a determination by the FDA within 60 days of its receipt of a BLA to file the application for review;

satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the proposed product is produced to assess compliance with current Good Manufacturing Practice, or cGMP, requirements and to assure that the facilities, methods and controls are adequate to preserve the biological product's continued safety, purity and potency, and of selected clinical investigations to assess compliance with GCPs; and

FDA review and approval of the BLA to permit commercial marketing of the product for particular indications for use in the United States.

Prior to commencing the first clinical trial with a product candidate in the U.S., we must submit an IND to the FDA. An IND is a request for authorization from the FDA to administer an investigational product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for human studies. The IND also includes results of animal and in vitro studies assessing the toxicology, pharmacokinetics, pharmacology, and pharmacodynamic characteristics of the product; chemistry, manufacturing, and controls information; and any available human data or literature to support the use of the investigational product. An IND must become effective before human clinical trials may begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period,

## Edgar Filing: CEL SCI CORP - Form 424B5

raises safety concerns or questions about the proposed clinical trial. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Submission of an IND therefore may or may not result in FDA authorization to commence a clinical trial.

S-37

---

**Table of Contents**

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical study. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. Furthermore, an independent IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial commences at that site, and must monitor the study until completed. Regulatory authorities, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. There are also requirements governing the reporting of ongoing clinical studies and clinical study results to public registries.

For purposes of approval of a Biologics License Application, or BLA, human clinical trials are typically conducted in three or four sequential phases that may overlap.

**Phase 1** The investigational product is initially introduced into healthy human subjects or patients with the target disease or condition. These studies are designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness.

**Phase 2** The investigational product is administered to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.

**Phase 3** The investigational product is administered to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval.

**Phase 4** In some cases, the FDA may require, or companies may voluntarily pursue, additional clinical trials after a product is approved to gain more information about the product. These so-called Phase 4 studies may be made a condition to approval of the BLA.

Phase 1, Phase 2 and Phase 3 testing may not be completed successfully within a specified period, if at all, and there can be no assurance that the data collected will support FDA approval or licensure of the product. Concurrent with clinical trials, companies may complete additional animal studies and develop additional information about the biological characteristics of the product candidate, and must finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

***BLA Submission and Review by the FDA***

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, nonclinical studies and clinical trials are submitted to the FDA

---

**Table of Contents**

as part of a BLA requesting approval to market the product for one or more indications. The BLA must include all relevant data available from pertinent preclinical and clinical studies, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls, and proposed labeling, among other things. Data can come from company-sponsored clinical studies intended to test the safety and effectiveness of a use of the product, or from a number of alternative sources, including studies initiated by investigators. The submission of a BLA requires payment of a substantial User Fee to the FDA, and the sponsor of an approved BLA is also subject to annual product and establishment user fees. These fees are typically increased annually. A waiver of user fees may be obtained under certain limited circumstances.

Once a BLA has been submitted, the FDA's goal is to review the application within ten months after it accepts the application for filing, or, if the application relates to an unmet medical need in a serious or life-threatening indication, six months after the FDA accepts the application for filing. The review process is often significantly extended by FDA requests for additional information or clarification. The FDA reviews a BLA to determine, among other things, whether a product is safe, pure and potent and the facility in which it is manufactured, processed, packed, or held meets standards designed to assure the product's continued safety, purity and potency. The FDA may convene an advisory committee to provide clinical insight on application review questions. Before approving a BLA, the FDA will typically inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

After the FDA evaluates a BLA and conducts inspections of manufacturing facilities where the investigational product and/or its drug substance will be produced, the FDA may issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete but the application is not ready for approval. A Complete Response Letter may request additional information or clarification, including new clinical studies. The FDA may delay or refuse approval of a BLA if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product.

If regulatory approval of a product is granted, such approval may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the BLA with a Risk Evaluation and Mitigation Strategy, or REMS, plan to mitigate risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing regulatory standards is not maintained or if problems occur after the product reaches the marketplace. In addition, the FDA may require one or more Phase 4 post-market studies and surveillance to further assess and monitor the product's safety and effectiveness after commercialization, and may limit further marketing of the product based on the results of these post-marketing studies. In addition, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our products under development.

A sponsor may seek approval of its product candidate under programs designed to accelerate the FDA's review and approval of new drugs and biological products that meet certain criteria. Specifically, new drugs and biological products are eligible for fast track designation if they are intended to treat a serious or life-threatening

---

**Table of Contents**

condition and demonstrate the potential to address unmet medical needs for the condition. For a fast track product, the FDA may consider sections of the BLA for review on a rolling basis before the complete application is submitted if relevant criteria are met. A fast track designated product candidate may also qualify for priority review, under which the FDA sets the target date for FDA action on the BLA at six months after the FDA accepts the application for filing. Priority review is granted where there is evidence that the proposed product would be a significant improvement in the safety or effectiveness of the treatment, diagnosis, or prevention of a serious condition. If criteria are not met for priority review, the application is subject to the standard FDA review period of 10 months after FDA accepts the application for filing. Priority review designation does not change the scientific/medical standard for approval or the quality of evidence necessary to support approval.

Under the accelerated approval program, the FDA may approve a BLA on the basis of either a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. Post-marketing studies or completion of ongoing studies after marketing approval are generally required to verify the biologic's clinical benefit in relationship to the surrogate endpoint or ultimate outcome in relationship to the clinical benefit. In addition, the Food and Drug Administration Safety and Innovation Act, or FDASIA, which was enacted and signed into law in 2012, established the new Breakthrough Therapy designation. A sponsor may seek FDA designation of its product candidate as a breakthrough therapy if the product candidate is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the therapy may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Sponsors may request the FDA to designate a breakthrough therapy at the time of or any time after the submission of an IND, but ideally before an end-of-phase 2 meeting with FDA. If the FDA designates a breakthrough therapy, it may take actions appropriate to expedite the development and review of the application, which may include holding meetings with the sponsor and the review team throughout the development of the therapy; providing timely advice to, and interactive communication with, the sponsor regarding the development of the drug to ensure that the development program to gather the nonclinical and clinical data necessary for approval is as efficient as practicable; involving senior managers and experienced review staff, as appropriate, in a collaborative, cross-disciplinary review; assigning a cross-disciplinary project lead for the FDA review team to facilitate an efficient review of the development program and to serve as a scientific liaison between the review team and the sponsor; and considering alternative clinical trial designs when scientifically appropriate, which may result in smaller trials or more efficient trials that require less time to complete and may minimize the number of patients exposed to a potentially less efficacious treatment.

Fast Track designation, priority review and breakthrough therapy designation do not change the standards for approval but may expedite the development or approval process.

**Post-Approval Requirements**

Any products manufactured or distributed by us pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing, annual user fee requirements for any marketed products and the establishments at which such products are manufactured, as well as new application fees for supplemental applications with clinical data. Biologic manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with GMP, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change,



## **Table of Contents**

may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance. We cannot be certain that we or our present or future suppliers will be able to comply with the cGMP regulations and other FDA regulatory requirements. If our present or future suppliers are not able to comply with these requirements, the FDA may, among other things, halt our clinical trials, require us to recall a product from distribution, or withdraw approval of the BLA.

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;

fines, warning letters or holds on post-approval clinical studies;

refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product license approvals;

product seizure or detention, or refusal to permit the import or export of products; or

injunctions or the imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising and promotion of biologics. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products.

## **Orphan Drug Designation**

The FDA may grant orphan drug designation to drugs or biologics intended to treat a rare disease or condition that affects fewer than 200,000 individuals in the United States, or if it affects more than 200,000 individuals in the United States, there is no reasonable expectation that the cost of developing and making the drug for this type of disease or condition will be recovered from sales in the United States.

In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. In addition, if a product receives the first FDA approval for the indication for which it has orphan designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other application to market the same drug for the same indication for a period of 7 years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity.

## **Table of Contents**

Orphan drug designation must be requested before submitting an application for marketing approval. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

### **Other Health Care Laws**

Our sales, promotion, medical education and other activities following product approval will be subject to regulation by numerous regulatory and law enforcement authorities in the United States in addition to the FDA, including potentially the Federal Trade Commission, the Department of Justice, the Centers for Medicare and Medicaid Services, other divisions of the Department of Health and Human Services and state and local governments. Our promotional and scientific/educational programs must comply with the anti-kickback provisions of the Social Security Act, the Foreign Corrupt Practices Act, the False Claims Act, the Physician Payments Sunshine Act, the Veterans Health Care Act and similar state laws.

Depending on the circumstances, failure to meet these applicable regulatory requirements can result in criminal prosecution, fines or other penalties, exclusion from government health care programs, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of pre-marketing product approvals, private qui tam actions brought by individual whistleblowers in the name of the government or refusal to allow us to enter into supply contracts, including government contracts.

### **Coverage and Reimbursement**

Sales of pharmaceutical products depend significantly on the availability of third-party coverage and reimbursement. Third-party payors include government health administrative authorities, managed care providers, private health insurers and other organizations. These third-party payors are increasingly challenging the price and examining the cost-effectiveness of medical products and services. In addition, significant uncertainty exists as to the reimbursement status of newly approved healthcare products and new drug classes, including biosimilars such as our product candidates. We may need to conduct expensive clinical studies to demonstrate the comparative cost-effectiveness of our products. The product candidates that we develop may not be considered cost-effective. It is time consuming and expensive for us to seek reimbursement from third-party payors. Reimbursement may not be available or sufficient to allow us to sell our products on a competitive and profitable basis.

The United States and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

### **Foreign Regulation**

In addition to regulations in the United States, we will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our products to the extent we choose to develop or sell any products outside of the United States. The approval process varies from country to country and the time may be longer or shorter than that required to obtain FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country.

**Table of Contents**

**MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS**

The following discussion is a summary of the material U.S. federal income tax consequences to non-U.S. holders (as defined below) of the purchase, ownership and disposition of our common stock issued pursuant to this offering, but does not purport to be a complete analysis of all potential tax consequences. The consequences of other U.S. federal tax laws, such as estate and gift tax laws, and any applicable state, local or non-U.S. tax laws are not discussed. This discussion is based on the United States Internal Revenue Code of 1986, as amended, or the Code, Treasury Regulations promulgated thereunder, judicial decisions, and published rulings and administrative pronouncements of the United States Internal Revenue Service, or IRS, in effect as of the date of this offering. These authorities may change or be subject to differing interpretations. Any such change or differing interpretation may be applied retroactively in a manner that could adversely affect a non-U.S. holder of our common stock. We have not sought and will not seek any rulings from the IRS regarding the matters discussed below. There can be no assurance that the IRS or a court will not take a contrary position regarding the tax consequences of the purchase, ownership and disposition of our common stock.

This discussion is limited to non-U.S. holders that hold our common stock as a capital asset within the meaning of Section 1221 of the Code (generally, property held for investment). This discussion does not address all U.S. federal income tax consequences relevant to a non-U.S. holder's particular circumstances, including the impact of the Medicare contribution tax on net investment income. In addition, it does not address consequences relevant to non-U.S. holders subject to particular rules, including, without limitation:

U.S. expatriates and certain former citizens or long-term residents of the United States;

persons subject to the alternative minimum tax;

persons holding our common stock as part of a hedge, straddle, or other risk reduction strategy or as part of a conversion transaction or other integrated investment;

banks, insurance companies, and other financial institutions;

real estate investment trusts or regulated investment companies;

brokers, dealers, or traders in securities or currencies;

controlled foreign corporations, passive foreign investment companies, and corporations that accumulate earnings to avoid U.S. federal income tax;

S corporations, partnerships, or other entities or arrangements treated as partnerships for U.S. federal income tax purposes, or investors in any such entities;

tax-exempt or governmental organizations;

persons deemed to sell our common stock under the constructive sale provisions of the Code;

## Edgar Filing: CEL SCI CORP - Form 424B5

persons who hold or receive our common stock pursuant to the exercise of any employee stock option or otherwise as compensation;

persons for whom our stock constitutes qualified small business stock within the meaning of Section 1202 of the Code; and

tax-qualified retirement plans.

If a partnership (or other entity treated as a partnership for U.S. federal income tax purposes) holds our common stock, the tax treatment of a partner in the partnership will depend on the status of the partner, the activities of the partnership, and certain determinations made at the partner level. Accordingly, partnerships holding our common stock and the partners in such partnerships should consult their tax advisors regarding the U.S. federal income tax consequences to them of the purchase, ownership, and disposition of our common stock.

S-43

---

**Table of Contents**

**THIS DISCUSSION IS FOR INFORMATION PURPOSES ONLY AND IS NOT, AND IS NOT INTENDED AS, LEGAL OR TAX ADVICE. INVESTORS SHOULD CONSULT THEIR TAX ADVISORS WITH RESPECT TO THE APPLICATION OF THE U.S. FEDERAL INCOME TAX LAWS TO THEIR PARTICULAR SITUATIONS AS WELL AS ANY TAX CONSEQUENCES OF THE PURCHASE, OWNERSHIP AND DISPOSITION OF OUR COMMON STOCK ARISING UNDER OTHER U.S. FEDERAL TAX LAWS OR UNDER THE LAWS OF ANY STATE, LOCAL, OR NON-U.S. TAXING JURISDICTION OR UNDER ANY APPLICABLE INCOME TAX TREATY.**

**Definition of a Non-U.S. Holder**

For purposes of this discussion, a non-U.S. holder is any beneficial owner of our common stock that is not a U.S. person, a partnership, or an entity disregarded as separate from its owner, each for U.S. federal income tax purposes. A U.S. person is any person that, for U.S. federal income tax purposes, is or is treated as any of the following:

an individual who is a citizen or resident of the United States;

a corporation (or other entity taxable as a corporation for U.S. federal income tax purposes) created or organized under the laws of the United States, any state thereof, or the District of Columbia;

an estate, the income of which is subject to U.S. federal income tax regardless of its source; or

a trust that (1) is subject to the primary supervision of a U.S. court and the control of one or more U.S. persons (within the meaning of Section 7701(a)(30) of the Code), or (2) has a valid election in effect to be treated as a U.S. person for U.S. federal income tax purposes.

