CEL SCI CORP
Form 10-K/A
April 17, 2015

FORM 10-K/A

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
(Mark One)

þ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended September 30, 2014.

OR

o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____.

Commission file number 1-11889

CEL-SCI CORPORATION
(Exact name of registrant as specified in its charter)

COLORADO (State or other jurisdiction of incorporation or organization)	84-0916344 (I.R.S. Employer Identification No.)
8229 Boone Blvd., Suite 802 Vienna, Virginia (Address of principal executive offices)	22182 (Zip Code)

Registrant's telephone number, including area code: (703) 506-9460
Securities registered pursuant to Section 12(b) of the Act: None
Securities registered pursuant to Section 12(g) of the Act:

Common Stock, $.01 par
value Series S Warrants
(Title of Class)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. o

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. o

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes þ No o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes þ No o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. þ

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of “large accelerated filer,” “accelerated filer” and “smaller reporting company” in Rule 12b-2 of the Exchange Act.

Large accelerated filer	o	Accelerated filer	þ
Non-accelerated filer (Do not check if a smaller reporting company)	o	Smaller reporting company	o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act): o Yes þ No

The aggregate market value of the voting stock held by non-affiliates of the Registrant, based upon the closing sale price of the registrant’s common stock on March 31, 2014, as quoted on the NYSE MKT, was $86,967,791.

As of December 11, 2014, the Registrant had 91,345,536 issued and outstanding shares of common stock.

Documents Incorporated by Reference: None

EXPLANATORY NOTE

This Amendment No. 1 on Form 10-K/A (Amendment No. 1) is being filed to amend CEL-SCI's Annual Report on Form 10-K for the fiscal year ended September 30, 2014 (the “Original Filing”) filed with the U.S. Securities and Exchange Commission on December 23, 2014. The purpose of this Amendment No. 1 is to:

expand the disclosure to Item 1. with respect to certain agreements;

add two risk factors in Item 1A.; and

file additional exhibits (Item 15).

Since there have been no changes to the other parts of the 10-K or the financial statements included in the Original Filing, only Items 1, 1A and 15, and the new exhibits are filed as part of this Amendment No. 1.

PART I

ITEM 1. BUSINESS

CEL-SCI is focused on finding the best way to activate the immune system to fight cancer and infectious diseases. Its lead investigational therapy Multikine (Leukocyte Interleukin, Injection) is currently in a pivotal Phase III clinical trial against head and neck cancer, for which CEL-SCI has received Orphan Drug Status from the U.S. FDA. If the primary endpoint of the FDA study is achieved, the results will be used to support applications to regulatory agencies around the world for worldwide commercial marketing approvals as a first line cancer therapy. Additional clinical indications for Multikine include cervical dysplasia in HIV/HPV co-infected women, for which a Phase I study was successfully concluded; and the treatment of peri-anal warts in HIV/HPV co-infected men and women, for which a Phase I trial is now underway in conjunction with the U.S. Navy under a Cooperative Research and Development Agreement.

CEL-SCI's immune therapy, Multikine, is being used in a different way than immune therapy is usually used. It is administered locally to treat local tumors or infections and it is given before any other therapy has been administered. For example, in the ongoing Phase III clinical trial, Multikine is given locally at the site of the tumor 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 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 higher efficacy with less or no toxicity.

CEL-SCI's focus on 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), 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 has operations in Vienna, Virginia, and in/near Baltimore, Maryland, USA.

CEL-SCI 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 website is www.cel-sci.com. CEL-SCI does not incorporate the information on its website into this report, and you should not consider it part of this report.

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.

CEL-SCI'S PRODUCTS

CEL-SCI's product pipeline consists of the following:

1) Multikine (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 in a Phase III clinical trial as a potential therapeutic agent directed at using the immune system to increase survival of advanced primary head and neck cancer patients. 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 seventeen 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 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 should 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.

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 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 head and neck cancer patients with advanced primary disease (approximately 66% of all head and neck cancer patients) could be candidates for this investigational therapy if it were to be approved by FDA.

