CEL SCI CORP
Form 10-K/A
December 11, 2017

FORM 10-K/A
(Amendment 2)

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

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

For the fiscal year ended September 30, 2016.

OR

( ) 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 | 84-0916344 |
| (State or other jurisdiction of incorporation or organization) | (I.R.S. Employer Identification No.) |
| 8229 Boone Blvd., Suite 802<br>Vienna, Virginia | 22182 |
| (Address of principal executive offices) | (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. [ ]

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

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 [X] No [ ]

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 [X] No [ ]

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. [X]

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 [ ] Accelerated filer [ X]

Non-accelerated filer [ ] (Do not check if a smaller reporting company) Smaller reporting company [ ]

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act): [ ] Yes [X] 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, 2016, as quoted on the NYSE MKT, was $60,807,407.

As of December 9, 2016, the Registrant had 7,548,976 issued and outstanding shares of common stock.

Documents Incorporated by Reference: None

EXPLANATORY NOTE

In October 2008, the Company entered into an agreement whereby the Company leased a building owned by a third party. The Company accounted for the arrangement as an operating lease under ASC 840, Accounting for Leases.

In November 2017, the Company determined that the lease should have been treated as a financing obligation rather than an operating lease.

Accordingly, this amended 10-K is filed to correct the manner in which the Company accounted for the lease. See Note 17. Restatement, in the financial statements enclosed herein, for further information.

In addition:

per share data, including earnings per share amounts, in this amended 10-K have been adjusted to reflect a 1 for 25 reverse stock split which became effective on the NYSE American on June 15, 2017;

management's report on internal control over financial reporting and its conclusion on disclosure controls and procedures have been revised to address the material weaknesses in internal control over financial reporting; and

the opinion of BDO USA, LLP on the effectiveness of the Company's internal control over financial reporting as of September 30, 2016 has been amended.

Except for the above, no other information included in the 10-K report filed on December 15, 2016 is amended by this Form 10-K/A.

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 3 clinical trial involving head and neck cancer, for which CEL-SCI has received Orphan Drug Status from the U.S. FDA. If the primary endpoint of this global 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 1 study was successfully concluded; and the treatment of peri-anal warts in HIV/HPV co-infected men and women.

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 Phase 3 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, CEL-SCI believes 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 3 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 and CEL-4000) 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 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 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 is 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. CEL-SCI is currently focused on the development of the following product candidates and technologies:

1)
Multikine, an investigational immunotherapy under development for the potential treatment of certain head and neck cancers, 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 and CEL-4000, vaccine product candidates 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

CEL-SCI's 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 use the body's own anti-tumor immune response. Multikine is the trademark that CEL-SCI has 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 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, such as the European Medicine Agency, or EMA. 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 CEL-SCI's manufacturing facility. CEL-SCI spent over 10 years and more than $80 million developing and validating the manufacturing process for Multikine. 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 normally used. It is designed to be administered locally to treat local tumors before any other therapy has been administered. For example, in the 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, CEL-SCI believes 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 no appreciable toxicity

Source: Adapted from Timar et al., Journal of Clinical Oncology 23(15) May 20, 2005

The first indication CEL-SCI is pursuing for its investigational drug product candidate Multikine is an indication for the neoadjuvant therapy in patients with squamous cell carcinoma of the head and neck, or SCCHN (hereafter also referred to as advanced primary head and neck cancer). As detailed below, the Phase 3 Clinical trial of the Multikine investigational drug as neoadjuvant therapy in SCCHN is currently on Partial Clinical Hold by the US FDA. SCCHN is a type of head and neck cancer, and CEL-SCI believes that, in the aggregate, there is a large, unmet medical need among head and neck cancer patients. CEL-SCI believes the last FDA approval of a therapy indicated for the treatment of advanced primary head and neck cancer was over 50 years ago. In the aggregate, head and neck cancer represents about 6% of the world's cancer cases, with approximately over 650,000 patients diagnosed worldwide each year, and nearly 60,000 patients diagnosed annually in the United States. Multikine investigational immunotherapy was granted Orphan Drug designation for neoadjuvant therapy in patients with SCCHN by the FDA in the United States.

Status of Phase 3 Clinical Trial

Following submissions to regulatory authorities in 24 countries around the world, including the FDA in the United States, a global Phase 3 clinical trial of the investigational Multikine therapy as a potential neoadjuvant therapy in patients with SCCHN was initially commenced in late 2010. This clinical trial is currently on Partial Clinical Hold.

This trial is currently primarily under the management of two clinical research organizations, or CROs: ICON Inc. (who acquired Aptiv Solutions, Inc., one of the two CROs), or ICON, and Ergomed Clinical Research Limited, or Ergomed. Ergomed is responsible for new patient enrollment and the clinical study management of the various study sites, although enrollment of new patients has been on hold since the Company received verbal notice of FDA's Partial Clinical Hold on September 26, 2016. The following chart reflects the number of patients enrolled per month from the point at which the study management was transferred to the new CROs and the enrolment since then and until the FDA put the study on Partial Clinical Hold.

The Phase 3 study was designed with the objective that, if the study endpoint, which is an improvement in overall survival of the subjects treated with the Multikine treatment regimen plus the current standard of care (SOC) as compared to subjects treated with the current SOC only, is satisfied, the study results are expected to be used to support applications that the Company plans to submit to regulatory agencies in order to seek commercial marketing approvals for Multikine in major markets around the world. This assessment can only be made when a certain number of deaths have occurred in these two main comparator groups of the study.