**Distributions**

We do not anticipate declaring or paying dividends to holders of our common stock in the foreseeable future. However, if we do make distributions of cash or property on our common stock, such distributions will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Amounts not treated as dividends for U.S. federal income tax purposes will constitute a return of capital and first be applied against and reduce a non-U.S. holder's adjusted tax basis in its common stock, but not below zero. Any excess will be treated as capital gain and will be treated as described below under Sale or Other Taxable Disposition.

Subject to the discussion below on effectively connected income, dividends paid to a non-U.S. holder of our common stock will be subject to U.S. federal withholding tax at a rate of 30% of the gross amount of the dividends (or such lower rate specified by an applicable income tax treaty, provided the non-U.S. holder furnishes a valid IRS Form W-8BEN or W-8BEN-E (or other applicable documentation) certifying qualification for the lower treaty rate). A non-U.S. holder that does not timely furnish the required documentation, but that qualifies for a reduced treaty rate, may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS. Non-U.S. holders should consult their tax advisors regarding their entitlement to benefits under any applicable income tax treaty.

If dividends paid to a non-U.S. holder are effectively connected with the non-U.S. holder's conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, the non-U.S. holder maintains a permanent establishment in the United States to which such dividends are attributable), the non-U.S. holder will be exempt from the U.S. federal withholding tax described above. To claim the exemption, the non-U.S. holder must furnish to the applicable withholding agent a valid IRS Form W-8ECI, certifying that the dividends are effectively connected with the non-U.S. holder's conduct of a trade or business within the United States.

Any such effectively connected dividends will be subject to U.S. federal income tax on a net income basis at the regular graduated rates. A non-U.S. holder that is a corporation also may be subject to a branch profits tax at



---

## **Table of Contents**

a rate of 30% (or such lower rate specified by an applicable income tax treaty) on such effectively connected dividends, as adjusted for certain items. Non-U.S. holders should consult their tax advisors regarding any applicable tax treaties that may provide for different rules.

### **Sale or Other Taxable Disposition**

A non-U.S. holder will not be subject to U.S. federal income tax on any gain realized upon the sale or other taxable disposition of our common stock unless:

the gain is effectively connected with the non-U.S. holder's conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, the non-U.S. holder maintains a permanent establishment in the United States to which such gain is attributable);

the non-U.S. holder is a nonresident alien individual present in the United States for 183 days or more during the taxable year of the disposition and certain other requirements are met; or

our common stock constitutes a U.S. real property interest, or USRPI, by reason of our status as a U.S. real property holding corporation, or USRPHC, for U.S. federal income tax purposes.

Gain described in the first bullet point above will generally be subject to U.S. federal income tax on a net income basis at the regular graduated U.S. federal income tax rates. A non-U.S. holder that is a corporation also may be subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on such effectively connected gain, as adjusted for certain items.

A non-U.S. holder described in the second bullet point above will be subject to U.S. federal income tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on any gain derived from the disposition, which may be offset by certain U.S. source capital losses of the non-U.S. holder (even though the individual is not considered a resident of the United States) provided the non-U.S. holder has timely filed U.S. federal income tax returns with respect to such losses.

With respect to the third bullet point above, we believe we are not currently and do not anticipate becoming a USRPHC. Because the determination of whether we are a USRPHC depends on the fair market value of our USRPIs relative to the fair market value of our other business assets and our non-U.S. real property interests, however, there can be no assurance we are not a USRPHC or will not become one in the future. Even if we are or were to become a USRPHC, gain arising from the sale or other taxable disposition by a non-U.S. holder of our common stock will not be subject to U.S. federal income tax if (i) such class of stock is regularly traded, as defined by applicable Treasury Regulations, on an established securities market, and (ii) such non-U.S. holder owned, actually or constructively, 5% or less of such class of our stock throughout the shorter of the five-year period ending on the date of the sale or other disposition or the non-U.S. holder's holding period for such stock; if the foregoing exception does not apply, then if we are or were to become a USRPHC a purchaser may be required to withhold 10% of the proceeds payable to a non-U.S. holder from a sale of our common stock and such non-U.S. holder generally will be taxed on its net gain derived from the disposition at the graduated U.S. federal income tax rates applicable to United States persons (as defined in the Code).

Non-U.S. holders should consult their tax advisors regarding potentially applicable income tax treaties that may provide for different rules.

### **Information Reporting and Backup Withholding**

Payments of dividends on our common stock will not be subject to backup withholding provided the applicable withholding agent does not have actual knowledge or reason to know such holder is a U.S. person and the holder either certifies its non-U.S. status, such as by providing a valid IRS Form W-8BEN, W-8BEN-E, or W-8ECI, or otherwise establishes an exemption. However, information returns are required to be filed with the IRS in connection with any dividends on our common stock paid to the non-U.S. holder, regardless of whether

## **Table of Contents**

any tax was actually withheld. In addition, proceeds of the sale or other taxable disposition of our common stock within the United States or conducted through certain U.S.-related brokers generally will not be subject to backup withholding or information reporting if the applicable withholding agent receives the certification described above and does not have actual knowledge or reason to know that such holder is a U.S. person, or the holder otherwise establishes an exemption. Proceeds of a disposition of our common stock conducted through a non-U.S. office of a non-U.S. broker generally will not be subject to backup withholding or information reporting.

Copies of these information returns that are filed with the IRS may also be made available under the provisions of a specific treaty or agreement to the tax authorities of the country in which the non-U.S. holder resides or is established.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules may be allowed as a refund or a credit against a non-U.S. holder's U.S. federal income tax liability, provided the required information is timely furnished to the IRS.

### **Additional Withholding Tax on Payments Made to Foreign Accounts**

Withholding taxes may be imposed under the Foreign Account Tax Compliance Act, or FATCA, on certain types of payments made to non-U.S. financial institutions and certain other non-U.S. entities. Specifically, a 30% withholding tax may be imposed on dividends on, or gross proceeds from the sale, or other disposition of, our common stock paid to a foreign financial institution or a non-financial foreign entity (each as defined in the Code), unless (1) the foreign financial institution undertakes certain diligence and reporting obligations, (2) the non-financial foreign entity either certifies it does not have any substantial United States owners (as defined in the Code) or furnishes identifying information regarding each substantial United States owner, or (3) the foreign financial institution or non-financial foreign entity otherwise qualifies for an exemption from these rules. If the payee is a foreign financial institution and is subject to the diligence and reporting requirements in (1) above, it must enter into an agreement with the U.S. Department of the Treasury requiring, among other things, that it undertake to identify accounts held by certain specified United States persons or United States-owned foreign entities (each as defined in the Code), annually report certain information about such accounts, and withhold 30% on certain payments to non-compliant foreign financial institutions and certain other account holders. Foreign financial institutions located in jurisdictions that have an intergovernmental agreement with the United States governing FATCA may be subject to different rules.

Under the applicable Treasury Regulations, withholding under FATCA generally applies to payments of dividends on our common stock, and will apply to payments of gross proceeds from the sale or other disposition of such stock on or after January 1, 2017. Prospective investors should consult their tax advisors regarding the potential application of these withholding provisions.



---

**Table of Contents**

**DESCRIPTION OF SECURITIES**

**Common stock**

The material terms and provisions of our common stock are described under the caption "Description of Securities" in the accompanying prospectus. As of May 5, 2015, we had 91,608,295 shares of our common stock outstanding. Our common stock is listed on the NYSE MKT under the symbol "CVM".

***Rights Agreement***

In November 2007, we declared a dividend of one Series A Right and one Series B Right, or collectively the Rights, for each share of our common stock which was outstanding on November 9, 2007. When the Rights become exercisable, each Series A Right will entitle the registered holder, subject to the terms of a Rights Agreement, to purchase from us one share of our common stock at a price equal to 20% of the market price of our common stock on the exercise date, although the price may be adjusted pursuant to the terms of the Rights Agreement. If after a person or group of affiliated persons has acquired 15% or more of our common stock or following the commencement of a tender offer for 15% or more of our outstanding common stock (i) we are acquired in a merger or other business combination and we are not the surviving corporation, (ii) any person consolidates or merges with us and all or part of our common shares are converted or exchanged for securities, cash or property of any other person, or (iii) 50% or more of our consolidated assets or earning power are sold, proper provision will be made so that each holder of a Series B Right will thereafter have the right to receive, upon payment of the exercise price of \$100 (subject to adjustment), that number of shares of common stock of the acquiring company which at the time of such transaction has a market value that is twice the exercise price of the Series B Right.

The description and terms of the Rights are set forth in a Rights Agreement between the Company and Computershare Trust Company, N.A., as Rights Agent.

***Distribution of Rights***

Initially, stockholders will not receive separate certificates for the Rights as the Rights will be represented by outstanding common stock certificates. Until the exercise date, the Rights cannot be bought, sold or otherwise traded separately from the common stock. Certificates for common stock will carry a notation that indicates that Rights are attached to the common stock and incorporate the terms of the Rights Agreement.

Separate certificates representing the Rights will be distributed as soon as practicable after the earliest to occur of:

15 business days following a public announcement that a person or group of affiliated or associated persons has acquired beneficial ownership of 15% or more of our outstanding common stock, or

15 business days (or such later date as may be determined by action of our board of directors prior to such time as any person or group of affiliated persons has acquired 15% or more of our common stock) following the commencement of, or announcement of an intention to make, a tender offer or exchange offer the consummation of which would result in the beneficial ownership by a person or group of 15% or more of our outstanding common stock.

The earlier of such dates described above is called the "distribution date".

Until the distribution date (or earlier redemption or expiration of the Rights), the surrender for transfer of any certificates for common stock outstanding as of the record date, even without such notation, will also constitute the transfer of the Rights associated with the common stock represented by such certificate. As soon as practicable following the distribution date, separate certificates evidencing the Rights will be mailed to holders of record of the common stock as of the close of business on the distribution date and such separate right certificates alone will evidence the Rights.

## **Table of Contents**

### *Exercise and Expiration*

The holders of the Rights are not required to take any action until the Rights become exercisable. The Rights are not exercisable until the distribution date. Holders of the Rights will be notified by us that the Rights have become exercisable. The Rights will expire on October 30, 2015, unless the expiration date is extended or unless the Rights are earlier redeemed by us as described below.

### *Redemption*

At any time prior to the distribution date, our board of directors may redeem the Rights in whole, but not in part, at a price of \$0.0001 per Right. Subject to the foregoing, the redemption of the Rights may be made effective at such time, on such basis and with such conditions as our board of directors in its sole discretion may establish. Immediately upon any redemption of the Rights, the right to exercise the Rights will terminate and the only entitlement of the holders of Rights will be to receive the redemption price.

### *Exchange Option*

At any time after a person or group of affiliated persons has acquired 15% or more of our common stock or following the commencement of a tender offer for 15% or more of our outstanding common stock, and prior to the acquisition by such person of 50% or more of the outstanding common stock, our board of directors may exchange the Rights (other than Rights owned by such person or group which have become void), in whole or in part, at an exchange ratio of one share of common stock per Right (subject to adjustment).

### *Other Provisions*

The terms of the Rights may be amended by our board of directors without the consent of the holders of the Rights, except that from and after such time a person or group of affiliated persons has acquired 15% or more of our common stock no such amendment may adversely affect the interests of the holders of the Rights.

Until a Right is exercised, the holder of the Right, as such, will not have any rights as a stockholder, including, without limitation, the right to vote or to receive dividends.

The Rights may have certain anti-takeover effects. The Rights will cause substantial dilution to a person or group that attempts to acquire us on terms not approved by our board of directors. However, the Rights should not interfere with any merger or other business combination approved by a majority of our board of directors because the Rights may be redeemed by us at any time prior to the distribution date. Thus, the Rights are intended to encourage persons who may seek to acquire control of us to initiate such an acquisition through negotiations with our board of directors. However, the effect of the Rights may be to discourage a third party from making a partial tender offer or otherwise attempting to obtain a substantial position in the equity securities of, or seeking to obtain control of, us. To the extent any potential acquisition is deterred by the Rights, the Rights may have the effect of preserving incumbent management in office.

### *Attorneys Fees in Stockholder Actions*

On February 18, 2015, we adopted new bylaws which include a fee-shifting provision in Article X for stockholder claims. Article X provides that in the event that any stockholder initiates or asserts a claim against us, or any of our officers or directors, including any derivative claim or claim purportedly filed on our behalf, and the stockholder does not obtain a judgment on the merits that substantially achieves, in substance and amount, the full remedy sought, then the stockholder will be obligated to reimburse us and any of our officers or directors named in the action, for all fees, costs and expenses of every kind and description, including but not limited to all reasonable attorneys fees and other litigation expenses, that we or our officers or directors who were named in the action may incur in connection with such claim.

**Table of Contents**

Our fee-shifting bylaw is not limited to specific types of actions, but is rather potentially applicable to the fullest extent permitted by law. There are several types of remedies that a stockholder may seek in connection with an action or proceeding against us, including declaratory or injunctive relief, or monetary damages. If a stockholder is not successful in obtaining a judgment that substantially achieves in substance, such as in the case of a claim for declaratory or injunctive relief, or amount, such as in the case of a claim for monetary damages, our and our officers and directors' litigation expenses may be shifted to the stockholder.

Fee-shifting bylaws are relatively new and untested. The case law and potential legislative action on fee shifting bylaws are evolving and there exists considerable uncertainty regarding the validity of, and potential judicial and legislative responses to, such bylaws. For example, it is unclear whether our ability to invoke our fee-shifting bylaw in connection with claims under the federal securities laws, including claims related to this offering, would be pre-empted by federal law. Similarly, it is unclear how courts might apply the standard that a stockholder must obtain a judgment that substantially achieves, in substance and amount, the full remedy sought. The application of our fee shifting bylaw in connection with such claims, if any, will depend in part on future developments of the law. We cannot assure you that we will or will not invoke our fee-shifting bylaw in any particular dispute, including any claims related to this offering.

If a stockholder that brings any such claim is unable to obtain the required judgment, the attorneys' fees and other litigation expenses that might be shifted to such a stockholder are potentially significant. This fee-shifting bylaw, therefore, may dissuade or discourage stockholders (and their attorneys) from initiating lawsuits or claims against us or our directors and officers. In addition, it may impact the fees, contingency or otherwise, required by potential plaintiffs' attorneys to represent our stockholders or otherwise discourage plaintiffs' attorneys from representing our stockholders at all. As a result, this bylaw may limit the ability of stockholders to affect the management and direction of our company, particularly through litigation or the threat of litigation.