In August 2008, CEL-SCI signed an agreement with Teva Pharmaceutical Industries Ltd., or Teva, that gives Teva the exclusive right and license to market, distribute and sell Multikine in Israel and Turkey for treatment of head and neck cancer, if approved. The agreement terminates on a country-by-country basis 10 years after the product launch in each country or upon a material breach or upon bankruptcy of either party. The agreement will automatically extend for additional two year terms unless either party gives notice of its intent not to extend the agreement. If CEL-SCI develops Multikine for other oncology indications and Teva indicates a desire to participate, the parties have agreed to negotiate in good faith with respect to Teva's participation and contribution in future clinical trials.

Teva has agreed to use all reasonable efforts to obtain regulatory approval to market and sell Multikine in its territory at its own cost and expense. Pursuant to the agreement, it is CEL-SCI's responsibility to supply Multikine and Teva's responsibility to sell Multikine, if approved. Net sales will be divided 50/50 between the two parties. Teva also initially agreed to fund certain activities relating to the conduct of a clinical trial in Israel as part of the global Phase III trial for Multikine. In January 2012, pursuant to an assignment and assumption agreement between CEL-SCI, Teva and GCP Clinical Studies Ltd., or GCP, Teva transferred all of its rights and obligations concerning the Phase III trial in Israel to GCP. GCP is now operating the Phase III trial in Israel pursuant to a service agreement with CEL-SCI.

In July 2011, Serbia and Croatia were added to Teva's territory, pursuant to a joinder agreement between CEL-SCI and PLIVA Hrvatska d.o.o., or PLIVA, an affiliate of Teva's, subject to similar terms as described above.

In consideration for the rights granted by CEL-SCI to PLIVA under the joinder agreement, CEL-SCI will be paid by PLIVA (in U.S. dollars):

$100,000 upon European Medicines Agency ("EMA") grant of Marketing Authorization for Multikine;

$50,000 upon Croatia's grant of reimbursement status for Multikine in Croatia; and

$50,000 upon Serbia's grant of reimbursement status for Multikine in Serbia.

In November 2000, CEL-SCI signed an agreement with Orient Europharma Co., Ltd., or Orient Europharma, of Taiwan, which agreement was amended in October 2008 and again in June 2010. Pursuant to this agreement, as amended, Orient Europharma has the exclusive marketing and distribution rights to Multikine, if approved, for head and neck cancer, naso-pharyngeal cancer and potentially cervical cancer indications in Taiwan, Singapore, Malaysia, Hong Kong, the Philippines, South Korea, Australia and New Zealand. CEL-SCI has granted Orient Europharma the first right of negotiation with respect to Thailand and China.

The agreement requires Orient Europharma to fund 10% of the cost of 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 nine centers in Taiwan where it has enrolled patients as part of the ongoing Phase 3 Multikine clinical trial and has made further financial contributions towards the cost of the ongoing Phase 3 clinical trial. If Multikine is approved for sale, Orient Europharma will purchase Multikine from CEL-SCI for 35% of the gross selling price in each country. Orient Europharma is obligated to use the same diligent efforts to develop, register, market, sell and distribute the Multikine in the territory as with its own products or other licensed products.

The agreement will terminate on a country-by-country basis 15 years after the product approval for Multikine in each country, at which point the agreement will be automatically extended for successive two year periods, unless either party gives notice of its intent not to extend the agreement. The agreement may also be terminated upon bankruptcy of either party or material misrepresentations that are not cured within 60 days. If the agreement ends before the 15 year term through no fault of either party, CEL-SCI will reimburse Orient Europharma for a prorated part of Orient Europhorma's costs towards the clinical trials of Multikine. If Orient Europharma fails to make certain minimum purchases of Multikine during the term of the agreement, Orient Europhorma's rights to the territory will become non-exclusive.

CEL-SCI has a licensing agreement with Byron Biopharma LLC, or Byron, under which CEL-SCI granted Byron an exclusive license to market and distribute Multikine in the Republic of South Africa, if approved. This license will terminate 20 years after marketing approval in South Africa or after bankruptcy or uncured material breach. After the 20-year period has expired, the agreement will be automatically extended for successive two year periods, unless either party gives notice of its intent not to extend the agreement.