The primary endpoint for the original protocol for this Phase 3 head and neck cancer study required that a 10% increase in overall survival be obtained in the Multikine group which also is administered CIZ (CIZ = low dose (non-chemotherapeutic) of cyclophosphamide, indomethacin and Zinc-multivitamins) all of which are thought to enhance Multikine activity), plus Standard of Care (Surgery + Radiotherapy or Chemoradiotherapy) arm of the study over the Control comparator (Standard of Care alone) arm. As the study originally was designed, the final determination of whether this endpoint had been successfully reached could only be determined when 298 events (deaths) had occurred in the combined comparator arms of the study. Under the original study design, the plan was to enroll 880 patients in order to be able to have 784 evaluable patients for the per-protocol analysis.

In August 2016, CEL-SCI announced that the currently available data from the Clinical Study reflected that the accumulation of deaths in the study was lower than that which was anticipated based on reported literature at the Phase 3 study's inception. If the number of deaths continued to be accumulated at the current rate, it had been determined that it would take longer than originally planned to complete the study. To minimize this eventuality, CEL-SCI decided it would be necessary to enroll up to 1,273 patients to have 1,146 evaluable patients. There were also other changes in the protocol, such as the required number of deaths (394) and the required increase in overall survival (6.5%) in favor of the Multikine comparator arm. With this increased patient enrollment, CEL-SCI expected a corresponding increase in the number of deaths, and, if this plan were implemented, the study could be completed in a more timely manner. As required by law and in order to be able to implement the plan, CEL-SCI submitted an amendment to the existing Phase 3 protocol for its head and neck cancer study to multiple regulatory agencies in the countries abroad where the Phase 3 study is being conducted as well as to the FDA to allow for this expansion in patient enrolment.

On September 26, 2016, CEL-SCI received verbal notice from the FDA that the Phase 3 clinical trial in advanced primary head and neck cancer has been placed on clinical hold. At such time, enrollment in the Phase 3 study was 928 patients. On October 21, 2016, CEL-SCI received a Partial Clinical Hold letter from the FDA and on November 21, 2016, CEL-SCI submitted a response to the FDA's Partial Clinical Hold letter.

In its partial clinical hold letter, FDA identified the following specific deficiencies: a) FDA stated that there is an unreasonable and significant risk of illness or injury to human subjects and cited among other things the absence of prompt reports by us to the FDA of IDMC recommendations to close the study entirely (made in spring of 2014) or at least to close it to accrual of new patients (made in spring of 2016); b) FDA stated that the investigator brochure is misleading, erroneous, and materially incomplete; and c) FDA stated that the plan or protocol is deficient in design to meet its stated objectives. In its partial clinical hold letter, FDA also identified the information needed to resolve these deficiencies. In addition, FDA's partial clinical hold letter included two requests relating to quality information regarding our investigational final drug product, which were noted by FDA as non-hold issues. CEL-SCI believes that its response submitted to FDA on November 18, 2016, addressed each of the deficiencies identified by FDA including detailing our belief that, under the applicable FDA guidance, there was no obligation to report the cited IDMC recommendations to the FDA at the time they were issued, and it also requested a face-to-face meeting with FDA, and outlined our commitment to diligently work with FDA in an effort to have the partial clinical hold for the study lifted. On December 8, 2016, the FDA advised CEL-SCI that the agency was denying CEL-SCI's request for a meeting at this time because FDA's review of CEL-SCI's November 17, 2016 response was ongoing. CEL-SCI was also advised that it will be receiving a letter addressing CEL-SCI's response by December 18, 2016.

Throughout the course of the Phase 3 study, 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 various points in the study at which the IDMC has completed review of the safety data and has issued recommendations, it has recommended that the Phase 3 study may continue, although on two occasions the IDMC has issued recommendations that would have closed the study entirely (spring of 2014) or at least closed it to accrual of new patients (spring of 2016). On one occasion, in the spring of 2014, the IDMC made a

recommendation that the study be closed for safety and efficacy reasons. However, following review of additional information submitted by us, the IDMC recommended that the study may continue. In the spring of 2016, with close to 800 patients enrolled, the IDMC made a recommendation that enrollment in the Phase 3 study should stop, but that patients already enrolled in the study should continue treatment and follow-up. CEL-SCI responded to this letter and indicated it would address the remaining three requests (generally relating to study design considerations) that were not part of the IDMC recommendation in a follow-up correspondence.

However, before CEL-SCI could provide our follow-up response to the remaining three requests, the IDMC sent another letter (a) indicating that our initial letter responding to the IDMC recommendation was unresponsive and (b) also indicating that the IDMC was deeply concerned about patient safety in the trial based on its review of cumulative data. The IDMC's initial letter in the spring of 2016 did not mention that the IDMC was concerned about safety. Instead, the initial letter in the spring of 2016 noted that the study should be closed to further accrual, and that patients who had been randomized may continue treatment and should be followed. The statement that patients who had been randomized may continue treatment suggested to us that safety was not an issue. Because no safety concern had been raised by the IDMC since the spring of 2014, when, after further communications with CEL-SCI, the IDMC issued its recommendation that the study should proceed, CEL-SCI believed based on the entirety of the course of correspondence with the IDMC that acute safety was not an issue underlying the IDMC's recommendation to halt accrual in the spring of 2016. As noted above, all other correspondence to CEL-SCI from the IDMC from study initiation through September 2015, with the exception of the recommendation in spring 2014, stated that the IDMC recommends “the study may continue". CEL-SCI responded to the IDMC’s recommendation in spring of 2016 with a statistical analysis showing that more patients were needed in order to complete the study in a reasonable amount of follow-up time, since the observed death rate in the study was lower than that which was predicted from the literature at the onset of the study. Subsequently a protocol amendment was prepared based on the analysis provided to the IDMC and submitted to FDA in July 2016, and a copy was then sent to the IDMC in response to its request for a copy of the submission. To date, CEL-SCI has not received a response from the IDMC regarding this protocol amendment. However, two months after the amendment was submitted to FDA, FDA placed the protocol on partial clinical hold. CEL-SCI expects to work through the concerns raised by the IDMC while CEL-SCI works through the partial hold with FDA. Ultimately, the decision as to whether CEL-SCI’s drug product candidate is safe and effective can only be made by FDA and/or by other regulatory authorities based upon an assessment of all of the data from an entire drug development program submitted as part of an application for marketing approval. As detailed elsewhere in this document, whether the partial clinical hold is lifted or not, the current Phase 3 clinical study for CEL-SCI’s investigational drug may or may not be able to be used as the pivotal study supporting a marketing application in the United States, and, if not, at least one entirely new Phase 3 pivotal study would need to be conducted to provide the pivotal study supporting a marketing application in the United States.