**Table of Contents****UNDERWRITING**

We have entered into an underwriting agreement with FBR Capital Markets & Co., or the underwriter, with respect to the shares subject to this offering. Subject to the terms and conditions in the underwriting agreement, we have agreed to sell to the underwriter, and the underwriter has agreed to purchase from us on a firm commitment basis \_\_\_\_\_ shares of our common stock.

The underwriting agreement provides that the obligation of the underwriter to purchase all of the shares being offered to the public is subject to approval of legal matters by counsel and the satisfaction of other conditions. These conditions include, among others, the continued accuracy of representations and warranties made by us in the underwriting agreement, delivery of legal opinions and the absence of any material changes in our assets, business or prospects after the date of this prospectus supplement. The underwriter is obligated to purchase all of our shares in this offering, other than those covered by the option to purchase additional shares described below, if it purchases any of our shares. The underwriter has advised us that the underwriter proposes to offer the common stock directly to the public at the public offering price listed on the cover page of this prospectus supplement and to selected dealers, who may include the underwriter, at the public offering price less a selling concession not in excess of \$ \_\_\_\_\_ per share for the common stock. After the completion of this offering, the underwriter may change the offering price and other selling terms. Sales of common stock made outside of the United States may be made by affiliates of the underwriter.

Pursuant to the underwriting agreement, we have agreed to indemnify the underwriter against certain liabilities, including liabilities under the Securities Act, or to contribute to payments which the underwriter or other indemnified parties may be required to make in respect of any such liabilities.

**Commissions and Expenses**

The following table provides information regarding the amount of the underwriting discounts and commissions to be paid to the underwriter by us. These amounts are shown assuming both no exercise and full exercise of the underwriter's option to purchase additional shares.

	Per Share	Without Option	With Option
Public offering price	\$	\$	\$
Underwriting discounts and commissions to be paid by us	\$	\$	\$
Proceeds, before expenses, to us	\$	\$	\$

Shares of our common stock trade on the NYSE MKT under the symbol CVM. We estimate that the total expenses of this offering payable by us, excluding underwriting discounts and commissions, will be approximately \$300,000. We have also agreed to reimburse the underwriter for certain of its expenses in an amount up to \$5,000.

**Option to Purchase Additional Shares**

We have granted the underwriter an option, which is exercisable for up to 30 days after the date of this prospectus supplement, to purchase a maximum of \_\_\_\_\_ additional shares of common stock from us. If the underwriter exercises all or part of this option, the underwriter will be obligated to purchase shares covered by the option at the public offering price that appears on the cover page of this prospectus supplement, less the underwriting discounts and commissions to be paid by us.

**Lock-Up Agreements**

Our executive officers and directors and certain of our significant stockholders have agreed to a 90-day lock-up from the date of this prospectus supplement. This means that, for a period of 90 days following the date of this prospectus supplement, such persons may not, without the prior written consent of FBR Capital Markets & Co., directly or indirectly, (1) offer for sale, sell, pledge, or otherwise dispose of (or enter into any

---

**Table of Contents**

transaction or device that is designed to, or could be expected to, result in the disposition by any person at any time in the future of) any shares of our common stock (including, without limitation, shares of our common stock that may be deemed to be beneficially owned by them in accordance with the rules and regulations of the SEC and shares of our common stock that may be issued upon exercise of any options or warrants) or securities convertible into or exercisable or exchangeable for our common stock, (2) enter into any swap or other derivatives transaction that transfers to another, in whole or in part, any of the economic benefits or risks of ownership of shares of our common stock, whether any such transaction described in clause (1) or (2) above is to be settled by delivery of common stock or other securities, in cash or otherwise, (3) make any demand for or exercise any right or cause to be filed a registration statement, including any amendments thereto, with respect to the registration of any shares of our common stock or securities convertible into or exercisable or exchangeable for common stock or any other securities of ours, or (4) publicly disclose the intention to do any of the foregoing.

These limitations do not apply to (a) transactions relating to shares of our common stock or other securities acquired in the open market after the completion of this offering, (b) bona fide gifts, sales or other dispositions of shares of any class of our capital stock, in each case that are made to family members or affiliates, including their partners (if a partnership) or members (if a limited liability company); provided the transferee/donee agrees to be bound by the restrictions included in the lock-up agreements and each party (donor, donee, transferor or transferee) shall not be required to make, or voluntarily make, any filing or public announcement of the transfer or disposition prior to the expiration of the 90-day period referred to above, (c) the exercise of warrants or the exercise of stock options granted pursuant to our stock option/incentive plans or otherwise outstanding on the date of this prospectus supplement; provided, that the restrictions shall apply to shares of our common stock issued upon such exercise or conversion, and (d) the establishment of any contract, instruction or plan that satisfies all of the requirements of Rule 10b5-1.

The 90-day period described above will be extended if:

during the last 17 days of the 90-day period we issue an earnings release or material news or a material event relating to us occurs; or

prior to the expiration of the 90-day period, we announce that we will release earnings results during the 16-day period beginning on the last day of the 90-day period, in which case the restrictions described above will continue to apply until the expiration of the 18-day period beginning on the issuance of the earnings release or the announcement of the material news or occurrence of material event unless such extension is waived in writing by FBR Capital Markets & Co.

In addition, the underwriting agreement provides that we will not, for a period of 90 days following the date of this prospectus supplement, offer, sell or distribute any of our securities, without the prior written consent of FBR Capital Markets & Co., subject to certain limited exceptions (including the issuance of approximately 34,000 shares a month to a consultant of the Company pursuant to a contract in existence on the date of this prospectus supplement).

**Stabilization**

Until the distribution of the securities offered by this prospectus supplement and the accompanying prospectus is completed, rules of the SEC may limit the ability of the underwriter to bid for and to purchase our common stock. As an exception to these rules, the underwriter may engage in transactions effected in accordance with Regulation M under the Exchange Act that are intended to stabilize, maintain or otherwise affect the price of our common stock. The underwriter may engage in over-allotment sales, syndicate covering transactions, stabilizing transactions and penalty bids in accordance with Regulation M.

Stabilizing transactions permit bids or purchases for the purpose of pegging, fixing or maintaining the price of the common stock, so long as stabilizing bids do not exceed a specified maximum.

Over-allotment involves sales by the underwriter of securities in excess of the number of securities the underwriter is obligated to purchase, which creates a short position. The short position may be either a

## **Table of Contents**

covered short position or a naked short position. In a covered short position, the number of shares of common stock over-allotted by the underwriter is not greater than the number of shares of common stock that it may purchase pursuant to its option to purchase additional shares. In a naked short position, the number of shares of common stock involved is greater than the number of shares it may purchase pursuant to its option to purchase additional shares. The underwriter may close out any covered short position by either exercising the option to purchase additional shares or purchasing shares of our common stock in the open market.

Covering transactions involve the purchase of securities in the open market after the distribution has been completed in order to cover short positions. In determining the source of securities to close out the short position, the underwriter will consider, among other things, the price of securities available for purchase in the open market as compared to the price at which it may purchase securities through its option to purchase additional shares. If the underwriter sells more shares of common stock than could be covered by its option to purchase additional shares, creating a naked short position, the position can only be closed out by buying securities in the open market. A naked short position is more likely to be created if the underwriter is concerned that there could be downward pressure on the price of the securities in the open market after pricing that could adversely affect investors who purchase in this offering.

Penalty bids permit the underwriter to reclaim a selling concession from a selected dealer when the securities originally sold by the selected dealer are purchased in a stabilizing or syndicate covering transaction.

These stabilizing transactions, covering transactions and penalty bids may have the effect of raising or maintaining the market price of our securities or preventing or retarding a decline in the market price of our common stock. As a result, the price of our securities may be higher than the price that might otherwise exist in the open market.

Neither we nor the underwriter make any representation or prediction as to the effect that the transactions described above may have on the prices of our securities. These transactions may occur on any trading market. If any of these transactions are commenced, they may be discontinued without notice at any time.

## **Electronic Prospectus**

This prospectus supplement and the accompanying prospectus may be made available in electronic format on Internet sites or through other online services maintained by the underwriter or its affiliates. In those cases, prospective investors may view offering terms online and may be allowed to place orders online. Other than this prospectus supplement and the accompanying prospectus in electronic format, any information on the underwriter's or its affiliates' websites and any information contained in any other website maintained by the underwriter or any affiliate of the underwriter is not part of this prospectus supplement and the accompanying prospectus or the registration statement of which this prospectus supplement and the accompanying prospectus form a part, has not been approved and/or endorsed by us or the underwriter and should not be relied upon by investors.

## **Non-U.S. Legends**

Other than in the United States, no action has been taken by us or the underwriter that would permit a public offering of the securities offered by this prospectus supplement and the accompanying prospectus in any jurisdiction where action for that purpose is required. The securities offered by this prospectus supplement and the accompanying prospectus may not be offered or sold, directly or indirectly, nor may this prospectus supplement and the accompanying prospectus or any other offering material or advertisements in connection with the offer and sale of any such securities be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons

---

**Table of Contents**

in possession of this prospectus supplement and the accompanying prospectus are advised to inform themselves about and to observe any restrictions relating to the offering and the distribution of this prospectus supplement and the accompanying prospectus. This prospectus supplement and the accompanying prospectus do not constitute an offer to sell or a solicitation of an offer to buy any securities offered by this prospectus supplement and the accompanying prospectus in any jurisdiction in which such an offer or a solicitation is unlawful.

***Notice to Prospective Investors in the EEA***

In relation to each Member State of the European Economic Area which has implemented the Prospectus Directive (each, a Relevant Member State ), from and including the date on which the European Union Prospectus Directive (the EU Prospectus Directive ) was implemented in that Relevant Member State (the Relevant Implementation Date ) an offer of securities described in this prospectus supplement and the accompanying prospectus may not be made to the public in that Relevant Member State prior to the publication of a prospectus in relation to the shares which has been approved by the competent authority in that Relevant Member State or, where appropriate, approved in another Relevant Member State and notified to the competent authority in that Relevant Member State, all in accordance with the EU Prospectus Directive, except that, with effect from and including the Relevant Implementation Date, an offer of securities described in this prospectus supplement and the accompanying prospectus may be made to the public in that Relevant Member State at any time:

to any legal entity which is a qualified investor as defined under the EU Prospectus Directive;

to fewer than 100 or, if the Relevant Member State has implemented the relevant provision of the 2010 PD Amending Directive, 150 natural or legal persons (other than qualified investors as defined in the EU Prospectus Directive); or

in any other circumstances falling within Article 3(2) of the EU Prospectus Directive, provided that no such offer of securities described in this prospectus supplement and the accompanying prospectus shall result in a requirement for the publication by us of a prospectus pursuant to Article 3 of the EU Prospectus Directive.

For the purposes of this provision, the expression an offer of securities to the public in relation to any securities in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and the securities to be offered so as to enable an investor to decide to purchase or subscribe for the securities, as the same may be varied in that Member State by any measure implementing the EU Prospectus Directive in that Member State. The expression EU Prospectus Directive means Directive 2003/71/EC (and any amendments thereto, including the 2010 PD Amending Directive, to the extent implemented in the Relevant Member State) and includes any relevant implementing measure in each Relevant Member State, and the expression 2010 PD Amending Directive means Directive 2010/73/EU.

***Notice to Prospective Investors in the United Kingdom***

This prospectus supplement and the accompanying prospectus are only being distributed to and is only directed at persons in the United Kingdom that are qualified investors within the meaning of Article 2(1)(e) of the Prospectus Directive that are also (i) to investment professionals falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, or the Order, and/or (ii) high net worth entities, and other persons to whom it may lawfully be communicated, falling with Article 49(2)(a) to (d) of the Order (all such persons together being referred to as relevant persons ).

This prospectus supplement and the accompanying prospectus and their contents are confidential and should not be distributed, published or reproduced (in whole or in part) or disclosed by recipients to any other persons in the United Kingdom. Any person in the United Kingdom who is not a relevant person should not act or rely on this prospectus supplement and the accompanying prospectus or any of their contents.

## **Table of Contents**

The underwriter has represented, warranted and agreed that:

- (A) it has only communicated or caused to be communicated and will only communicate or cause to be communicated an invitation or inducement to engage in investment activity (within the meaning of Section 21 of the Financial Services and Markets Act 2000, as amended, or the FSMA) received by it in connection with the issue or sale of the Shares in circumstances in which Section 21(1) of the FSMA does not apply to us; and
- (B) it has complied and will comply with all applicable provisions of the FSMA with respect to anything done by it in relation to the shares of our common stock in, from or otherwise involving the United Kingdom.

### ***Notice to Prospective Investors in Germany***

Any offer or solicitation of securities within Germany must be in full compliance with the German Securities Prospectus Act (Wertpapierprospektgesetz WpPG). The offer and solicitation of securities to the public in Germany requires the publication of a prospectus that has to be filed with and approved by the German Federal Financial Services Supervisory Authority (Bundesanstalt für Finanzdienstleistungsaufsicht BaFin). This prospectus supplement and the accompanying prospectus have not been and will not be submitted for filing and approval to the BaFin and, consequently, will not be published. Therefore, this prospectus supplement and the accompanying prospectus do not constitute a public offer under the German Securities Prospectus Act (Wertpapierprospektgesetz). This prospectus supplement and the accompanying prospectus and any other document relating to our common stock, as well as any information contained therein, must therefore not be supplied to the public in Germany or used in connection with any offer for subscription of our common stock to the public in Germany, any public marketing of our common stock or any public solicitation for offers to subscribe for or otherwise acquire our common stock. This prospectus supplement and the accompanying prospectus and other offering materials relating to the offer of our common stock are strictly confidential and may not be distributed to any person or entity other than the designated recipients hereof.