Pursuant to the agreement, Byron will be responsible for registering Multikine in South Africa. If Multikine is approved for sale in South Africa, CEL-SCI will be responsible for manufacturing the product, while Byron will be responsible for sales in South Africa. Sales revenues will be divided between CEL-SCI and Byron. CEL-SCI will be paid fifty (50%) percent of the net sales of Multikine.

On April 23, 2013, CEL-SCI announced that it had replaced Inventiv Health Clinical, the clinical research organization (CRO) running its Phase III clinical trial. This was necessary since the patient enrollment in the study dropped off substantially following a takeover of Pharmanet by Inventiv which caused many of the members of Inventiv's study team to leave Inventiv. CEL-SCI has hired two CRO's who will manage the global Phase III study: Aptiv Solutions, Inc., or Aptiv, and Ergomed Clinical Research Limited, or Ergomed, which are both international leaders in managing oncology trials. Ergomed is in charge of all data generation and patient accrual globally, while Aptiv is in charge of data management and data monitoring. The study is currently being expanded to about 100 clinical sites globally.

As of November 30, 2014, the last update given by CEL-SCI, the study had enrolled approximately 310 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) more clinical centers are added throughout the world. Full enrollment of the planned 880 patients is expected by about the end of 2015.

On April 19, 2013, October 10, 2013 and October 24, 2013, CEL-SCI entered into co-development agreements with Ergomed. These three agreements all relate to an overall agreement to work jointly on the clinical development of Multikine. Under the April 2013 agreement, Ergomed will contribute up to $10 million towards the ongoing Phase 3 study in head and neck cancer 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, from sales of Multikine. In this first agreement, Ergomed's contribution towards the study will be a 30% reduction of the amounts billed, up to a maximum of $10 million. In the second agreement, dated October 10, 2013, Ergomed's contribution will be a 50% reduction of the amounts billed, up to a maximum of $3 million, for the costs of the clinical trial(s) for Multikine in HIV/HPV co-infected women with cervical intraepithelial neoplasia, or cervical dysplasia. In the third agreement, dated October 24, 2013, Ergomed's contribution towards the study will be a 50% reduction of the amounts billed, up to a maximum of $3 million, towards the clinical and regulatory costs for trials of Multikine in HIV/HPV co-infected men and women with anal intraepithelial neoplasia, or peri-anal warts. The contributions of Ergomed towards the three clinical studies will be a combined maximum of $16 million. Ergomed will be repaid at a rate four times the aggregate amount of discounted clinical services it provides, in the form of a 5% royalty on sales of Multikine and/or 5% of certain payments from licensees of Multikine. By way of example, if Ergomed's contribution towards the three development programs is the maximum amount of $16 million in reductions of the amounts billed for such programs, then Ergomed will have the right to receive up to $64 million in the form of a 5% royalty on sales of Multikine and/or 5% of certain payments from licensees of Multikine.

The terms of the three Ergomed agreements are the same. CEL-SCI will have the right to conduct, and, using commercially reasonable efforts, will have the sole responsibility for the clinical development of, as well as the commercialization and intellectual property maintenance for Multikine and will bear all associated costs for these activities. Ergomed will have primary responsibility for new patient enrollment in the Phase 3 clinical trial.

The terms of the agreements commence on the dates they are signed and expire on the date on which both parties have fulfilled all of their obligations contemplated by the agreements, unless sooner terminated pursuant to the terms of the agreements, or unless agreed to in writing by both parties.

CEL-SCI estimates the total cash cost of the Phase III trial, with the exception of the parts that will be paid by its partner, Orient Europharma, to be approximately $28.2 million after September 30, 2014. This is in addition to approximately $16.4 million which has been paid as of September 30, 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.

In October 2013, CEL-SCI announced it entered into a CRADA with the U.S. Naval Medical Center, San Diego. Pursuant to this agreement, the Naval Medical Center is currently conducting a 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 (HPV), 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. On September 29, 2014 CEL-SCI

announced that the first volunteer patient had been enrolled and administered Multikine.