CEL-SCI estimates that the total remaining cash cost of the Phase 3 clinical trial, excluding any costs that will be paid by CEL-SCI's partners, would be approximately $12.1 million after September 30, 2016. This ís based on the executed contract costs with the CROs only and does not include other related costs, e.g. the manufacturing of the drug. Should the FDA allow the amended protocol filed with them to proceed, which requires an enrollment of up to 1,273 subjects, the remaining cost of the Phase 3 clinical trial will be higher than currently estimated. This is in addition to the approximately $34.5 million that CEL-SCI already had spent on the trial as of September 30, 2016. This estimate is based on information currently available under the contracts with the CROs responsible for managing the Phase 3 clinical trial. This number may be affected by the rate of any future patient enrollment, rate of death accumulation in the study, 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 clinical trial will be higher than currently estimated.

Follow-Up Analysis of Overall Survival in Phase 2 Patients

Prior to starting the Phase 3 study, CEL-SCI had tested Multikine in over 200 patients. The following is a summary of results from CEL-SCI’s last Phase 2 study conducted with Multikine. This study employed the same treatment protocol as is being followed in CEL-SCI’s Phase 3 study:

Reported potential for improved survival: 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 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, or OS, rate at a median of 3.33 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. 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 the 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 CEL-SCI's 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 clinical trial and the 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 the Multikine product candidate to become a treatment for advanced primary head and neck cancer, 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 final 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 (Timar et al JCO 2005). 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).

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.

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, CEL-SCI 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 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, CEL-SCI 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, CEL-SCI calculated the number of patients experiencing a favorable response as eight patients out of 19 (or 42.1%) (Timar et al, JCO 2005).

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.

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 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, the 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.

In October 2013, CEL-SCI signed 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 was to conduct a Phase 1 study, approved by the Human Subjects Institutional Review Board, of CEL-SCI’s investigational immunotherapy, Multikine, in HIV/HPV co-infected men and women with peri-anal warts. The purpose of this study was 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.

In July 2015, CEL-SCI added a clinical site at the University of California, San Francisco, or UCSF, and Key Opinion Leader, or KOL, to the ongoing Phase 1 study. In August 2016, the U.S. Navy discontinued this Phase 1 study because of difficulties in enrolling patients. UCSF is continuing with the study.

In October 2013, CEL-SCI 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 is supporting the development of Multikine with UCSF.

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 doctors at UCSF, 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, the 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, except one subject volunteer, all appeared to tolerate the treatment with no reported serious adverse events.

Development Agreements for Multikine

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 3 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 3 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 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 ten centers in Taiwan, four centers in Malaysia, three centers in Philippines and one center in Thailand to enroll patients as part of the Phase 3 Multikine clinical trial and has made further financial contributions towards the cost of the 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 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.

INTELLECTUAL PROPERTY

Patents and other proprietary rights are essential to CEL-SCI's business. CEL-SCI files patent applications to protect its technologies, inventions and improvements to its inventions that CEL-SCI considers important to the development of its 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), Japan (issued in November 2012 and currently set to expire in 2025), and two in Europe (issued in September 2015 and May 2016 both currently set to expire in 2025).

CEL-SCI has one 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 2021, 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. One pending U.S. application is a joint application with Northeast Ohio Medical University ("Neoucom"). If granted, CEL-SCI will share the ability to use the patent, unless CEL-SCI licenses the rights to the patent application and any ensuing patent from Neoucom.

As of December 1, 2016, 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 3 clinical trial, CEL-SCI needed to build a dedicated manufacturing facility to produce Multikine. This facility has been completed and validated, and has produced multiple clinical lots for the Phase 3 clinical trial. The facility has also passed review by a European Union Qualified Person on several 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 3 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). 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. 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. See Item 2 of this report for more information concerning the terms of this lease.

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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.

On July 15, 2014 CEL-SCI announced that it has been awarded a Phase 1 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 is funding the further development of CEL-SCI's LEAPS technology as a potential treatment for rheumatoid arthritis, an autoimmune disease of the joints. The work is being 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.

With the support of the SBIR grant, CEL-SCI is developing two new drug candidates, CEL-2000 and CEL-4000, as potential rheumatoid arthritis therapeutic vaccines. The data from animal studies using the CEL-2000 treatment vaccine demonstrated that it could be used as an effective treatment against rheumatoid arthritis with fewer administrations than those required by other anti-rheumatoid arthritis treatments currently on the market for arthritic conditions associated with the Th17 signature cytokine TNF- . The data for CEL-4000 indicates it could be effective against rheumatoid arthritis cases where a Th1 signature cytokine (IFN-c) is dominant. CEL-2000 and CEL-4000 have the potential to be a more disease-specific therapy, significantly less expensive, act at an earlier step in the disease process than current therapies and may be useful in patients not responding to existing rheumatoid arthritis therapies. CEL-SCI believes this represents a large unmet medical need in the rheumatoid arthritis market.

On November 14, 2016, CEL-SCI announced new preclinical data that demonstrate its investigational new drug candidate CEL-4000 has the potential for use as a therapeutic vaccine to treat rheumatoid arthritis. This efficacy study was supported in part by the SBIR Phase I Grant and was conducted in collaboration with Drs. Katalin Mikecz and Tibor Glant, and their research team at Rush University Medical Center in Chicago, IL.