### ***Notice to Prospective Investors in Switzerland***

This document, as well as any other material relating to the shares which are the subject of the offering contemplated by this prospectus supplement and the accompanying prospectus, do not constitute an issue prospectus pursuant to Article 652a and/or 1156 of the Swiss Code of Obligations. The shares will not be listed on the SIX Swiss Exchange and, therefore, the documents relating to the shares, including, but not limited to, this document, do not claim to comply with the disclosure standards of the listing rules of SIX Swiss Exchange and corresponding prospectus schemes annexed to the listing rules of the SIX Swiss Exchange. The shares are being offered in Switzerland by way of a private placement, i.e., to a small number of selected investors only, without any public offer and only to investors who do not purchase the shares with the intention to distribute them to the public. The investors will be individually approached by the issuer from time to time. This document, as well as any other material relating to the shares, is personal and confidential and does not constitute an offer to any other person. This document may only be used by those investors to whom it has been handed out in connection with the offering described herein and may neither directly nor indirectly be distributed or made available to other persons without express consent of the issuer. It may not be used in connection with any other offer and shall in particular not be copied and/or distributed to the public in (or from) Switzerland.

### **Relationships**

The underwriter and its affiliates have provided in the past to us and our affiliates and may provide from time to time in the future certain commercial banking, financial advisory, investment banking and other services for us and such affiliates in the ordinary course of their business, for which they have received and may continue to receive customary fees and commissions. In addition, from time to time, certain of the underwriter and its affiliates may effect transactions for their own account or the account of customers, and hold on behalf of themselves or their customers, long or short positions in our debt or equity securities or loans, and may do so in the future.



**Table of Contents**

**LEGAL MATTERS**

The validity of the issuance of the securities offered hereby will be passed upon for us by Hart & Hart LLC, Denver, Colorado. Certain legal matters will be passed upon for the underwriter by Latham & Watkins LLP, Los Angeles, California.

**EXPERTS**

The financial statements as of September 30, 2014 and 2013 and for each of the three years in the period ended September 30, 2014 and management's assessment of the effectiveness of internal control over financial reporting as of September 30, 2014 incorporated by reference in this prospectus supplement and the accompanying prospectus have been so incorporated in reliance on the reports of BDO USA, LLP, an independent registered public accounting firm, incorporated herein by reference, given on the authority of said firm as experts in auditing and accounting.

**WHERE YOU CAN FIND MORE INFORMATION**

This prospectus supplement and the accompanying prospectus are part of the registration statement on Form S-3 we filed with the SEC under the Securities Act of 1933, as amended, and do not contain all the information set forth in the registration statement. Whenever a reference is made in this prospectus supplement or the accompanying prospectus to any of our contracts, agreements or other documents, the reference may not be complete, and you should refer to the exhibits that are a part of the registration statement or the exhibits to the reports or other documents incorporated by reference into this prospectus supplement and the accompanying prospectus for a copy of such contract, agreement or other document. You may inspect a copy of the registration statement, including the exhibits and schedules, without charge, at the SEC's public reference room mentioned below, or obtain a copy from the SEC upon payment of the fees prescribed by the SEC.

We are subject to the requirements of the Securities Exchange Act of 1934, as amended, and are required to file reports, proxy statements and other information with the Securities and Exchange Commission. Copies of any such reports, proxy statements and other information filed by us can be read and copied at the Commission's Public Reference Room at 100 F. Street, N.E., Washington, D.C. 20549. The public may obtain information on the operation of the Public Reference Room by calling the Commission at 1-800-SEC-0330. The Commission maintains an Internet site that contains reports, proxy and information statements, and other information regarding us. The address of that site is <http://www.sec.gov>. Our reference to the SEC's Internet site is intended to be an inactive textual reference only.

You can find information about us on our website at <http://www.cel-sci.com>. Information found on our website is not part of this prospectus supplement or the accompanying prospectus.

**Table of Contents**

**INCORPORATION OF DOCUMENTS BY REFERENCE**

We incorporate by reference the filed documents listed below, except as superseded, supplemented or modified by this prospectus supplement or the accompanying prospectus, and any future filings we will make with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act:

our Annual Report on Forms 10-K and 10-K/A for the fiscal year ended September 30, 2014;

our Quarterly Report on Form 10-Q for the three months ended December 31, 2014;

our Current Reports on Form 8-K filed with the SEC on October 22, 2014, October 23, 2014, February 18, 2015, March 18, 2015 and April 2, 2015;

our Definitive Proxy Statement, which was filed with the SEC on April 21, 2015;

the description of our common stock contained in our Registration Statement on Form 8-A filed with the SEC on July 2, 1996 and all amendments and reports updating that description; and

the description of our Series S warrants contained in our Registration Statement on Form 8-A filed with the SEC on January 3, 2014 and all amendments and reports updating that description.

To the extent that any information contained in any current report on Form 8-K, or any exhibit thereto, was furnished to, rather than filed with, the SEC, such information or exhibit is specifically not incorporated by reference in this prospectus supplement or the accompanying prospectus.

All documents filed with the Commission by us pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act subsequent to the date of this prospectus supplement and prior to the termination of this offering shall be deemed to be incorporated by reference into this prospectus supplement and the accompanying prospectus and to be a part of this prospectus supplement and the accompanying prospectus from the date of the filing of such documents. Any statement contained in a document incorporated or deemed to be incorporated by reference shall be deemed to be modified or superseded for the purposes of this prospectus supplement and the accompanying prospectus to the extent that a statement contained in this prospectus supplement or the accompanying prospectus or in any subsequently filed document that also is or is deemed to be incorporated by reference into this prospectus supplement and the accompanying prospectus modifies or supersedes such statement. Such statement so modified or superseded shall not be deemed, except as so modified or superseded, to constitute a part of this prospectus supplement and the accompanying prospectus.

We will provide, without charge, to each person to whom a copy of this prospectus supplement and the accompanying prospectus is delivered, including any beneficial owner, upon the written or oral request of such person, a copy of any or all of the documents incorporated by reference above (other than exhibits to these documents, unless the exhibits are specifically incorporated by reference into this prospectus). Requests should be directed to:

CEL-SCI Corporation

8229 Boone Blvd., #802

Vienna, Virginia 22182

(703) 506-9460



**Table of Contents**

**PROSPECTUS**

**CEL-SCI CORPORATION**

**Common Stock**

CEL-SCI Corporation may offer from time to time shares of common stock, preferred stock, convertible preferred stock, rights, warrants, or securities issuable upon the conversion or exercise of these securities, at an initial offering price not to exceed \$75,000,000, at prices and on terms to be determined at or prior to the time of sale in light of market conditions at the time of sale.

Specific terms pertaining to the securities offered by this prospectus will be set forth in one or more accompanying prospectus supplements, together with the terms of the offering and the initial price and the net proceeds to CEL-SCI from the sale. The prospectus supplement will set forth, without limitation, the terms of the offering and sale of such securities.

CEL-SCI may sell the securities offered by this prospectus directly, through agents designated from time to time, or through underwriters or dealers. If any agents of CEL-SCI or any underwriters or dealers are involved in the sale of the securities, the names of the agents, underwriters or dealers, any applicable commissions and discounts, and the net proceeds to CEL-SCI will be set forth in the applicable prospectus supplement.

CEL-SCI may not use this prospectus to complete sales of its securities unless this prospectus is accompanied by a prospectus supplement.

The securities offered by this prospectus are speculative and involve a high degree of risk and should be purchased only by persons who can afford to lose their entire investment. For a description of certain important factors that should be considered by prospective investors, see Risk Factors beginning on page 10 of this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or has passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a criminal offense.

On June 25, 2013, CEL-SCI's shareholders approved a reverse split of CEL-SCI's common stock. The reverse split became effective on the NYSE MKT on September 25, 2013. On that date, every ten issued and outstanding shares of CEL-SCI's common stock automatically converted into one outstanding share. All references to shares of common stock and per share data for all periods presented have been adjusted to reflect the reverse stock split on a retroactive basis.

CEL-SCI's common stock is traded on the NYSE MKT under the symbol CVM. On June 16, 2014 the closing price of CEL-SCI's common stock on the NYSE MKT was \$1.09.

Date of this Prospectus is July 8, 2014

**Table of Contents**

**TABLE OF CONTENTS**

	<b>Page</b>
<u>Prospectus Summary</u>	1
<u>Forward Looking Statements</u>	9
<u>Risk Factors</u>	10
<u>Comparative Share Data</u>	17
<u>Market for CEL-SCI's Common Stock</u>	20
<u>Plan of Distribution</u>	22
<u>Description of Securities</u>	24
<u>Experts</u>	25
<u>Indemnification</u>	25
<u>Additional Information</u>	25

**Table of Contents**

**PROSPECTUS SUMMARY**

**THIS SUMMARY IS QUALIFIED BY THE OTHER INFORMATION APPEARING ELSEWHERE IN THIS PROSPECTUS.**

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 immunotherapy is Multikine(R) (Leukocyte Interleukin, Injection), currently being studied in a pivotal global Phase III clinical trial as a potential first-line treatment for advanced primary head and neck cancer. Multikine is also being used in a Phase I study with the Naval Medical Center, San Diego under a Cooperative Research and Development Agreement (CRADA) 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 treatment of peri-anal warts and assess its effect on anal intraepithelial dysplasia (AIN) in HIV/HPV co-infected men and women.

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 viable treatments available to them and there are, to CEL-SCI'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.

CEL-SCI is also investigating a different peptide-based 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 ([www.jci.org/articles/view/67550](http://www.jci.org/articles/view/67550)), 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 possibly Spanish Flu.

CEL-SCI Corporation was formed as a Colorado corporation in 1983. CEL-SCI's principal office is located at 8229 Boone Boulevard, Suite 802, Vienna, VA 22182. CEL-SCI's telephone number is 703-506-9460 and its web site is [www.cel-sci.com](http://www.cel-sci.com). CEL-SCI does not incorporate the information on its website into this prospectus supplement or accompanying prospectus, and you should not consider it part of this prospectus supplement or accompanying prospectus.

CEL-SCI makes its electronic filings with the Securities and Exchange Commission (SEC), including its annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to these reports available on its website free of charge as soon as practicable after they are filed or furnished to the SEC.

---

**Table of Contents**

**CEL-SCI S PRODUCTS**

CEL-SCI s 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**

CEL-SCI s lead investigational therapy, Multikine (Leukocyte Interleukin, Injection), 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 CEL-SCI has registered for this investigational therapy, and this proprietary name is subject to FDA review in connection with CEL-SCI 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. Neither has its safety or efficacy been established for any use.

Multikine has been cleared by the regulators in ten 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 60-80 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.

In this clinical trial Multikine is given to cancer patients first, i.e., 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, CEL-SCI believes 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.

---

**Table of Contents**

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.

During the early investigational phase, in Phase I and Phase II clinical trials in over 220 subjects who received the investigational therapy Multikine in doses of 200 to 3200 IU (international units), no serious adverse events were reported as being expressly due to administration of this investigational therapy, and subjects in those clinical trials and the treating physicians reported that this investigational therapy was well tolerated in those early-stage clinical trials. Adverse events which were reported included pain at the injection site, local minor bleeding and edema at the injection site, diarrhea, headache, nausea, and constipation. No abnormal laboratory results were reported following Multikine treatment other than those commonly seen by treating physicians in this patient population regardless of Multikine administration. Similarly, in these early-phase clinical studies in patients, there was no reported increased toxicity of follow-on treatments as a result of Multikine administration. No complications following surgery (such as increased time for wound healing) were reported. No definitive conclusions can be drawn from these data about the safety or efficacy profile of this investigational therapy, further research is required and the global Phase III study is ongoing in an effort to confirm these results.

The following is a summary of results from CEL-SCI's last Phase II study conducted with Multikine. This study used the same treatment protocol as is being used in CEL-SCI's Phase III study:

In the final Phase II clinical study, using the same dosage and treatment regimen as is being used in the Phase III study, head and neck cancer patients with locally advanced primary disease who received the investigational therapy Multikine as first-line investigational therapy followed by surgery and radiotherapy were reported by the clinical investigators to have had a 63.2% overall survival (OS) rate at 3.5 years from surgery. This percentage OS was arrived at as follows: of the 22 subjects enrolled in this final Phase II study, the consent for the survival follow-up portion of the study was received from 19 subjects. One subject did not consent to the follow-up portion of the study. The other 2 subjects did not have squamous cell carcinoma of the oral cavity and were thus not evaluable per the protocol. 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 year from treatment. Therefore, the results of CEL-SCI's final Phase II 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 well-controlled Phase III clinical trial of this investigational therapy that is currently in progress. Subject to completion of that Phase III trial and FDA's review and acceptance of CEL-SCI's entire data set on this investigational therapy, CEL-SCI believes that these early-stage clinical trial results indicate the potential for this investigational therapy to become a treatment for advanced primary head and neck cancer.

Reported average of 50% reduction in tumor cells in Phase II trials: The clinical investigators who administered the three week Multikine treatment regimen used in Phase II studies 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



---

**Table of Contents**

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 such as radiation and chemotherapy (Timar et al JCO 2005).

Reported 12% complete response in the final Phase II trial: The clinical investigators who administered the three week Multikine investigational treatment regimen used in the final Phase II study reported that, as was determined in a controlled pathology study, the tumor apparently was no longer present (as determined by histopathology) in approximately 12 % of patients (2 of 17 evaluable by pathology). This determination was made by three pathologists blinded to the study from the surgical specimen after a three week treatment with Multikine (Timar et al JCO 2005).

Adverse events reported in clinical trials: In clinical trials conducted to date with the Multikine investigational therapy, adverse events which have been reported by the clinical investigators as possibly or probably related to Multikine administration included pain at the injection site, local minor bleeding and edema at the injection site, diarrhea, headache, nausea, and constipation. The clinical significance of these and other data, to date, from the multiple Multikine clinical trials is not yet known. These preliminary clinical data do suggest the potential to demonstrate a possible improvement in the clinical outcome for patients treated with Multikine.

Subject to completion of CEL-SCI's global Phase III clinical trial and FDA's review of CEL-SCI's entire data set on this investigational therapy, if the FDA were to conclude that the safety and efficacy of this investigational therapy is established, the early-phase clinical data is encouraging in suggesting the potential that approximately 60-66% (2/3) of head and neck cancer patients with advanced primary disease could be candidates for this investigational therapy if it were to be approved by FDA.

CEL-SCI has an agreement with Teva Pharmaceutical Industries, Ltd., which provides Teva with the exclusive license to market and distribute Multikine in Israel, Turkey, and, later on added Serbia and Croatia. Pursuant to the agreement, Teva has signed up three hospitals and enrolled patients in Israel as part of the Phase III trial. Revenues will be divided between CEL-SCI and Teva.