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 AIN in HIV/HPV co-infected men and women.

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

Multikine is being given to the HIV/HPV co-infected patients with peri-anal warts since promising early results were seen in another Institutional Review Board approved Multikine Phase I study conducted at the University of Maryland. In this study, investigational therapy Multikine was given to HIV/HPV co-infected women with cervical dysplasia resulting in visual and histological evidence of clearance of lesions. Furthermore, elimination of a number of HPV strains was determined by in situ polymerase chain reaction (PCR) performed on tissue biopsy collected before and after Multikine treatment. As reported by the investigators in the earlier study, the study volunteers all appeared to tolerate the treatment with no reported serious adverse events.

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

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.

INTELLECTUAL PROPERTY

Patents and other proprietary rights are essential to our business. CEL-SCI files patent applications to protect our technologies, inventions and improvements to our inventions that CEL-SCI considers important to the development of our business. CEL-SCI files for patent registration in the United States and in key foreign markets. CEL-SCI'S intellectual property portfolio covers its proprietary technologies, including Multikine and LEAPS, by multiple issued patents and pending patent applications.

Multikine is protected by a US patent, which is a composition-of-matter patent issued in May 2005 that, in its current format, expires in 2024. Additional composition-of-matter patents for Multikine have been issued in Germany (issued in June 2011 and currently set to expire in 2025), China (issued in May 2011 and currently set to expire in 2024), and Japan (issued in November 2012 and currently set to expire in 2025).

CEL-SCI has three patent applications pending in Europe for Multikine, which, if issued, would extend protection through 2026, subject to any potential patent term extensions. In addition to the patents and applications that offer certain protections for Multikine, the method of manufacture for Multikine, a complex biological product, is held by CEL-SCI as trade secret.

LEAPS is protected by patents in the United States issued in February 2006, April 2007, and August 2007. The LEAPS patents, which expire in 2021, 2022 and 2022, respectively, include overlapping claims, with composition of both matter (new chemical entity), process and methods-of-use, to maximize and extend the coverage in their current format. Additional patent applications are pending in the United States and Europe that could offer protection through 2034.

CEL-SCI has six patent applications pending in the United States and one in Europe for LEAPS, which, if issued, would extend protection through 2034, subject to any potential patent term extensions. Two pending U.S. applications are joint applications with Northeast Ohio Medical University ("Neoucom"), and one is a joint application with the National Institutes of Health ("NIH"). If granted, CEL-SCI will share the ability to use the patents, unless CEL-SCI licenses the rights to the patent application and any ensuing patent from Neoucom or NIH.

As of the date of this report, there were no contested proceedings and/or third party claims with respect to CEL-SCI's patents or patent applications.

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 Union Qualified Person on two different occasions.

CEL-SCI's lease on the manufacturing facility expires on October 31, 2028. 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. See Item 2 of this report for more information concerning the terms of this lease.

LEAPS

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

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

Using the LEAPS technology, 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 potential 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. FDA 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 was 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 LEAPS H1N1 activated dendritic cells (DCs) to treat the H1N1 virus. Scientists at the NIAID found that H1N1-infected mice treated with LEAPS-H1N1 DCs showed a survival advantage over mice treated with control DCs. The work was performed in collaboration with scientists led by Kanta Subbarao, M.D., Chief of the Emerging Respiratory Diseases Section in NIAID's Division of Intramural Research, part of the National Institutes of Health, USA.

In July 2013, CEL-SCI announced the publication of the results of additional influenza studies by researchers from the NIAID in the Journal of Clinical Investigation (www.jci.org/articles/view/67550). The studies described in the publication show that when CEL-SCI's investigational J-LEAPS Influenza Virus treatments were used "in vitro" to activate DCs, these activated DCs, 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®. 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-) and their action on reducing TNF- 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.