In March 2015, CEL-SCI and its collaborators published a review article on vaccine therapies for rheumatoid arthritis based in part on work supported by the SBIR grant. The article is entitled “Rheumatoid arthritis vaccine therapies: perspectives and lessons from therapeutic Ligand Epitope Antigen Presentation System vaccines for models of rheumatoid arthritis” and was published in Expert Rev. Vaccines 1 - 18 and can be found at http://www.ncbi.nlm.nih.gov/ pubmed/25787143.

In August 2012, Dr. Zimmerman, CEL-SCI’s Senior Vice President of Research, Cellular Immunology, 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-c) and their action on reducing TNF- and other inflammatory cytokines as well as 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.

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, where a Th17 signature cytokine (TNF- ) is dominant. 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” Int Immunopharmacol. 2010 Apr; 10(4):412-21 http://www. ncbi.nlm.nih.gov/pubmed/20074669.

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 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.

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 some level of 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 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 1B. RISK FACTORS

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

Risks Related to CEL-SCI

CEL-SCI has identified a material weakness in its internal control over financial reporting which could, if not remediated, result in material misstatements in CEL-SCI's financial statements.

CEL-SCI's management is responsible for establishing and maintaining adequate internal control over our financial reporting, as defined in Rule 13a-15(f) under the Exchange Act. CEL-SCI's management identified a material weakness in the internal control over financial reporting as of September 30, 2016. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company's annual or interim financial statements will not be prevented or detected on a timely basis.

CEL-SCI discovered an error in the way it accounted for the lease for its manufacturing facility. The accounting error was determined to be a material weakness in CEL-SCI's internal control over financial reporting as of September 30, 2016 relating to CEL-SCI's financial close process for non-routine transactions including the accounting for leases and the assessment of impairment of long-lived assets. The errors were identified during the course of the preparation of its financial statements and other financial data for its fiscal year ended September 30, 2017, as well as its assessment of its disclosure controls and procedures and internal control over financial reporting as of the date.

If the remedial measures CEL-SCI has begun implementing that are designed to address this material weakness are insufficient to address this material weakness, or if additional material weaknesses or significant deficiencies in CEL-SCI's internal control are discovered or occur in the future, the financial statements may contain material misstatements and CEL-SCI could be required to restate the financial results.

CEL-SCI's Phase 3 Study has been placed on partial clinical hold by the FDA

CEL-SCI received a partial clinical hold letter from FDA stating that its Phase 3 study had been placed on clinical hold, precluding CEL-SCI from continuing the study except that patients enrolled prior to September 26, 2016 may continue to receive protocol-specified treatment at the discretion of the treating physician with written confirmation of their consent to remain on study after receiving an updated informed consent document. The FDA's partial clinical hold letter identified the following specific deficiencies: there is an unreasonable and significant risk of illness or injury to human subjects; the investigator brochure is misleading, erroneous, and materially incomplete; and that the plan or protocol is deficient in design to meet its stated objectives. In its partial clinical hold letter, the FDA also identified the information needed to resolve these deficiencies. Although CEL-SCI believes it addressed each of the deficiencies identified by the FDA in its November 17, 2016 response to the FDA, CEL-SCI nevertheless requested a face-to-face meeting with the FDA. On December 8, 2016, the FDA advised CEL-SCI that the agency was denying CEL-SCI's request for a meeting at this time because FDA's review of CEL-SCI's November 17, 2016 response was ongoing. CEL-SCI was also advised that it will be receiving a letter addressing CEL-SCI's response by December 18, 2016. CEL-SCI will not be able to enroll any additional patients in the Phase 3 study unless FDA lifts the clinical hold. In addition, in the spring of 2016, the IDMC recommended to CEL-SCI that new patient enrollment should stop in the Phase 3 study, but patients already on study should continue to be treated and followed. CEL-SCI expects to work through the concerns raised by the IDMC while CEL-SCI works through the partial hold with FDA. However, if the clinical hold is not removed or if it is determined that the study has been compromised or if the IDMC does not allow enrollment to continue, the study may be terminated.

CEL-SCI has incurred significant losses since inception, and CEL-SCI anticipates that it will continue to incur significant losses for the foreseeable future and may never achieve or maintain profitability.

CEL-SCI has a history of net losses, expects 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 its formation and through September 30, 2016, CEL-SCI incurred net losses of approximately $286 million. CEL-SCI has relied principally upon the proceeds from the public and private sales of its securities to finance its activities to date. To date, CEL-SCI has not commercialized any products or generated any revenue from the sale of products, and CEL-SCI does not expect to generate any product revenue for the foreseeable future. CEL-SCI does not know whether or when it will generate product revenue or become profitable.

CEL-SCI is heavily dependent on the success of Multikine which is under clinical development. CEL-SCI cannot be certain that Multikine will receive regulatory approval or be successfully commercialized even if CEL-SCI receives regulatory approval. On September 26, 2016, FDA placed CEL-SCI's Phase 3 clinical trial for Multikine on partial clinical hold. CEL-SCI will not be able to enroll any additional patients in the Phase 3 clinical trial unless FDA removes the clinical hold. In addition, prior to FDA's issuance of the partial clinical hold, CEL-SCI was discussing with its Independent Data Monitoring Committee issues related to enrollment of additional patients in trial. Multikine is the only product candidate in late-stage clinical development, and CEL-SCI's business currently depends heavily on its successful development, regulatory approval and commercialization. CEL-SCI has no drug products for sale currently and may never be able to develop approved and marketable drug products.