CEL-SCI has an agreement with Orient Europharma of Taiwan which provides Orient Europharma with the exclusive marketing rights to Multikine for all cancer indications in Taiwan, Singapore, Hong Kong, Malaysia, South Korea, the Philippines, Australia and New Zealand. The agreement requires Orient Europharma to fund the clinical trials needed to obtain marketing approvals in these countries for head and neck cancer, naso-pharyngeal cancer and potentially cervical cancer. Orient Europharma has signed up nine centers in Taiwan where it has enrolled patients as part of the Phase III trial. Revenues will be divided between CEL-SCI and Orient Europharma.

CEL-SCI has a licensing agreement with Byron Biopharma LLC ( Byron ) under which CEL-SCI granted Byron an exclusive license to market and distribute Multikine in the Republic of South Africa. Pursuant to the agreement, Byron will be responsible for registering the product in South Africa. Once Multikine has been approved for sale, CEL-SCI will be responsible for manufacturing the product, while Byron will be responsible for sales in South Africa. Revenues will be divided between CEL-SCI and Byron.

In August 2011, CEL-SCI entered into an exclusive Sales, Marketing and Distribution agreement with IDC-GP Pharm LLC ( IDC-GP Pharm ) under which CEL-SCI granted IDC-GP Pharm an exclusive license to market Multikine in the countries of Argentina and Venezuela (the Territory ). The agreement expired on August 4, 2013 since IDC-GP Pharma did not receive regulatory approval of Multikine in any country in the territory.

On April 23, 2013, the CEL-SCI announced that it has replaced the clinical research organizations (CRO) running its Phase III clinical trial. This was necessary since the patient enrollment in the study dropped off substantially following a takeover of the CRO which caused most of the members of the CRO's study team to

---

**Table of Contents**

leave the CRO. CEL-SCI has hired two CROs who will manage the global Phase III study; Aptiv Solutions and Ergomed who are both international leaders in managing oncology trials. Both CROs will help CEL-SCI expand the trial by 60-80 clinical sites globally.

As of May 1, 2014, the last update given by CEL-SCI, the study had enrolled 183 patients. CEL-SCI expects to see a further increase in the number of patients enrolled in the study at an accelerating pace as (i) the current centers finalize all logistical issues and (ii) an additional 50-60 centers are added throughout the world. Full enrollment of the planned 880 patients is expected by the end of 2015.

In April 2013, CEL-SCI entered into a co-development agreement with Ergomed. Under the co-development agreement, Ergomed will contribute up to \$10 million towards the study in the form of offering discounted clinical services in exchange for a single digit percentage of milestone and royalty payments, up to a specified maximum amount, only from sales of Multikine. Ergomed, a privately-held firm headquartered in Europe with global operations, has entered into multiple similar co-development agreements, including one with Genzyme (purchased by Sanofi in 2011 for over \$20 billion). Ergomed will be responsible for the majority of the new patient enrollment since it has a novel model for clinical site management to accelerate patient recruitment and retention. For example, Ergomed has almost 25 physicians who can directly call on clinical sites to aid recruitment and retention. Some of the Ergomed physicians also have the experience of being clinical investigators themselves. CEL-SCI believes that this interaction on a physician to physician level is what is needed to help increase enrollment in the Multikine study.

CEL-SCI estimates the total cash cost of the Phase III trial, with the exception of the parts that will be paid by its partners, to be approximately \$31.3 million after June 16, 2014. This is in addition to approximately \$13.3 million which has been spent as of June 16, 2014. This estimate is based on information currently available in CEL-SCI's contracts with the Clinical Research Organizations responsible for managing the Phase III trial. This number can be affected by the speed of 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 III trial will be higher than currently estimated.

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 will be 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.

## **Table of Contents**

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 U.S. 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 viable treatments available to them and there are, to CEL-SCI'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.

## **Manufacturing Facility**

Before starting the Phase III trial, CEL-SCI needed to build a dedicated manufacturing facility to produce Multikine. This facility has been completed and validated, and has produced several clinical lots for the Phase III clinical trial. The facility has also passed review by a European Qualified Person on two different occasions.

CEL-SCI completed validation of its new manufacturing facility in January 2010. The state-of-the-art facility is being used to manufacture Multikine for CEL-SCI's Phase III clinical trial. In addition to using this facility to manufacture Multikine, CEL-SCI, only if the facility is not being used for Multikine, may 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, priority will always be given to Multikine as management considers the Multikine supply to the clinical studies and preparation for a final marketing approval 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.

## **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.

---

## **Table of Contents**

Using the LEAPS technology, CEL-SCI has 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.

In September 2009, the U.S. Food and Drug Administration advised CEL-SCI that it could proceed with its first clinical trial to evaluate the effect of LEAPS-H1N1 treatment on the white blood cells of hospitalized H1N1 patients. This followed an expedited initial review of CEL-SCI's regulatory submission for this study proposal.

In November 2009, CEL-SCI announced that The Johns Hopkins University School of Medicine had given clearance for CEL-SCI's first clinical study to proceed using LEAPS-H1N1. Soon after the start of the study, the number of hospitalized H1N1 patients dramatically declined and the study has been unable to complete the enrollment of patients.

Additional work on this treatment for the pandemic flu 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](http://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 its LEAPS technology, CEL-SCI 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.

In February 2010 CEL-SCI announced that its CEL-2000 vaccine demonstrated that it was able to block the progression of rheumatoid arthritis in a mouse model. The results were published in the scientific peer-reviewed Journal of International Immunopharmacology (online edition) in an article titled "CEL-2000: A Therapeutic Vaccine for Rheumatoid Arthritis Arrests Disease Development and Alters Serum Cytokine/Chemokine Patterns in the Bovine Collagen Type II Induced Arthritis in the DBA Mouse Model" with lead author Daniel Zimmerman, Ph.D., Senior Vice President of Research, Cellular Immunology at CEL-SCI. The study was co-authored by scientists from CEL-SCI, Washington Biotech, Northeastern Ohio Universities Colleges of Medicine and Pharmacy and Boulder BioPath.

In August 2012, Dr. Zimmerman gave a Keynote presentation at the OMICS 2nd International Conference on Vaccines and Vaccinations in Chicago. This presentation showed how the LEAPS peptides administered altered only select cytokines specific for each disease model, thereby improving the status of the test animals and even preventing death and morbidity. These results support the growing body of evidence that provides for its mode of action by a common format in these unrelated conditions by regulation of Th1 (e.g., IL12 and IFN-a)

---

**Table of Contents**

and their action on reducing TNF-a and other inflammatory cytokines as well regulation of antibodies to these disease associated antigens. This was also illustrated by a schematic model showing how these pathways interact and result in the overall effect of protection and regulation of cytokines in a beneficial manner.

Even though the various LEAPS drug candidates have not yet been given to humans, they have been tested in vitro with human cells. They have induced similar cytokine responses that were seen in these animal models, which may indicate that the LEAPS technology might translate to humans. The LEAPS candidates have demonstrated protection against lethal herpes simplex virus (HSV1) and H1N1 influenza infection, as a prophylactic or therapeutic agent in animals. They have also shown efficacy in animals in two autoimmune conditions, curtailing and sometimes preventing disease progression in arthritis and myocarditis animal models. CEL-SCI's belief is that the LEAPS technology may be a significant alternative to the vaccines currently available on the market today for these diseases.

None of the LEAPS investigational products have been approved for sale, barter or exchange by the FDA or any other regulatory agency for any use to treat disease in animals or humans. The safety or efficacy of these products has not been established for any use. Lastly, no definitive conclusions can be drawn from the early-phase, preclinical-trials data involving these investigational products. Before obtaining marketing approval from the FDA in the United States, and by comparable agencies in most foreign countries, these product candidates must undergo rigorous preclinical and clinical testing which is costly and time consuming and subject to unanticipated delays. There can be no assurance that these approvals will be granted.

**THE OFFERING**

**Securities Offered:**

CEL-SCI may offer from time to time shares of common stock, preferred stock, rights and warrants, or securities issuable upon the conversion or exercise of such securities at an initial offering price not to exceed \$75,000,000, at prices and on terms to be determined at or prior to the time of sale in light of market conditions at the time of sale. CEL-SCI may not use this prospectus to complete sales of its securities unless this prospectus is accompanied by a prospectus supplement. See the Plan of Distribution section of this prospectus for additional information concerning the manner in which CEL-SCI's securities may be offered.

Common Stock Outstanding: As of June 16, 2014 CEL-SCI had 65,970,785 outstanding shares of common stock. The number of outstanding shares does not give effect to shares which may be issued upon the exercise and/or conversion of options, warrants or other convertible securities.

See Comparative Share Data for more information.

**Risk Factors:**

The purchase of the securities offered by this prospectus involves a high degree of risk. Risk factors include the lack of revenues and history of loss, need for additional capital and need for FDA approval.

See the Risk Factors section of this prospectus for additional Risk Factors.

Common Stock  
NYSE MKT Symbol:

CVM

Series S Warrants

NYSE MKT Symbol:

CVM WS

8

**Table of Contents**

**FORWARD LOOKING STATEMENTS**

This prospectus contains various forward-looking statements that are based on CEL-SCI's beliefs as well as assumptions made by and information currently available to CEL-SCI. When used in this prospectus, the words believe, expect, anticipate, estimate and similar expressions are intended to identify forward-looking statements. Such statements may include statements regarding seeking business opportunities, payment of operating expenses, and the like, and are subject to certain risks, uncertainties and assumptions which could cause actual results to differ materially from projections or estimates. Factors which could cause actual results to differ materially are discussed at length under the heading Risk Factors. Should one or more of the enumerated risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those anticipated, estimated or projected. Investors should not place undue reliance on forward-looking statements, all of which speak only as of the date made.

**Table of Contents**

**RISK FACTORS**

Investors should be aware that this offering involves the risks described below, which could adversely affect the price of CEL-SCI's common stock. In addition to the other information contained in this prospectus, the following factors should be considered carefully in evaluating an investment in the securities offered by this prospectus.

**Risks Related to CEL-SCI**

Since CEL-SCI has earned only limited revenues and has a history of losses, CEL-SCI will require additional capital to remain in operation, complete its clinical trials and fund pre-marketing expenses.

CEL-SCI has had only limited revenues since it was formed in 1983. Since the date of its formation and through March 31, 2014, CEL-SCI incurred net losses of approximately \$(230,000,000). CEL-SCI has relied principally upon the proceeds of public and private sales of its securities to finance its activities to date.

If CEL-SCI cannot obtain additional capital, CEL-SCI may have to postpone development and research expenditures, which will delay CEL-SCI's ability to produce a competitive product. Delays of this nature may depress the price of CEL-SCI's common stock. In addition, although CEL-SCI is not aware of a direct competitor for Multikine, it is possible that one exists. There are many potential competitors of LEAPS. If competitors develop, any delay in the development of CEL-SCI's products may provide opportunities to those competitors.

The condition of the overall economy may continue to affect both the availability of capital and CEL-SCI's stock price. In addition, future capital raises, which will be necessary for CEL-SCI's survival, will be further dilutive to current shareholders. There can be no assurance that CEL-SCI will be able to raise the capital it will need.

All of CEL-SCI's potential products, with the exception of Multikine, are in the early stages of development, and any commercial sale of these products will be many years away.

Even potential product sales from Multikine are years away, since cancer trials can be lengthy. Accordingly, CEL-SCI expects to incur substantial losses for the foreseeable future.

Since CEL-SCI does not intend to pay dividends on its common stock, any potential return to investors will result only from any increases in the price of CEL-SCI's common stock.

At the present time, CEL-SCI intends to use available funds to finance its operations. Accordingly, while payment of dividends rests within the discretion of CEL-SCI's Directors, no common stock dividends have been declared or paid by CEL-SCI and CEL-SCI has no intention of paying any common stock dividends in the foreseeable future. Any gains for CEL-SCI's investors will most likely result from increases in the price of CEL-SCI's common stock, which has been volatile in the recent past. If CEL-SCI's stock price does not increase, which likely will depend primarily upon the results of the Multikine clinical trials, an investor is unlikely to receive any return on an investment in CEL-SCI's common stock.

The costs of CEL-SCI's product development and clinical trials are difficult to estimate and will be very high for many years, preventing CEL-SCI 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. CEL-SCI's estimates of the costs associated with future clinical trials and research may be substantially lower than what CEL-SCI actually experiences. It is impossible to predict what CEL-SCI will face in the development of a product, such as LEAPS. The purpose of clinical trials is to provide both CEL-SCI and regulatory authorities with safety and efficacy data in humans. It is



---

**Table of Contents**

relatively common to revise a trial or add subjects to a trial in progress. These examples of common vagaries in product development and clinical investigations demonstrate how predicted costs may exceed reasonable expectations. The different and often complex steps necessary to obtain regulatory approval, especially that of the United States Food and Drug Administration ( FDA ) and the European Union 's European Medicine 's Agency ( EMA ), involve significant costs and may require several years to complete. CEL-SCI expects that it 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 CEL-SCI 's clinical trials and research programs are primarily based upon the amount of capital available to CEL-SCI and the extent to which it receives regulatory approvals for clinical trials. CEL-SCI has established estimates of the future costs of the Phase III clinical trial for Multikine, but, as explained above, that estimate may not prove correct.

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. CEL-SCI is committed to maintaining high standards of corporate governance and public disclosure. Complying with evolving interpretations of new or changing legal requirements may cause CEL-SCI to incur higher costs as it revises current practices, policies and procedures, and may divert management time and attention from potential revenue-generating activities to compliance matters. If CEL-SCI 's 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, CEL-SCI 's reputation may also be harmed. Further, CEL-SCI 's board members, chief executive officer and president could face an increased risk of personal liability in connection with the performance of their duties. As a result, CEL-SCI may have difficulty attracting and retaining qualified board members and executive officers, which could harm its business.

CEL-SCI has not established a definite plan for the marketing of Multikine.