On July 15, 2014, CEL-SCI announced that it has been awarded a Phase I Small Business Innovation Research (SBIR) grant in the amount of $225,000 from the National Institute of Arthritis Muscoskeletal and Skin Diseases, which is part of the National Institutes of Health. The grant will fund the further development of CEL-SCI's LEAPS technology as a potential treatment for rheumatoid arthritis, an autoimmune disease of the joints. The work will be conducted at Rush University Medical Center in Chicago, Illinois in the laboratories of Tibor Glant, MD, Ph.D., The Jorge O. Galante Professor of Orthopedic Surgery; Katalin Mikecz, MD, Ph.D. Professor of Orthopedic Surgery & Biochemistry; and Allison Finnegan, Ph.D. Professor of Medicine.

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.

ITEM 1A. RISK FACTORS

The risks described below could adversely affect the price of CEL-SCI's common stock.

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 September 30, 2014, CEL-SCI incurred net losses of approximately $238 million. CEL-SCI has relied principally upon the proceeds of the 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 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 difficult 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, president and other executive officers 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 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.

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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.

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 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, 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 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 September 30, 2014, CEL-SCI's stock price has ranged from a low of $0.53 per share to a high of $1.90 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 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 November 30, 2014, there were outstanding options which allows the holders to purchase approximately 6,840,000 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 35,863,000 shares of CEL-SCI's common stock, at prices ranging between $0.53 and $5.50 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 conversion of the note or 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.

CEL-SCI may have exposure for certain securities CEL-SCI sold in October 2013.

In September 2012, CEL-SCI filed a shelf registration statement covering the sale of $50,000,000 of securities (the "2012 Registration Statement"), and in January 2013 CEL-SCI filed another shelf registration statement covering the sale of an additional $50,000,000 of securities (the "2013 Registration Statement"). In October 2013, CEL-SCI filed a prospectus supplement to the 2012 Registration Statement for the sale in an underwritten public offering of 17,826,087 shares of CEL-SCI's 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, CEL-SCI 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. CEL-SCI subsequently realized that at the time of the October 2013 offering CEL-SCI had approximately $28.9 million available for issuance under the 2012 Registration Statement. As a result, CEL-SCI offered 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. CEL-SCI had securities available under the 2013 Registration Statement to register all of the securities not covered by the 2012 Registration Statement. In December 2013, CEL-SCI 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 CEL-SCI has taken to mitigate CEL-SCI's possible non-compliance with securities laws will not prevent regulators from asserting that CEL-SCI violated the law, from imposing penalties and fines against CEL-SCI with respect to any potential violations of securities laws, and may subject CEL-SCI to possible claims for damages from certain investors.

Under CEL-SCI's amended bylaws, shareholders that initiate certain proceedings may be obligated to reimburse CEL-SCI and its officers and directors for all fees, costs and expenses incurred in connection with such proceedings if the claim proves unsuccessful.

On February 18, 2015, CEL-SCI adopted new bylaws which include a fee-shifting provision in Article X for shareholder claims. Article X provides that in the event that any shareholder initiates or asserts a claim against CEL-SCI, or any of its officers or directors, including any derivative claim or claim purportedly filed on CEL-SCI's behalf, and the shareholder does not obtain a judgment on the merits that substantially achieves, in substance and amount, the full remedy sought, then the shareholder will be obligated to reimburse CEL-SCI and any of its officers or directors named in the action, for all fees, costs and expenses of every kind and description that CEL-SCI or its officers or directors may incur in connection with the claim. In adopting Article X, it is CEL-SCI's 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 shareholders 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 CEL-SCI's 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 CEL-SCI's ability to invoke its fee-shifting bylaw in connection with claims under the federal securities laws would be pre-empted by federal law. Similarly, it is unclear how courts might apply the standard that a claiming shareholder must obtain a judgment that substantially achieves, in substance and amount, the full remedy sought. The application of CEL-SCI's fee-shifting bylaw in connection with such claims, if any, will depend in part on future developments of the law. CEL-SCI cannot assure you that it will or will not invoke its fee-shifting bylaw in any particular dispute. In addition, given the unsettled state of the law related to fee-shifting bylaws, such as CEL-SCI's, CEL-SCI may incur significant additional costs associated with resolving disputes with respect to such bylaw, which could adversely affect CEL-SCI's business and financial condition.