Even if CEL-SCI succeeds in developing and commercializing one or more of its product candidates, CEL-SCI expects to continue to incur significant operating and capital expenditures as CEL-SCI:

continues to undertake preclinical development and clinical trials for product candidates;

seeks regulatory approvals for product candidates;

implements additional internal systems and infrastructure.

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

Even if CEL-SCI does achieve profitability, it may not be able to sustain or increase profitability on a quarterly or annual basis. The failure to become and remain profitable could depress the value of CEL-SCI and could impair its ability to raise capital, expand its business, maintain research and development efforts, diversify product offerings or even continue in operation. A decline in the value of CEL-SCI could cause its stockholders to lose all or part of their investment.

CEL-SCI will require substantial additional capital to remain in operation. A failure to obtain this necessary capital when needed could force CEL-SCI to delay, limit, reduce or terminate the product candidates' development or commercialization efforts.

As of September 30, 2016, CEL-SCI had cash and cash equivalents of $2.9 million.  CEL-SCI believes that it will continue to expend substantial resources for the foreseeable future developing Multikine, LEAPS and any other product candidates or technologies that it may develop or acquire. These expenditures will include costs associated with research and development, potentially obtaining regulatory approvals and having the 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 the current and anticipated clinical trials is highly uncertain, CEL-SCI cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of the product candidates.

CEL-SCI's 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 the applications to and meetings with the FDA, the EMA and other regulatory authorities and the consequential effect on operating costs;

assuming favorable Phase 3 clinical results, the cost, timing and outcome of the 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 CEL-SCI 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 the products, if any of the product candidates are approved for marketing, including product manufacturing, marketing, sales and distribution costs;

the revenue, if any, received from commercial sales of the product candidates for which CEL-SCI receives marketing approval;

the cost of having the product candidates manufactured for clinical trials and in preparation for commercialization;

the ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of such agreements;

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

the extent to which CEL-SCI acquires or in-licenses other products or technologies.

Based on the current operating plan, and absent any future financings or strategic partnerships, CEL-SCI believes that its existing cash and cash equivalents and investments will be sufficient to fund the projected operating expenses and capital expenditure requirements into the second quarter of fiscal year 2017. However, CEL-SCI's operating plan may change as a result of many factors currently unknown to CEL-SCI, and CEL-SCI may need additional funds sooner than planned. Additional funds may not be available when CEL-SCI needs them on terms that are acceptable to CEL-SCI, or at all. If adequate funds are not available to CEL-SCI on a timely basis, CEL-SCI 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 CEL-SCI develops or acquires, or delay, limit, reduce or terminate its sales and marketing capabilities or other activities that may be necessary to commercialize its product candidates. Due to recurring losses from operations and future liquidity needs, there is substantial doubt about CEL-SCI's ability to continue as a going concern without additional capital becoming available. The doubt about CEL-SCI's ability to continue as a going concern could have an adverse impact on CEL-SCI's ability to execute its business plan, result in the reluctance on the part of certain suppliers to do business with CEL-SCI, or adversely affect CEL-SCI's ability to raise additional debt or equity capital.

The costs of the product candidates 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. The 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 candidate, such as Multikine. 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. The difficult and often complex steps necessary to obtain regulatory approval, especially that of the FDA and the 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 the clinical trials and research programs are primarily based upon the amount of capital available to CEL-SCI and the extent to which CEL-SCI receives regulatory approvals for clinical trials. CEL-SCI has established estimates of the future costs of the Phase 3 clinical trial for Multikine, but, as explained above, the estimates may not prove correct.

An adverse determination in any current or future lawsuits or arbitration proceedings to which CEL-SCI is a party could have a material adverse effect on CEL-SCI.

CEL-SCI is 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). CEL-SCI initiated the proceedings against inVentiv Health Clinical, LLC, or inVentiv, the former third-party CRO, and is seeking payment for damages related to inVentiv's prior involvement in the Phase 3 clinical trial of Multikine. The arbitration claim, initiated under the Commercial Rules of the American Arbitration Association, alleges (i) breach of contract, (ii) fraud in the inducement, and (iii) common law fraud. Currently, CEL-SCI is seeking at least $50 million in damages in its amended statement of claim.

In an amended statement of claim, CEL-SCI asserted the claims set forth above as well as an additional claim for professional malpractice. The arbitrator subsequently granted inVentiv's motion to dismiss the professional malpractice claim based on the "economic loss doctrine" which, under New Jersey law, is a legal doctrine that, under certain circumstances, prohibits bringing a negligence-based claim alongside a claim for breach of contract. The arbitrator denied the remainder of inVentiv's motion, which had sought to dismiss certain other aspects of the amended statement of claim. In particular, the arbitrator rejected inVentiv's argument that several aspects of the amended statement of claim were beyond the arbitrator's jurisdiction.

In connection with the pending arbitration proceedings, inVentiv has asserted counterclaims against CEL-SCI 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 the 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 CEL-SCI 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. CEL-SCI believes inVentiv's counterclaims are meritless and intends 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 CEL-SCI's business, results, financial condition and liquidity.

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In October 2015 CEL-SCI signed an arbitration funding agreement with a company established by Lake Whillans Litigation Finance, LLC, a firm specializing in funding litigation expenses. Pursuant to the agreement, an affiliate of Lake Whillans provides CEL-SCI with up to $5 million in funding for litigation expenses to support its arbitration claims against inVentiv. The funding is available to CEL-SCI to fund the expenses of the ongoing arbitration and will only be repaid if CEL-SCI receives proceeds from the arbitration.

The arbitration hearing on the merits began on September 26, 2016.

Additionally, CEL-SCI may also be the target of claims asserting violations of securities fraud and derivative actions, or other litigation or arbitration proceedings in the future. Any future litigation could result in substantial costs and divert management's attention and resources. These lawsuits or arbitration proceedings may result in large judgments or settlements against CEL-SCI, any of which could have a material adverse effect on its business, operating results, financial condition and liquidity.