CEL-SCI has not established a definitive plan for marketing nor has it established a price structure for any of its products. However, CEL-SCI intends, if it is in a position to do so, to sell Multikine itself in certain markets and to enter into written marketing agreements with various major pharmaceutical firms with established sales forces. The sales forces in turn would, CEL-SCI believes, target CEL-SCI 's products to cancer centers, physicians and clinics involved in head and neck cancer. CEL-SCI has already licensed Multikine 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. CEL-SCI believes that these companies have the resources to market Multikine appropriately in their respective territories, but there is no guarantee that they will. There is no assurance that CEL-SCI will find qualified parties willing to market CEL-SCI 's product in other areas.

CEL-SCI may encounter problems, delays and additional expenses in developing marketing plans with outside firms. In addition, even if Multikine is cost effective and proven to increase overall survival, CEL-SCI may experience other limitations involving the proposed sale of Multikine, such as uncertainty of third-party reimbursement. There is no assurance that CEL-SCI can successfully market any products which it may develop.

CEL-SCI hopes to expand its clinical development capabilities in the future, and any difficulties hiring or retaining key personnel or managing this growth could disrupt CEL-SCI 's operations.

CEL-SCI is highly dependent on the principal members of CEL-SCI 's management and development staff. If the Multikine clinical trial is successful, CEL-SCI expects to expand its clinical development and manufacturing capabilities, which will involve hiring additional employees. Future growth will require CEL-SCI

---

**Table of Contents**

to continue to implement and improve CEL-SCI's managerial, operational and financial systems and to continue to retain, recruit and train additional qualified personnel, which may impose a strain on CEL-SCI's administrative and operational infrastructure. The competition for qualified personnel in the biopharmaceutical field is intense. CEL-SCI is highly dependent on its ability to attract, retain and motivate highly qualified management and specialized personnel required for clinical development. Due to CEL-SCI's limited resources, CEL-SCI may not be able to manage effectively the expansion of its operations or recruit and train additional qualified personnel. If CEL-SCI is unable to retain key personnel or manage its growth effectively, CEL-SCI may not be able to implement its business plan.

Multikine is made from components of human blood, which involves inherent risks that may lead to product destruction or patient injury.

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 require CEL-SCI to destroy batches of Multikine or cause injuries to patients who receive the product, thereby subjecting CEL-SCI to possible financial losses, lawsuits, and harm to its business.

Although CEL-SCI has product liability insurance for Multikine, the successful prosecution of a product liability case against CEL-SCI could have a materially adverse effect upon its business if the amount of any judgment exceeds CEL-SCI's insurance coverage. Such a suit also could damage the reputation of Multikine and make successful marketing of the product less likely. CEL-SCI commenced the Phase III clinical trial for Multikine in December 2010. Although no claims have been brought to date, participants in CEL-SCI's clinical trials could bring civil actions against CEL-SCI for any unanticipated harmful effects arising from the use of Multikine or any drug or product that CEL-SCI may attempt to develop.

**Risks Related to Government Approvals**

CEL-SCI's product candidates must undergo rigorous preclinical and clinical testing and regulatory approvals, which could be costly and time-consuming and subject CEL-SCI to unanticipated delays or prevent CEL-SCI from marketing any products.

Therapeutic agents, drugs and diagnostic products are subject to approval, prior to general marketing, from the FDA in the United States, the EMA in the European Union, and by comparable agencies in most foreign countries. Before obtaining marketing approval, these product candidates must undergo costly and time consuming preclinical and clinical testing which could subject CEL-SCI to unanticipated delays and may prevent CEL-SCI from marketing its product candidates. There can be no assurance that such approvals will be granted.

CEL-SCI cannot be certain when or under what conditions it will undertake future clinical trials. A variety of issues may delay CEL-SCI's Phase III clinical trial for Multikine or preclinical and early clinical trials for other products. For example, early trials, or the plans for later trials, may not satisfy the requirements of regulatory authorities, such as the FDA. CEL-SCI may fail to find subjects willing to enroll in CEL-SCI's trials. CEL-SCI manufactures Multikine, but relies on third party vendors for managing the trial process and other activities, and these vendors may fail to meet appropriate standards. Accordingly, the clinical trials relating to CEL-SCI's product candidates may not be completed on schedule, the FDA or foreign regulatory agencies may order CEL-SCI to stop or modify its research, or these agencies may not ultimately approve any of CEL-SCI's product candidates for commercial sale. Varying interpretations of the data obtained from pre-clinical and clinical testing could delay, limit or prevent regulatory approval of CEL-SCI's product candidates. The data collected from CEL-SCI's clinical trials may not be sufficient to support regulatory approval of its various product candidates, including Multikine. CEL-SCI's failure to adequately demonstrate the safety and efficacy of any of its product candidates would delay or prevent regulatory approval of its product candidates in the United States, which could prevent CEL-SCI from achieving profitability. Although CEL-SCI had positive results in its Phase II trials for Multikine, those results were for a very small sample set, and CEL-SCI will not know definitively how Multikine will perform until CEL-SCI is well into, or completes, its Phase III clinical trial.

## Table of Contents

The requirements governing the conduct of clinical trials, manufacturing, and marketing of CEL-SCI's product candidates, including Multikine, outside the United States vary from country to country. Foreign approvals may take longer to obtain than FDA approvals and can require, among other things, additional testing and different trial designs. Foreign regulatory approval processes include all of the risks associated with the FDA approval process. Some of those agencies also must approve prices for products approved for marketing. Approval of a product by the FDA or the EMA does not ensure approval of the same product by the health authorities of other countries. In addition, changes in regulatory requirements for product approval in any country during the clinical trial process and regulatory agency review of each submitted new application may cause delays or rejections.

CEL-SCI has only limited experience in filing and pursuing applications necessary to gain regulatory approvals. CEL-SCI's lack of experience may impede its ability to obtain timely approvals from regulatory agencies, if at all. CEL-SCI will not be able to commercialize Multikine and other product candidates until it has obtained regulatory approval. In addition, regulatory authorities may also limit the types of patients to which CEL-SCI or others may market Multikine or CEL-SCI's other products. Any failure to obtain or any delay in obtaining required regulatory approvals may adversely affect the ability of CEL-SCI or potential licensees to successfully market CEL-SCI's products. Even if CEL-SCI obtains regulatory approval for its product candidates, CEL-SCI will be subject to stringent, ongoing government regulation.

If CEL-SCI's products receive regulatory approval, either in the United States or internationally, CEL-SCI will continue to be subject to extensive regulatory requirements. These regulations are wide-ranging and govern, among other things:

product design, development and manufacture;

product application and use

adverse drug experience;

product advertising and promotion;

product manufacturing, including good manufacturing practices

record keeping requirements;

registration and listing of CEL-SCI's establishments and products with the FDA, EMA and other state and national agencies;

product storage and shipping;

drug sampling and distribution requirements;

electronic record and signature requirements; and

labeling changes or modifications.

CEL-SCI and any third-party manufacturers or suppliers must continually adhere to federal regulations setting forth requirements, known as current Good Manufacturing Practices, or cGMPs, and their foreign equivalents, which are enforced by the FDA, the EMA and other national

## Edgar Filing: CEL SCI CORP - Form 424B5

regulatory bodies through their facilities inspection programs. If CEL-SCI's facilities, or the facilities of CEL-SCI's contract manufacturers or suppliers, cannot pass a pre-approval plant inspection, the FDA, EMA, or other national regulators will not approve the marketing applications of CEL-SCI's product candidates. In complying with cGMP and foreign regulatory requirements, CEL-SCI and any of its potential third-party manufacturers or suppliers will be obligated to expend time, money and effort in production, record-keeping and quality control to ensure that CEL-SCI's products meet applicable specifications and other requirements.

If CEL-SCI does not comply with regulatory requirements at any stage, whether before or after marketing approval is obtained, CEL-SCI may be subject to license suspension or revocation, criminal prosecution, seizure,

## **Table of Contents**

injunction, fines, be forced to remove a product from the market or experience other adverse consequences, including restrictions or delays in obtaining regulatory marketing approval for such products or for other products for which it seeks approval. This could materially harm CEL-SCI's financial results, reputation and stock price. Additionally, CEL-SCI may not be able to obtain the labeling claims necessary or desirable for product promotion. CEL-SCI may also be required to undertake post-marketing trials, which will be evaluated by applicable authorities to determine if CEL-SCI's products may remain on the market. If CEL-SCI or other parties identify adverse effects after any of CEL-SCI's products are on the market, or if manufacturing problems occur, regulatory approval may be suspended or withdrawn. CEL-SCI may be required to reformulate its products, conduct additional clinical trials, make changes in product labeling or indications of use, or submit additional marketing applications to support any changes. If CEL-SCI encounters any of the foregoing problems, its business and results of operations will be harmed and the market price of its common stock may decline.

CEL-SCI cannot predict the extent of adverse government regulations which might arise from future legislative or administrative action. Without government approval, CEL-SCI will be unable to sell any of its products.

Foreign governments often impose strict price controls, which may adversely affect CEL-SCI's future profitability.

CEL-SCI intends to seek approval to market Multikine in both the United States and foreign jurisdictions. If CEL-SCI obtains approval in one or more foreign jurisdictions, CEL-SCI will be subject to rules and regulations in those jurisdictions relating to Multikine. In some foreign countries, particularly in the European Union, prescription drug pricing is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a drug candidate. To obtain reimbursement or pricing approval in some countries, CEL-SCI may be required to conduct a clinical trial that compares the cost-effectiveness of Multikine to other available therapies. If reimbursement of Multikine is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, CEL-SCI may be unable to achieve or sustain profitability.

### **Risks Related to Intellectual Property**

CEL-SCI may not be able to achieve or maintain a competitive position, and other technological developments may result in CEL-SCI's proprietary technologies becoming uneconomical or obsolete.

CEL-SCI is involved in a biomedical field that is undergoing rapid and significant technological change. The pace of change continues to accelerate. The successful development of products from CEL-SCI's compounds, compositions and processes through CEL-SCI-financed research, or as a result of possible licensing arrangements with pharmaceutical or other companies, is not assured.

Many companies are working on drugs designed to cure or treat cancer or cure and treat viruses, such as HPV or H1N1. Many of these companies have financial, research and development, and marketing resources, which are much greater than CEL-SCI's, and are capable of providing significant long-term competition either by establishing in-house research groups or by forming collaborative ventures with other entities. In addition, smaller companies and non-profit institutions are active in research relating to cancer and infectious diseases. CEL-SCI's market share will be reduced or eliminated if CEL-SCI's competitors develop and obtain approval for products that are safer or more effective than CEL-SCI's products.

CEL-SCI's patents might not protect CEL-SCI's technology from competitors, in which case CEL-SCI may not have any advantage over competitors in selling any products which it may develop.

Certain aspects of CEL-SCI's technologies are covered by U.S. and foreign patents. In addition, CEL-SCI has a number of new patent applications pending. There is no assurance that the applications still pending or which may be filed in the future will result in the issuance of any patents. Furthermore, there is no assurance as

---

## **Table of Contents**

to the breadth and degree of protection any issued patents might afford CEL-SCI. Disputes may arise between CEL-SCI and others as to the scope and validity of these or other patents. Any defense of the patents could prove costly and time consuming and there can be no assurance that CEL-SCI will be in a position, or will deem it advisable, to carry on such a defense. A suit for patent infringement could result in increasing costs, delaying or halting development, or even forcing CEL-SCI to abandon a product. Other private and public concerns, including universities, may have filed applications for, may have been issued, or may obtain additional patents and other proprietary rights to technology potentially useful or necessary to CEL-SCI. CEL-SCI currently is not aware of any such patents, but the scope and validity of such patents, if any, and the cost and availability of such rights are impossible to predict. Also, as far as CEL-SCI relies upon unpatented proprietary technology, there is no assurance that others may not acquire or independently develop the same or similar technology.

Much of CEL-SCI's intellectual property is protected as a trade secret, not as a patent.

Much of CEL-SCI's intellectual property pertains to its manufacturing system, certain aspects of which may not be suitable for patent filing and must be protected as trade secrets. Those trade secrets must be protected diligently by CEL-SCI to protect their disclosure to competitors, since legal protections after disclosure may be minimal or non-existent. Accordingly, much of CEL-SCI's value is dependent upon its ability to keep its trade secrets confidential. Although CEL-SCI takes measures to ensure confidentiality, CEL-SCI may fail in that attempt. In addition, in some cases a regulator considering CEL-SCI's application for product approval may require the disclosure of some or all of CEL-SCI's proprietary information. In such a case, CEL-SCI must decide whether to disclose the information or forego approval in a particular country. If CEL-SCI is unable to market its products in key countries, CEL-SCI's opportunities and value may suffer.

### **Risks Related to CEL-SCI's Common Stock**

Since the market price for CEL-SCI's common stock is volatile, investors may not be able to sell any of CEL-SCI's shares at a profit.

The market price of CEL-SCI's common stock, as well as the securities of other biopharmaceutical and biotechnology companies, have historically been highly volatile, and the market has from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. During the twelve months ended May 31, 2014, CEL-SCI's post-split stock price has ranged from a low of \$0.53 per share to a high of \$2.70 per share. Factors such as fluctuations in CEL-SCI's operating results, announcements of technological innovations or new therapeutic products by CEL-SCI or its competitors, governmental regulation, developments in patent or other proprietary rights, public concern as to the safety of products developed by CEL-SCI or other biotechnology and pharmaceutical companies, publications by market analysts, law suits, and general market conditions may have a significant effect on the future market price of CEL-SCI's common stock.

Future sales of CEL-SCI's securities may dilute the value of current investors' holdings.

The provisions in CEL-SCI's Articles of Incorporation relating to CEL-SCI's preferred stock allow CEL-SCI's directors to issue preferred stock with rights to multiple votes per share and dividend rights which would have priority over any dividends paid with respect to CEL-SCI's common stock. The issuance of preferred stock with such rights may make more difficult the removal of management even if such removal would be considered beneficial to shareholders generally, and will have the effect of limiting shareholder participation in certain transactions such as mergers or tender offers if such transactions are not favored by incumbent management. In addition, CEL-SCI has issued warrants in the past and may do so in the future. These warrants, providing a future right to purchase shares of CEL-SCI's common stock at an established price, may further dilute the ownership of current shareholders.