If a shareholder 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 shareholder are potentially significant. This fee-shifting bylaw, therefore, may dissuade or discourage shareholders (and their attorneys) from initiating lawsuits or claims against CEL-SCI or its directors and officers. In addition, it may impact the fees, contingency or otherwise, required by potential plaintiffs' attorneys to represent our shareholders or otherwise discourage plaintiffs' attorneys from representing CEL-SCI's shareholders at all. As a result, this bylaw may limit the ability of shareholders 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 CEL-SCI and its directors and officers.

Article X of CEL-SCI's amended bylaws provides that shareholder claims brought against CEL-SCI, or its officers or directors, including any derivative claim or claim purportedly filed on behalf of CEL-SCI, 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 shareholder's ability to bring a claim in a judicial forum the shareholder finds favorable for disputes with CEL-SCI or its directors or officers, and may have the effect of discouraging lawsuits with respect to claims that may benefit CEL-SCI or its shareholders.

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

(a) See the Financial Statements attached to this Report.

Exhibits

3(a)	Articles of Incorporation	Incorporated by reference to Exhibit 3(a) of CEL-SCI's combined Registration Statement on Form S-1 and Post-Effective Amendment ("Registration Statement"), Registration Nos. 2-85547-D and 33-7531.
3(b)	Amended Articles	Incorporated by reference to Exhibit 3(a) of CEL-SCI's Registration Statement on Form S-1, Registration Nos. 2-85547-D and 33-7531.
3(c)	Amended Articles (Name change only)	Filed as Exhibit 3(c) to CEL-SCI's Registration Statement on Form S-1 Registration Statement (No. 33-34878).
3(d)	Bylaws	Incorporated by reference to Exhibit 3(b) of CEL-SCI's Registration Statement on Form S-1, Registration Nos. 2-85547-D and 33-7531.
3(e)	Amended Bylaws	Incorporated by reference to Exhibit 3(ii) of CEL-SCI’s report on Form 8-K dated March 16, 2015.
4	Shareholders Rights Agreement	Incorporated by reference to Exhibit 4 of CEL-SCI’S report on Form 8-K dated November 7, 2007.
4(b)	2014 Incentive Stock Option Plans	Incorporated by reference to the exhibits filed with the Company’s registration statements on Form S¬8 (File numbers 333-117088, 333-140792, 333-162265, 333-179477, and 333-184092.
4(c)	Non-Qualified Stock Option Plans	Incorporated by reference to the exhibits filed with the Company’s registration statements on Form S¬8 (File numbers 333-117088, 333-140792, 333-162265, 333-179477, 333-184092 and 333-198244).
4(d)	Stock Bonus Plans	Incorporated by reference to the exhibits filed with the Company’s registration statements on Form S¬8 (File numbers 333-117088, 333-140792, 333-162265, 333-179477, and 333-184092.
4(e)	Stock Compensation Plan	Incorporated by reference to the exhibits filed with the Company’s registration statements on Form S¬8 (File numbers 333-117088, 333-140792, 333-162265, 333-179477, and 333-184092.
4(f)	2014 Incentive Stock Bonus Plan	Incorporated by reference to Exhibit 4(c) filed with the Company’s registration statement on Form S-8 (333-198244).
10(d)		

Employment Agreement with Maximilian de Clara	Incorporated by reference to Exhibit 10(d) of CEL-SCI's report on Form 8-K (dated April 21, 2005) and Exhibit 10(d) to CEL-SCI's report on Form 8-K dated September 8, 2006.