CEL-SCI has received a subpoena from the Securities and Exchange Commission.

CEL-SCI has received subpoenas from the Securities and Exchange Commission, which is conducting a non-public, private investigation relating to certain of CEL-SCI's private and public financings as well as reports, articles and other publications prepared by third parties concerning CEL-SCI, the pending arbitration between CEL-SCI and CEL-SCI's former CRO, inVentiv Health, and CEL-SCI's Phase 3 clinical trial. This is the first SEC investigation involving CEL-SCI. While CEL-SCI is confident that it has the appropriate policies and procedures in place to ensure compliance with all SEC rules and regulations, CEL-SCI cannot predict when the SEC will conclude its investigation or the outcome of the investigation. CEL-SCI is cooperating fully with the SEC in this matter.

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 CEL-SCI revises current practices, policies and procedures, and may divert management time and attention from potential revenue-generating activities to compliance matters. If the 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 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, if approved.

CEL-SCI has not established a definitive plan for marketing nor has CEL-SCI established a price structure for any of its product candidates, if approved. However, CEL-SCI intends, if it is in a position to do so, to sell Multikine itself 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, CEL-SCI believes, focus on selling Multikine to targeted cancer centers, physicians and clinics involved in the treatment of head and neck cancer. CEL-SCI has 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. CEL-SCI believes 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 CEL-SCI will be able to find qualified third-party partners to market its products in other areas, on terms that are favorable to CEL-SCI, or at all.

CEL-SCI 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, CEL-SCI may experience other limitations involving the proposed sale of Multikine, such as uncertainty of third-party coverage and reimbursement. There is no assurance that CEL-SCI can successfully market Multikine, if approved, or any other product candidates 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 its operations.

CEL-SCI is highly dependent on the principal members of its management and development staff. If the Phase 3 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 its managerial, operational and financial systems and continue to retain, recruit and train additional qualified personnel, which may impose a strain on its administrative and its 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 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 future growth effectively, CEL-SCI may not be able to implement its business plan.

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

CEL-SCI faces an inherent risk of product liability as a result of the clinical testing of Multikine and other product candidates, and will face an even greater risk if CEL-SCI commercializes any of its product candidates. For example, CEL-SCI may be sued if its 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 contaminated Multikine, or could require CEL-SCI to destroy batches of Multikine, thereby subjecting CEL-SCI to possible financial losses, lawsuits and harm to its business.

If CEL-SCI cannot successfully defend itself against product liability claims, CEL-SCI may incur substantial liabilities or be required to limit or cease the clinical testing or commercialization of its 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 other product candidates, if approved;

injury to CEL-SCI’s 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 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 other product candidates; and

a decline in the price of CEL-SCI’s common stock.

Although CEL-SCI has product liability insurance for Multikine in the amount of $5.0 million, 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 the insurance coverage. Any claim that may be brought against CEL-SCI could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by CEL-SCI’s insurance or that is in excess of the limits of the insurance coverage. CEL-SCI’s insurance policies also have various exclusions, and CEL-SCI may be subject to a claim for which CEL-SCI has no coverage. CEL-SCI may have to pay any amounts

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

CEL-SCI's commercial success depends, in part, upon attaining significant market acceptance of its product candidates, if approved, among physicians, patients, healthcare payors and major operators of cancer clinics.

Even if CEL-SCI obtains regulatory approval for its 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 CEL-SCI receives 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 a product candidate over alternative treatments, especially with respect to patient subsets that are targeted with a product candidate;

the safety of a 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 sales and marketing efforts.

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

Our Independent Registered Public Accountants have included in its report on our financial statements a paragraph stating that we may be unable to continue as a going concern.

As a result of our recurring losses from operations, our independent registered public accounting firm, BDO USA, LLP, has issued a report in connection with their audit of our financial statements for the year ended September 30, 2016, that included an explanatory paragraph referring to our recurring losses from operations and expressing substantial doubt in our ability to continue as a going concern without additional capital becoming available. The doubt about our ability to continue as a going concern could have an adverse impact on our ability to execute our business plan, result in the reluctance on the part of certain suppliers to do business with us, or adversely affect our ability to raise additional debt or equity capital.

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.

CEL-SCI's 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 CEL-SCI to unanticipated delays and may prevent CEL-SCI from marketing the 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 the 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. CEL-SCI's current and future clinical trials may not be successful.

Although CEL-SCI is involved in Phase 1 and Phase 3 clinical trials for Multikine, CEL-SCI may experience delays in the clinical trials and CEL-SCI does not know whether the clinical trials will need to be redesigned, enroll patients on a timely basis 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 the planned trials;

obtaining regulatory approval to commence a trial;

suspending enrollment in clinical trials, as in the case of the partial clinical hold issued by FDA related to our Phase 3 clinical trial for Multikine;

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 the 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 competence of the CRO running the study, 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 CEL-SCI is investigating. Furthermore, CEL-SCI relies on CROs and clinical trial sites to ensure the proper and timely conduct of the clinical trials and while CEL-SCI has agreements governing their committed activities, CEL-SCI has limited influence over their actual performance.

On October 31, 2013, CEL-SCI commenced arbitration proceedings against inVentiv Health Clinical, LLC, or inVentiv, its former clinical research organization (CRO). The arbitration claim, initiated under the Commercial Rules of the American Arbitration Association, alleges (i) breach of contract, (ii) fraud in the inducement, and (iii) common law fraud. Currently, CEL-SCI is seeking at least $50 million in damages in its amended statement of claim.

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 CEL-SCI 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 CEL-SCI 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.