In order to raise additional capital, CEL-SCI may need to sell shares of its common stock, or securities convertible into common stock, at prices that may be below the prevailing market price of CEL-SCI's common

## **Table of Contents**

stock at the time of sale. Since CEL-SCI's stock price has been volatile, even a sale at market price one week may represent a substantial discount over the prior week's price. Future sales of CEL-SCI's securities will dilute CEL-SCI's current stockholders and investors and may have a negative effect on the market price of its common stock.

Shares issuable upon the conversion of a note or upon the exercise of outstanding warrants and options may substantially increase the number of shares available for sale in the public market and may depress the price of CEL-SCI's common stock.

As of June 16, 2014, there were outstanding options which allows the holders to purchase approximately 5,996,000 shares of CEL-SCI's common stock, at prices ranging between \$0.85 and \$20.00 per share, outstanding warrants which allow the holders to purchase approximately 36,767,000 shares of CEL-SCI's 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 CEL-SCI's common stock at a conversion price of \$4.00. The outstanding options and warrants could adversely affect CEL-SCI's 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 CEL-SCI may be able to obtain additional capital through a new offering of securities on terms more favorable to CEL-SCI 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 CEL-SCI's 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 CEL-SCI's existing stockholders.

Substantially all of the shares of common stock that are issuable upon the conversions of the note, of the exercise of outstanding options and warrants, may be sold in the public market. The sale of common stock described above, or the perception that such sales could occur, may adversely affect the market price of CEL-SCI's common stock.

Any decline in the price of CEL-SCI's common stock may encourage short sales, which could place further downward pressure on the price of CEL-SCI's common stock. Short selling is a practice of selling shares which are not owned by a seller at that time, with the expectation that the market price of the shares will decline in value after the sale, providing the short seller a profit.

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

**Table of Contents**

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.

**COMPARATIVE SHARE DATA****Number of Shares**

Shares outstanding as of June 16, 2014: 65,970,785.

The number of shares outstanding as of June 16, 2014 excludes shares which may be issued upon the exercise of the options or warrants, or the conversion of the note, described below.

Other Shares Which May Be Issued:

	Number of Shares	Note Reference
Shares issuable upon exercise of Series L warrants	70,000	A
Shares issuable upon the exercise of Series N warrants	2,844,627	B
Shares issuable upon the exercise of warrants held by private investors	54,250	C
Shares issuable upon exercise of options granted to CEL-SCI's officers, directors, employees, consultants, and third parties	5,995,681	D
Shares issuable upon exercise of Series A warrants	130,347	E
Shares issuable upon conversion of note payable to officer and director	276,014	F
Shares issuable upon exercise of warrants held by officer and director	349,754	F
Shares issuable upon exercise of Series B warrants	50,000	G
Shares issuable upon exercise of Series C warrants	463,487	H
Shares issuable upon exercise of Series E warrants	71,428	I
Shares issuable upon exercise of Series F warrants	1,200,000	J
Shares issuable upon exercise of Series G warrants	66,667	J
Shares issuable upon exercise of Series H warrants	1,200,000	K
Shares issuable upon exercise of Series P warrants	590,001	L
Shares issuable upon exercise of Series Q warrants	1,200,000	M
Shares issuable upon exercise of Series R warrants	2,625,000	N
Shares issuable upon exercise of Series S warrants	23,624,326	O
Shares issuable upon exercise of Series T warrants	1,782,057	P
Shares issuable upon exercise of Series U warrants	445,514	P

A. The Series L warrants allow the holders to purchase up to:

70,000 shares of CEL-SCI's common stock at a price of \$2.50 per share at any time on or before April 2, 2015.

B. On August 18, 2008, CEL-SCI sold 138,339 shares of common stock and 207,508 Series N warrants in a private financing for \$1,037,500. In June 2009, an additional 116,667 shares and 181,570 Series N warrants were issued to the investors. In October 2011, an additional 83,333 shares and 129,693 Series N warrants were issued to the investors. In October 2013, an additional 764,602 shares and 1,189,961 Series N warrants were issued to the investors. In December 2013, an additional 798,481 shares and 1,242,688 Series N warrants were issued to the investors. In January 2014, CEL-SCI offered to the investors to extend the Series N warrants by one year and allow for cashless exercise in exchange for cancelling the reset provision in the warrant agreement. One of the investors accepted this offer. As of June 16, 2014, 106,793 Series N Warrants had been exercised. The remaining 2,844,627 Series N warrants entitle the holders to purchase one share of CEL-SCI's common stock at a price of \$0.52731 per share at any time prior to August 18, 2015.





**Table of Contents**

- C. Between May 30, 2003 and July 8, 2009, CEL-SCI sold shares of its common stock in private transactions. In some cases warrants were issued as part of the financings. The names of the warrant holders and the terms of the warrants are shown below:

Warrant Holder	Shares Issuable			Expiration Date
	Issue Date	Upon Exercise of Warrants	Exercise Price	
Cher Ami Holdings	7/18/05	37,500	\$ 6.50	7/18/14
Christian Schleuning	7/8/09	16,750	\$ 5.00	1/8/15

The shares of common stock issuable upon the exercise of these warrants were registered by means of a separate registration statement.

- D. The options are exercisable at prices ranging from \$0.85 to \$20.00 per share. CEL-SCI may also grant options to purchase additional shares under its Incentive Stock Option and Non-Qualified Stock Option Plans.
- E. Between June 23 and July 1, 2009, CEL-SCI sold 1,509,935 shares of its common stock at a price of \$4.00 per share. The investors in this offering also received 1,011,656 Series A warrants. Each Series A warrant entitles the holder to purchase one share of CEL-SCI's common stock. The Series A warrants may be exercised at any time prior to December 24, 2014 at a price of \$5.00 per share. As of June 16, 2014, 881,309 Series A warrants had been exercised. The remaining 130,347 Series A warrants entitle the holders to purchase one share of CEL-SCI's common stock at a price of \$5.00 per share.
- F. Between December 2008 and June 2009, Maximilian de Clara, CEL-SCI's President and a director, loaned CEL-SCI \$1,104,057. The loan was initially payable at the end of March, 2009, but was extended to the end of June, 2009. At the time the loan was due, and in accordance with the loan agreement, CEL-SCI issued Mr. de Clara a warrant which entitles Mr. de Clara to purchase 164,824 shares of CEL-SCI's common stock at a price of \$4.00 per share. The warrant is exercisable at any time prior to December 24, 2014. Although the loan was to be repaid from the proceeds of a financing, CEL-SCI's Directors deemed it beneficial not to repay the loan and negotiated a second extension of the loan with Mr. de Clara on terms similar to the June 2009 financing. Pursuant to the terms of the second extension the note is now due on July 6, 2014, but, at Mr. de Clara's option, the loan can be converted into shares of CEL-SCI's common stock. The number of shares which will be issued upon any conversion will be determined by dividing the amount to be converted by \$4.00. As further consideration for the second extension, Mr. de Clara received warrants which allow Mr. de Clara to purchase 184,930 shares of CEL-SCI's common stock at a price of \$5.00 per share at any time prior to January 6, 2015. On May 13, 2011, to recognize Mr. de Clara's willingness to agree to subordinate his note to convertible preferred shares and convertible debt, CEL-SCI extended the maturity date of the note to July 6, 2015. The loan from Mr. de Clara bears interest at 15% per year and is secured by a lien on substantially all of CEL-SCI's assets. CEL-SCI does not have the right to prepay the loan without Mr. de Clara's consent. As of June 16, 2014, none of the warrants issued to Mr. De Clara had been exercised.
- G. On August 31, 2009, CEL-SCI borrowed \$2,000,000 from two institutional investors. The loans are evidenced by CEL-SCI's Series B promissory notes which were repaid in September 2009. The Series B note holders also received Series B warrants which allow the holders to purchase up to 50,000 shares of CEL-SCI's common stock at a price of \$6.80 per share. The Series B warrants may be exercised at any time prior to September 4, 2014. As of June 16, 2014, none of the Series B Warrants had been exercised.
- H. On August 20, 2009, CEL-SCI sold 1,078,444 shares of its common stock to a group of private investors for \$4,852,995 or \$4.50 per share. The investors also received Series C warrants which entitle the investors to purchase 539,220 shares of CEL-SCI's common stock. The Series C warrants may be exercised at any time prior to February 20, 2015 at a price of \$5.50 per share. As of June 16, 2014, 75,733 Series C warrants had been exercised. The remaining 463,487 Series C warrants entitle the holders to purchase one share of CEL-SCI's common stock at a price of \$5.50 per share.
- I. On September 21, 2009, CEL-SCI sold 1,428,572 shares of its common stock to a group of private investors for \$20,000,000 or \$14.00 per share. The investors also received Series D warrants which entitle the

**Table of Contents**

investors to purchase up to 471,428 shares of CEL-SCI's common stock. The Series D warrants could be exercised at any time prior to September 21, 2011 at a price of \$15.00 per share. On September 21, 2011, all Series D warrants expired. CEL-SCI paid Rodman & Renshaw, LLC, the placement agent for the offering, a cash commission of \$1,000,000, as well as an expense reimbursement of \$37,500. CEL-SCI also issued Rodman & Renshaw 71,428 Series E warrants. Each Series E warrant entitles the holder to purchase one share of CEL-SCI's common stock. The Series E warrants may be exercised at any time prior to August 12, 2014 at a price of \$17.50 per share. As of June 16, 2014, none of the Series E warrants had been exercised.

J. On October 3, 2011 CEL-SCI sold 1,333,333 shares of its common stock to a group of private investors for \$4,000,000 or \$3.00 per share. The investors also received Series F warrants which entitle the investors to purchase up to 1,200,000 shares of CEL-SCI's common stock. The Series F warrants may be exercised at any time prior to October 6, 2014 at a price of \$4.00 per share. CEL-SCI paid Chardan Capital Markets, LLC, the placement agent for this offering, a cash commission of \$140,000, and issued 66,667 Series G warrants to Chardan. Each Series G warrant entitles the holder to purchase one share of CEL-SCI's common stock. The Series G warrants may be exercised at any time prior to August 12, 2014 at a price of \$4.00 per share. As of June 16, 2014, none of the Series F or G warrants had been exercised.

K. On January 25, 2012, CEL-SCI sold 1,600,000 shares of its common stock to institutional investors for \$5,760,000 or \$3.60 per share. The investors also received Series H warrants which entitle the investors to purchase up to 1,200,000 shares of CEL-SCI's common stock. The Series H warrants may be exercised at any time prior to August 1, 2015 at a price of \$5.00 per share. As of June 16, 2014, none of the Series H Warrants had been exercised.

L. On February 10, 2012, CEL-SCI issued 590,001 Series P warrants to the former holder of the Series O warrants as an inducement for the early exercise of the Series O warrants. The Series P warrants allow the holder to purchase up to 590,001 shares of CEL-SCI's common stock at a price of \$4.50 per share. The Series P warrants are exercisable at any time prior to March 7, 2017. As of June 16, 2014, none of the Series P Warrants had been exercised.

M. On June 21, 2012, CEL-SCI sold 1,600,000 shares of its common stock to institutional investors for \$5,600,000 or \$3.50 per share. The investors also received Series Q warrants which allow the investors to purchase up to 1,200,000 shares of CEL-SCI's common stock. The Series Q warrants may be exercised at any time after prior to December 22, 2015 at a price of \$5.00 per share. As of June 16, 2014, none of the Series Q Warrants had been exercised.

N. On December 4, 2012, CEL-SCI sold 3,500,000 shares of its common stock to institutional investors for \$10,500,000 or \$3.00 per share. The investors also received Series R warrants which entitle the investors to purchase up to 2,625,000 shares of CEL-SCI's common stock. The Series R warrants may be exercised at any time prior to December 7, 2016 at a price of \$4.00 per share. As of June 16, 2014, none of the Series R Warrants had been exercised.

O. On October 11, 2013, CEL-SCI, in an underwritten public offering, sold 17,826,087 shares of its common stock, as well as 20,475,000 Series S warrants, for net proceeds of approximately \$16,424,000, after deduction for underwriting discounts and commissions. The Series S warrants may be exercised at any time prior to October 11, 2018 at a price of \$1.25 per share.

On December 24, 2013, CEL-SCI closed a public offering of 4,761,905 units of common stock and warrants at a price of \$0.63 per unit for net proceeds of \$2,790,000, net of underwriting discounts and commissions and offering expenses of the Company. Each unit consisted of one share of common stock and one Series S warrant to purchase one share of common stock. The Series S warrants are immediately exercisable, expire on October 11, 2018, and have an exercise price of \$1.25. The underwriters purchased an additional 476,190 units of common stock and warrants pursuant to the overallotment option, for which the Company received net proceeds of approximately \$279,000.

**Table of Contents**

On February 7, 2014, the warrants issued in connection with the public offerings in October and December 2013 began trading on the NYSE MKT under the ticker symbol CVM WS . As of June 16, 2014, 2,088,769 Series S Warrants had been exercised. The remaining 23,624,326 Series S warrants entitle the holders to purchase one share of CEL-SCI s common stock at a price of \$1.25 per share.

P. On April 17, 2014, CEL-SCI closed a public offering of 7,128,229 shares of common stock and warrants to purchase an aggregate of 1,782,057 shares of common stock. The units were sold at a price of \$1.40 per unit and resulted in net proceeds of approximately \$9.23 million. The warrants are immediately exercisable, expire on October 17, 2014, and have an exercise price of \$1.58 per share. As of June 16, 2014, none of the Series T Warrants had been exercised.

CEL-SCI issued Dawson James Securities, Inc. and Laidlaw & Company (UK) Ltd. 445,514 Series U warrants for being joint book-running managers and underwriters for this offering. Each Series U warrant entitles the holder to purchase one share of CEL-SCI s common stock. The Series U warrants may be exercised beginning October 17, 2014 at a price of \$1.75 per share and expire on October 17, 2017. As of June 16, 2014, none of the Series U warrants had been exercised.

**MARKET FOR CEL-SCI S COMMON STOCK**

As of June 16, 2014 there were approximately 1,370 record holders of CEL-SCI s common stock. CEL-SCI s common stock is traded on the NYSE MKT under the symbol CVM .

On June 25, 2013, CEL-SCI s shareholders approved a reverse split of CEL-SCI s common stock. The reverse split became effective on the NYSE MKT on September 25, 2013. On that date, every ten issued and outstanding shares of CEL-SCI s common stock automatically converted into one outstanding share.