10(f)	Securities Purchase Agreement (together with schedule required by Instruction 2 to Item 601 of Regulation S-K) pertaining to Series K notes and warrants, together with the exhibits to the Securities Purchase Agreement	Incorporated by reference to Exhibit 10 to CEL-SCI's report on Form 8-K dated August 4, 2006.
10(g)	Subscription Agreement (together with Schedule required by Instruction 2 to Item 601 of Regulation S-K) pertaining to April 2007 sale of 20,000,000 shares of CEL-SCI's common stock, 10,000,000 Series L warrants and 10,000,000 Series M Warrants	Incorporated by reference to Exhibit 10 of CEL-SCI's report on Form 8-K dated April 18, 2007
10(h)	Warrant Adjustment Agreement with Laksya Ventures	Incorporated by reference to Exhibit 10(i) of CEL-SCI's report on Form 8-K dated August 3, 2010
10(i)	Employment Agreement with Patricia Prichep (2013-2016)	Incorporated by reference to Exhibit 10(j) of CEL-SCI's report on Form 8-K dated August 30, 2013
10(j)	Employment Agreement with Eyal Taylor (2013-2016)	Incorporated by reference to Exhibit 10(k) of CEL-SCI's report on Form 8-K dated August 30, 2013.
10(k)	Amendment to Employment Agreement with Maximilian de Clara	Incorporated by reference to Exhibit 10(l) of CEL-SCI's report on Form 8-K dated August 30, 2010 and Exhibit 10(l) of CEL-SCI's report on Form 8-K dated August 30, 2013.
10(l)	First Amendment to Development Supply and Distribution Agreement with Orient Europharma.*	Incorporated by reference to Exhibit 10(m) filed with CEL-SCI's 10-K report for the year ended September 30, 2010.
10(m)	Exclusive License and Distribution Agreement with Teva Pharmaceutical Industries Ltd.*	Incorporated by reference to Exhibit 10(n) filed with CEL-SCI's 10-K report for the year ended September 30, 2010.
10(n)	Lease Agreement*	Incorporated by reference to Exhibit 10(o) filed with CEL-SCI's 10-K report for the year ended September 30, 2010.
10(o)	Promissory Note with Maximilian de Clara, together with Amendments 1 and 2	Incorporated by reference to Exhibit 10(p) filed with CEL-SCI's 10-K report for the year ended September 30, 2010.
10(p)	Licensing Agreement with Byron Biopharma	Incorporated by reference to Exhibit 10(i) of CEL-SCI's report on Form 8-K dated March 27, 2009
10(q)	At Market Issuance Sales Agreement with McNicoll, Lewis & Vlak LLC	Incorporated by reference to Exhibit 10(r) filed with CEL-SCI's 10-K report for the year ended September 30, 2010

10(z)	Development, Supply and Distribution Agreement with Orient Europharma	Incorporated by reference to Exhibit 10(z) filed with CEL-SCI's report on Form 10-K for the year ended September 30, 2003.
10(za)	Employment Agreement with Geert Kersten. Amendment to Employment Agreement	Incorporated by reference to Exhibit 10(za) to CEL-SCI's report on Form 8-K dated September 1, 2011 and Exhibit 10(za) of CEL-SCI's report on Form 8-K dated August 30, 2013.
10(aa)	Securities Purchase Agreement and form of the Series F warrants, which is and exhibit to the Securities Purchase Agreement	Incorporated by reference to Exhibit 10(aa) of CEL-SCI's report on Form 8-K dated October 3, 2011.