Should CEL-SCI's allegations be found to be true, regulatory authorities may rule the data collected by that the former CRO unusable in support of our marketing applications. Even if CEL-SCI's allegations are not found to be true, regulatory authorities may rule the data collected by that former CRO unusable in support of our marketing applications. In either case, CEL-SCI has proposed to enroll approximately 125 additional subjects in its Phase 3 study beyond the study design that was in place prior to FDA's imposition of a partial clinical hold on the study, but those additional subjects can only be enrolled if the partial clinical hold is lifted. The need to enroll those additional patients will cause additional delays in our clinical testing and development program, and there is no guarantee that the partial clinical hold will be lifted, that if the partial clinical hold is lifted the study will be in a position that additional patients can be recruited and enrolled, or that CEL-SCI can successfully enroll the additional patients necessary to complete the study if the clinical hold is lifted. Currently, the Phase 3 study has been placed on partial clinical hold by FDA. In its partial clinical hold letter, FDA identified the following specific deficiencies: a) FDA stated that there is an unreasonable and significant risk of illness or injury to human subjects; b) FDA stated that the investigator brochure is misleading, erroneous, and materially incomplete; and c) FDA stated that the plan or protocol is deficient in design to meet its stated objectives. In its partial clinical hold letter, FDA also identified the information needed to resolve these deficiencies. In CEL-SCI's response submitted to FDA on November 18, 2016, CEL-SCI believes it addressed each of the deficiencies identified by FDA, requested a face-to-face meeting with FDA, and detailed its commitment to diligently work with FDA in an effort to have the partial clinical hold for the study lifted. On December 8, 2016, the FDA advised CEL-SCI that the agency was denying CEL-SCI's request for a meeting at this time because FDA's review of CEL-SCI's November 17, 2016 response was ongoing. CEL-SCI was also advised that it will be receiving a letter addressing CEL-SCI's response by December 18, 2016. If the partial clinical hold is not ever lifted, the Phase 3 study will not be able to be completed to its prespecified endpoints in a timely manner, if at all, and, if the Phase 3 study cannot be completed to its prespecified endpoints, the study would not be able to be used as the pivotal study supporting a marketing application in the United States, and at least one entirely new Phase 3 pivotal study would need to be conducted to provide the pivotal study supporting a marketing application in the United States. Even if the partial clinical hold is lifted, if it is not lifted in a timely fashion, the nature and duration of the partial clinical hold could irreparably harm the data from the Phase 3 study such that it may no longer be able to be used as the pivotal study supporting a marketing application in the United States. Even if the partial clinical hold is lifted in a timely fashion, it remains possible that the regulatory authorities could determine that the Phase 3 study is not sufficient to be used as a single pivotal study supporting a marketing application in the United States. In either of these latter circumstances, at least one entirely new Phase 3 pivotal study would need to be conducted to provide the pivotal study supporting a marketing application in the United States. If there is a need to conduct an additional Phase 3 pivotal study, any such requirement would have significant and severe material consequences for CEL-SCI and could impact its ability to continue as a going concern.

CEL-SCI could also encounter significant delays and/or need to terminate a development program for a product candidate if physicians encounter unresolved ethical issues associated with enrolling patients in clinical trials of the product candidates in addition to existing treatments that have established safety and efficacy profiles. Further, a clinical trial may be suspended or terminated by CEL-SCI, one or more of the IRBs for the institutions in which such trials are being conducted, by CEL-SCI upon a final recommendation by the Independent Data Monitoring Committee, or IDMC, with which CEL-SCI agrees for such trial, or by FDA or other regulatory authorities due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or the clinical protocols, as a result of inspection of the clinical trial operations or trial site(s) by FDA or other regulatory authorities, the imposition of a clinical hold or partial clinical hold such as the partial clinical hold currently imposed by FDA on the Phase 3 study of our investigational drug Multikine as detailed elsewhere in this prospectus supplement, 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. The occurrence of any one or more of these events would have significant and severe material consequences for us and could impact our ability to continue as an ongoing concern.

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If CEL-SCI experiences termination of, or delays in the completion of, any clinical trial of its product candidates, the commercial prospects for the product candidates will be harmed, and the ability to generate product revenues will be delayed. In addition, any delays in completing the clinical trials will increase the costs, slow the product development and approval process and jeopardize the ability to commence product sales and generate revenues. Any of these occurrences may harm CEL-SCI's 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 a delay or the denial of regulatory approval for the product candidates.

CEL-SCI cannot be certain when or under what conditions it will undertake future clinical trials. A variety of issues may delay the Phase 3 clinical trial for Multikine, such as patients in the Phase 3 clinical trial dying at a slower rate than projected and the existing partial clinical hold, or preclinical and early clinical trials for the 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. CEL-SCI may fail to find subjects willing to enroll in the trials. CEL-SCI manufactures Multikine in its manufacturing facility, but relies 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 the product candidates may not be completed on schedule, the FDA or foreign regulatory agencies may order CEL-SCI to stop or modify research, or these agencies may not ultimately approve any of the 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 the product candidates. The data collected from the clinical trials may not be sufficient to support regulatory approval of the various product candidates, including Multikine. The failure to adequately demonstrate the safety and efficacy of any of the product candidates would delay or prevent regulatory approval of the product candidates in the United States, which could prevent CEL-SCI from achieving profitability. Although CEL-SCI had positive results in the Phase 2 trials for Multikine, those results were for a very small sample set, and CEL-SCI will not know how Multikine will perform in a larger set of subjects until CEL-SCI is well into, or completes, the 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, termination of the Phase 3 study, 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 CEL-SCI.

The requirements governing the conduct of clinical trials, manufacturing and marketing of the 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. The lack of experience may impede the 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 CEL-SCI has obtained regulatory approval. In addition, regulatory authorities may also limit the types of patients to which CEL-SCI or its third-party partners may market Multikine or the other product candidates. Any failure to obtain or any delay in obtaining required regulatory approvals may adversely affect CEL-SCI's or its third-party partners' ability to successfully market the product candidates.