As a result of the reverse stock split, the number of CEL-SCI s outstanding shares of common stock decreased from 310,005,272 (pre-split) shares to 31,001,686 (post-split) shares. In addition, by reducing the number of CEL-SCI s outstanding shares, CEL-SCI s loss per share in all prior periods will increase by a factor of ten.

Shown below are the post-split range of high and low quotations for CEL-SCI s common stock for the periods indicated as reported on the NYSE MKT. The market quotations reflect inter-dealer prices, without retail mark-up, mark-down or commissions and may not necessarily represent actual transactions.

<b>Quarter Ending</b>	<b>High</b>	<b>Low</b>
12/31/11	\$ 4.20	\$ 2.70
3/31/12	\$ 6.50	\$ 2.80
6/30/12	\$ 5.80	\$ 3.30
9/30/12	\$ 4.70	\$ 3.10
12/31/12	\$ 3.90	\$ 2.60
3/31/13	\$ 2.90	\$ 2.10
6/30/13	\$ 3.10	\$ 2.00
9/30/13	\$ 2.70	\$ 1.60
12/31/13	\$ 1.80	\$ 0.53
3/31/14	\$ 1.90	\$ 0.59

Holders of common stock are entitled to receive dividends as may be declared by the Board of Directors out of legally available funds and, in the event of liquidation, to share pro rata in any distribution of CEL-SCI s assets after payment of liabilities. The Board of Directors is not obligated to declare a dividend. CEL-SCI has not paid any dividends on its common stock and CEL-SCI does not have any current plans to pay any common stock dividends.

**Table of Contents**

The provisions in CEL-SCI's Articles of Incorporation relating to CEL-SCI's preferred stock would allow CEL-SCI's directors to issue preferred stock with rights to multiple votes per share and dividend rights which would have priority over any dividends paid with respect to CEL-SCI's common stock. The issuance of preferred stock with such rights may make more difficult the removal of management, even if such removal would be considered beneficial to shareholders generally, and will have the effect of limiting shareholder participation in certain transactions such as mergers or tender offers if such transactions are not favored by incumbent management.

The market price of CEL-SCI's common stock, as well as the securities of other biopharmaceutical and biotechnology companies, have historically been highly volatile, and the market has from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. Factors such as fluctuations in CEL-SCI's operating results, announcements of technological innovations or new therapeutic products by CEL-SCI or its competitors, governmental regulation, developments in patent or other proprietary rights, public concern as to the safety of products developed by CEL-SCI or other biotechnology and pharmaceutical companies, and general market conditions may have a significant effect on the market price of CEL-SCI's common stock.

---

**Table of Contents**

**PLAN OF DISTRIBUTION**

CEL-SCI may sell shares of its common stock, preferred stock, convertible preferred stock, rights, or warrants, as well as any issuable shares upon the conversion or exercise of such securities, in and/or outside the United States:

(i) through underwriters or dealers; (ii) directly to a limited number of purchasers or to a single purchaser; or (iii) through agents. The applicable prospectus supplement with respect to the offered securities will set forth the name or names of any underwriters or agents, if any, the purchase price of the offered securities and the proceeds to CEL-SCI from such sale, any delayed delivery arrangements, any underwriting discounts and other items constituting underwriters' compensation, the public offering price and any discounts or concessions allowed or reallocated or paid to dealers and any compensation paid to an underwriter or a placement agent. The public offering price and any discounts or concessions allowed or reallocated or paid to dealers may be changed from time to time.

Notwithstanding the above, the maximum commission or discount to be received by any NASD member or independent broker-dealer will not be greater than 10% in connection with the sale of any securities offered by means of this prospectus or any related prospectus supplement, exclusive of any non-accountable expense allowance. Any securities issued by CEL-SCI to any FINRA member or independent broker-dealer in connection with an offering of CEL-SCI's securities will be considered underwriting compensation and may be restricted from sale, transfer, assignment, or hypothecation for a number of months following the effective date of the offering, except to officers or partners (not directors) of any underwriter or member of a selling group and/or their officers or partners.

CEL-SCI's securities may be sold:

At a fixed price.

As the result of the exercise of warrants or rights, or the conversion of preferred shares, at fixed or varying prices, as determined by the terms of the warrants, rights or convertible securities.

At varying prices in at the market offerings.

In privately negotiated transactions, at fixed prices which may be changed, at market prices prevailing at the time of sale, at prices related to such prevailing market prices or at negotiated prices.

If underwriters are used in the sale, the offered securities will be acquired by the underwriters for their own account and may be resold from time to time in one or more transactions, including negotiated transactions, at a fixed public offering price or at varying prices determined at the time of sale. The securities may be offered to the public either through underwriting syndicates represented by one or more managing underwriters or directly by one or more firms acting as underwriters. The underwriter or underwriters with respect to a particular underwritten offering of securities will be named in the prospectus supplement relating to such offering and, if an underwriting syndicate is used, the managing underwriter or underwriters will be set forth on the cover of such prospectus supplement. Unless otherwise set forth in the prospectus supplement, the obligations of the underwriters to purchase the offered securities will be subject to conditions precedent and the underwriters may be obligated to purchase all the offered securities if any are purchased.

If dealers are utilized in the sale of offered securities in respect of which this prospectus is delivered, CEL-SCI will sell the offered securities to the dealers as principals. The dealers may then resell the offered securities to the public at varying prices to be determined by the dealers at the time of resale. The names of the dealers and the terms of the transaction will be set forth in the prospectus supplement relating to the securities sold to the dealers.

If an agent is used in an offering, the agent will be named, and the terms of the agency will be set forth, in the prospectus supplement. Unless otherwise indicated in the prospectus supplement, an agent will act on a best efforts basis for the period of its appointment.

**Table of Contents**

The securities may be sold directly by CEL-SCI to institutional investors or others, who may be deemed to be underwriters within the meaning of the Securities Act of 1933 with respect to any resale of the securities purchased by the institutional investors. The terms of any of the sales, including the terms of any bidding or auction process, will be described in the applicable prospectus supplement.

CEL-SCI may permit agents or underwriters to solicit offers to purchase its securities at the public offering price set forth in a prospectus supplement pursuant to a delayed delivery arrangement providing for payment and delivery on the date stated in the prospectus supplement. Any delayed delivery contract will contain definite fixed price and quantity terms. The obligations of any purchaser pursuant to a delayed delivery contract will not be subject to any market outs or other conditions other than the condition that the delayed delivery contract will not violate applicable law. In the event the securities underlying the delayed delivery contract are sold to underwriters at the time of performance of the delayed delivery contract, those securities will be sold to those underwriters. Each delayed delivery contract shall be subject to CEL-SCI's approval. CEL-SCI will pay the commission indicated in the prospectus supplement to underwriters or agents soliciting purchases of securities pursuant to delayed delivery arrangements accepted by CEL-SCI.

Notwithstanding the above, while prospectus supplements may provide specific offering terms, or add to or update information contained in this prospectus, any fundamental changes to the offering terms will be made by means of a post-effective amendment.

Agents, dealers and underwriters may be entitled under agreements entered into with CEL-SCI to indemnification from CEL-SCI against certain civil liabilities, including liabilities under the Securities Act, or to contribution with respect to payments made by such agents, dealers or underwriters.

**Table of Contents**

**DESCRIPTION OF SECURITIES**

**Common Stock**

CEL-SCI is authorized to issue 600,000,000 shares of common stock, (the common stock ). Holders of common stock are each entitled to cast one vote for each share held of record on all matters presented to shareholders. Cumulative voting is not allowed; hence, the holders of a majority of the outstanding common stock can elect all directors.

Holders of common stock are entitled to receive such dividends as may be declared by the Board of Directors out of funds legally available therefor and, in the event of liquidation, to share pro rata in any distribution of CEL-SCI's assets after payment of liabilities. The board is not obligated to declare a dividend. It is not anticipated that dividends will be paid in the foreseeable future.

Holders of common stock do not have preemptive rights to subscribe to additional shares if issued by CEL-SCI. There is no conversion, redemption, sinking fund or similar provision regarding the common stock. All of the outstanding shares of common stock are fully paid and non-assessable.

**Preferred Stock**

CEL-SCI is authorized to issue up to 200,000 shares of preferred stock. CEL-SCI's Articles of Incorporation provide that the Board of Directors has the authority to divide the preferred stock into series and, within the limitations provided by Colorado statute, to fix by resolution the voting power, designations, preferences, and relative participation, special rights, and the qualifications, limitations or restrictions of the shares of any series so established. As the Board of Directors has authority to establish the terms of, and to issue, the preferred stock without shareholder approval, the preferred stock could be issued to defend against any attempted takeover of CEL-SCI. As of June 16, 2014 no shares of preferred stock were outstanding.

**Warrants Held by Private Investors**

See Comparative Share Data for information concerning CEL-SCI's outstanding options, warrants and convertible securities.

**Transfer Agent**

Computershare Trust Company, Inc., of Denver, Colorado, is the transfer agent for CEL-SCI's common stock.



**Table of Contents**

**EXPERTS**

The financial statements as of September 30, 2013 and 2012 and for each of the three years in the period ended September 30, 2013 and management's assessment of the effectiveness of internal control over financial reporting as of September 30, 2013 incorporated by reference in this Prospectus, have been so incorporated in reliance on the reports of BDO USA, LLP, an independent registered public accounting firm, incorporated herein by reference, given on the authority of said firm as experts in auditing and accounting.

**INDEMNIFICATION**

CEL-SCI's bylaws authorize indemnification of a director, officer, employee or agent of CEL-SCI against expenses incurred by him in connection with any action, suit, or proceeding to which he is named a party by reason of his having acted or served in such capacity, except for liabilities arising from his own misconduct or negligence in performance of his duty. In addition, even a director, officer, employee, or agent of CEL-SCI who was found liable for misconduct or negligence in the performance of his duty may obtain such indemnification if, in view of all the circumstances in the case, a court of competent jurisdiction determines such person is fairly and reasonably entitled to indemnification. Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers, or persons controlling CEL-SCI pursuant to the foregoing provisions, CEL-SCI has been informed that in the opinion of the Securities and Exchange Commission, such indemnification is against public policy as expressed in the Act and is therefore unenforceable.

**ADDITIONAL INFORMATION**

CEL-SCI is subject to the requirements of the Securities Exchange Act of 1934 and is required to file reports, proxy statements and other information with the Securities and Exchange Commission. Copies of any such reports, proxy statements and other information filed by CEL-SCI can be read and copied at the Commission's Public Reference Room at 100 F Street, N.E., Washington, D.C., 20549. The public may obtain information on the operation of the Public Reference Room by calling the Commission at 1-800-SEC-0330. The Commission maintains an Internet site that contains reports, proxy and information statements, and other information regarding CEL-SCI. The address of that site is <http://www.sec.gov>.

CEL-SCI will provide, without charge, to each person to whom a copy of this prospectus is delivered, including any beneficial owner, upon the written or oral request of such person, a copy of any or all of the documents incorporated by reference below (other than exhibits to these documents, unless the exhibits are specifically incorporated by reference into this prospectus). Requests should be directed to:

CEL-SCI Corporation 8229 Boone Blvd., #802 Vienna, Virginia 22182 (703) 506-9460

The following documents filed with the Commission by CEL-SCI (Commission File No. 001-11889) are incorporated by reference into this prospectus:

- (1) Annual Report on Form 10-K for the fiscal year ended September 30, 2013.
- (2) Report on Form 8-K filed on October 10, 2013.
- (3) Report on Form 8-K filed on October 11, 2013.
- (4) Report on Form 8-K filed on November 1, 2013.
- (5) Report on Form 8-K filed on December 19, 2013.
- (6) Report on Form 8-K filed on December 24, 2013.

(7) Report on Form 8-K filed on April 14, 2014.

**Table of Contents**

- (8) Report on Form 8-K filed on April 15, 2014.
  
- (9) Report on Form 8-K filed on April 18, 2014.
  
- (10) Quarterly report on Form 10-Q for the three months ended December 31, 2013.
  
- (11) Quarterly report on Form 10-Q for the six months ended March 31, 2014.

(12) Proxy statement relating to the annual meeting of shareholders to be held on July 22, 2014.

All documents filed with the Commission by CEL-SCI pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act subsequent to the date of this prospectus and prior to the termination of this offering shall be deemed to be incorporated by reference into this prospectus and to be a part of this prospectus from the date of the filing of such documents. Any statement contained in a document incorporated or deemed to be incorporated by reference shall be deemed to be modified or superseded for the purposes of this prospectus to the extent that a statement contained in this prospectus or in any subsequently filed document which also is or is deemed to be incorporated by reference in this prospectus modifies or supersedes such statement. Such statement so modified or superseded shall not be deemed, except as so modified or superseded, to constitute a part of this prospectus.

Investors are entitled to rely upon information in this prospectus or incorporated by reference at the time it is used by CEL-SCI to offer and sell securities, even though that information may be superseded or modified by information subsequently incorporated by reference into this prospectus.

CEL-SCI has filed with the Securities and Exchange Commission a Registration Statement under the Securities Act of 1933, as amended, with respect to the securities offered by this prospectus. This prospectus does not contain all of the information set forth in the Registration Statement. For further information with respect to CEL-SCI and such securities, reference is made to the Registration Statement and to the exhibits filed with the Registration Statement. Statements contained in this prospectus as to the contents of any contract or other documents are summaries which are not necessarily complete, and in each instance reference is made to the copy of such contract or other document filed as an exhibit to the Registration Statement, each such statement being qualified in all respects by such reference. The Registration Statement and related exhibits may also be examined at the Commission's internet site.

No dealer salesman or other person has been authorized to give any information or to make any representations, other than those contained in this prospectus. Any information or representation not contained in this prospectus must not be relied upon as having been authorized by CEL-SCI. This prospectus does not constitute an offer to sell, or a solicitation of an offer to buy, the securities offered hereby in any state or other jurisdiction to any person to whom it is unlawful to make such offer or solicitation. Neither the delivery of this prospectus nor any sale made hereunder shall, under any circumstances, create an implication that there has been no change in the affairs of CEL-SCI since the date of this prospectus.

**Table of Contents**

**\$35,000,000**

**Common Stock**

**Prospectus Supplement**

**FBR**

**, 2015**