10(bb)	Placement Agent Agreement	Incorporated by reference to Exhibit 10(bb) of CEL-SCI's report on Form 8-K dated October 3, 2011.
10(cc)	Securities Purchase Agreement, together with the form of the Series H warrant, which is an exhibit to the securities Purchase Agreement	Incorporated by reference to Exhibit 10(cc) of CEL-SCI's report on Form 8-K dated January 25, 2012.
10(dd)	Placement Agent Agreement	Incorporated by reference to Exhibit 10(dd) of CEL-SCI's report on Form 8-K dated January 25, 2012.
10(ee)	Warrant Amendment Agreement, together with the form of the Series P warrant, which is an exhibit to the Warrant Amendment Agreement	Incorporated by reference to Exhibit 10(ee) of CEL-SCI's report on Form 8-K dated February 10, 2012.
10(ff)	Placement Agent Agreement	Incorporated by reference to Exhibit 10(ff) of CEL-SCI's report on Form 8-K dated February 10, 2012.
10(gg)	Securities Purchase Agreement and the form of the Series Q warrant, which is an exhibit to the Securities Purchase Agreement	Incorporated by reference to Exhibit 10(gg) of CEL-SCI's report on Form 8-K dated June 18, 2012.
10(hh)	Placement Agent Agreement	Incorporated by reference to Exhibit 10(hh) of CEL-SCI's report on Form 8-K dated June 18, 2012.
10 (ii)	Securities Purchase Agreement and the form of the Series R warrant, which is an exhibit to the Securities Purchase Agreement	Incorporated by reference to Exhibit 10(ii) of CEL-SCI's report on Form 8-K dated December 5, 2012.
10 (jj)	Placement Agent Agreement	Incorporated by reference to Exhibit 10(jj) of CEL-SCI's report on Form 8-K dated December 5, 2012.
10 (nn)	Underwriting Agreement, together with the form of Series S warrant which is an exhibit to the underwriting agreement	Incorporated by reference to Exhibit 1.1 of CEL-SCI's report on Form 8-K dated October 8, 2013.
10 (oo)	Underwriting Agreement, together with the form of Series S warrant which is an exhibit to the underwriting agreement	Incorporated by reference to Exhibit 1.1 of CEL-SCI's report on Form 8-K dated December 19, 2013.
10 (pp)	Underwriting Agreement, together with the form of Series T warrant which is an exhibit to the warrant agent agreement	Incorporated by reference to Exhibit 1.1 of CEL-SCI's report on Form 8-K dated April 15, 2014.

10 (qq)	Underwriting Agreement, together with the form of Series S warrant which is an exhibit to the warrant agent agreement	Incorporated by reference to Exhibit 1.1 of CEL-SCI's report on Form 8-K dated October 23, 2014.
10 (rr)	Assignment and Assumption Agreement with Teva Pharmaceutical Industries, Ltd. and GCP Clinical Studies, Ltd.	
10 (ss)	Service Agreement with GCP Clinical Studies, Ltd., together with Amendment 1 thereto*	
10 (tt)	Joinder Agreement with PLIVA Hrvatska d.o.o.	
10 (uu)	Master Service Agreement with Ergomed Clinical Research, Ltd., and Clinical Trial Orders thereunder	

10 (vv)	Co-Development and Revenue Sharing Agreement with Ergomed Clinical Research Ltd., dated April 19, 2013, as amended
10 (ww)	Co-Development and Revenue Sharing Agreement II: Cervical Intraepithelial Neoplasia in HIV/HPV co-infected women, with Ergomed Clinical Research Ltd., dated October 10, 2013, as amended
10 (xx)	Co-Development and Revenue Sharing Agreement III: Anal warts and anal intraepithelial neoplasia in HIV/HPV co-infected patients, with Ergomed Clinical Research Ltd., dated October 24, 2013
10 (yy)	Master Services Agreement with Aptiv Solutions, Inc.
10 (zz)	Project Agreement Number 1 with Aptiv Solutions, Inc. together with Amendments 1 and 2 thereto*
10 (aaa)	Second Amendment to Development Supply and Distribution Agreement with Orient Europharma
10 (bbb)	Amended and Restated Promissory Note with Maximilian de Clara
23.1	Consent of BDO USA, LLP
31	Rule 13a-14(a) Certifications
32	Section 1350 Certifications

* Portions of this exhibit have been omitted pursuant to a request for confidential treatment filed with the Commission under Rule 24b-2 of the Securities Exchange Act of 1934. The omitted confidential material has been filed separately with the Commission. The location of the omitted confidential information is indicated in the exhibit with asterisks (*)

SIGNATURES

In accordance with Section 13 or 15(a) of the Exchange Act, the Registrant has caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized on the 17th day of April 2015.

CEL-SCI CORPORATION

By: /s/ Maximilian de Clara
Maximilian de Clara, President

Pursuant to the requirements of the Securities Act of l934, this Report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Maximilian de Clara Maximilian de Clara	Director	April 17, 2015
/s/ Geert R. Kersten Geert R. Kersten	Chief Executive, Principal Accounting, Principal Financial Officer and a Director	April 17, 2015
/s/ Alexander G. Esterhazy Alexander G. Esterhazy	Director	April 17, 2015
/s/ Dr. Peter R. Young Dr. Peter R. Young	Director	April 17, 2015