Even if CEL-SCI obtains regulatory approval for its investigational products, CEL-SCI will be subject to stringent, ongoing government regulation.

If CEL-SCI's investigational 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 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 investigational products. 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 the 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 of its 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 the facilities, or the facilities of the 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 the marketing applications for the product candidates, or may withdraw any prior approval. 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 the product candidates 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, 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 CEL-SCI 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. If CEL-SCI or other parties identify adverse effects after any of the products are on the market, or if manufacturing problems occur, regulatory approval may be suspended or withdrawn. CEL-SCI may be required to reformulate 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.

The FDA and other governmental authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of CEL-SCI's product candidates. If CEL-SCI is slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if CEL-SCI is not able to maintain regulatory compliance, CEL-SCI may lose any marketing approval that it may have obtained, which would adversely affect its business, prospects and ability to achieve or sustain profitability. 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 product candidates.

CEL-SCI's 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 the product candidates could cause CEL-SCI 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 the clinical trials could reveal a high and unacceptable severity and/or prevalence of these or other side effects. In such an event, the trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order CEL-SCI to cease further development of, or deny approval of, the 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 CEL-SCI's business, financial condition and prospects significantly.

Additionally, if one or more of the product candidates receives marketing approval, and CEL-SCI 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;

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

CEL-SCI could be sued and held liable for harm caused to patients; and

CEL-SCI's reputation may suffer.

Any of these events could prevent CEL-SCI from achieving or maintaining market acceptance of a particular product candidate, if approved, and could significantly harm its business, results of operations and prospects.

CEL-SCI relies on third parties to conduct its preclinical and clinical trials. If these third parties do not successfully carry out their contractual duties and meet regulatory requirements, or meet expected deadlines, CEL-SCI may not be able to obtain regulatory approval for or commercialize the product candidates and its business could be substantially harmed.

CEL-SCI has relied upon and plans to continue to rely upon third-party CROs to prepare for, conduct, monitor and manage data for its ongoing preclinical and clinical programs. CEL-SCI relies on these parties for all aspects of the execution of its preclinical studies and clinical trials, and although CEL-SCI diligently oversees and carefully manages the CROs, CEL-SCI directly controls only certain aspects of their activities and relies upon them to provide timely, complete, and accurate reports on the conduct of the studies. Although such third parties provide support and represent CEL-SCI for regulatory purposes in the context of the clinical trials, ultimately CEL-SCI is responsible for ensuring that each of the studies is conducted in accordance with the applicable protocol, legal, regulatory, and scientific standards, and the reliance on the CROs does not relieve CEL-SCI of its regulatory responsibilities. CEL-SCI and the CROs acting on CEL-SCI's behalf as well as principal investigators and trial sites are required to comply with Good Clinical Practice, or 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 the products in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators, and trial sites. If CEL-SCI or any of the CROs fail to comply with applicable GCPs or other applicable regulations, the clinical data generated in the clinical trials may be determined to be unreliable and CEL-SCI may therefore need to enroll additional subjects in the clinical trials, or the FDA, EMA or comparable foreign regulatory authorities may require CEL-SCI to perform an additional clinical trial or trials before approving the marketing applications. Moreover, if CEL-SCI or any of the CROs, principal investigators, or trial sites, fail to comply with applicable regulatory and GCP requirements, then CEL-SCI, the CROs, principal investigators, or trial sites may be subject to enforcement actions, such as fines, warning letters, untitled letters, clinical holds, civil or criminal penalties, and/or injunctions. CEL-SCI cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of the clinical trials comply with GCP regulations. In addition, the clinical trials must be conducted with product produced under GMP regulations. The failure to comply with these regulations may require CEL-SCI to delay or repeat clinical trials, which would delay the regulatory approval process.

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For example, CEL-SCI is currently involved in a dispute with the former CRO relating to the conduct of the Phase 3 study where CEL-SCI alleges (i) breach of contract, (ii) fraud in the inducement and (iii) fraud. In connection with this dispute, CEL-SCI has alleged that the 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. Should CEL-SCI's allegations be found to be true regulatory authorities may rule the data collected by that former CRO unusable in support of the marketing applications. This would result in CEL-SCI having to enroll approximately 125 additional subjects in the Phase 3 study beyond its current plans, which could cause additional delays in the clinical testing and development program. Currently the Phase 3 study is on partial clinical hold.

If any of the relationships with the third-party CROs terminate, CEL-SCI may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. In addition, the CROs are not CEL-SCI's employees, and except for remedies available to CEL-SCI under the agreements with such CROs, CEL-SCI cannot control whether or not they devote sufficient time and resources to the 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 the clinical protocols, regulatory requirements or for other reasons, the clinical trials may be extended, delayed or terminated, and CEL-SCI may not be able to obtain regulatory approval for or successfully commercialize the product candidates. As a result, CEL-SCI's results of operations and the commercial prospects for the product candidates would be harmed, the costs could increase and the 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 may occur, which can materially impact CEL-SCI's ability to meet the desired clinical development timelines. Though CEL-SCI diligently oversees and carefully manages its relationships with the CROs, there can be no assurance that CEL-SCI will not encounter similar challenges or delays in clinical development in the future or that these delays or challenges will not have a material adverse impact on CEL-SCI's business, financial condition and prospects.

CEL-SCI has 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 CEL-SCI 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.

Even though CEL-SCI has received orphan drug designation for Multikine for the treatment of squamous cell carcinoma of the head and neck, CEL-SCI 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 CEL-SCI seeks 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 CEL-SCI is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Further, even if CEL-SCI obtains 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.

The 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 CEL-SCI obtains marketing approval. The current and future arrangements with healthcare professionals, principal investigators, consultants, customers (actual and potential) and third-party payors may expose CEL-SCI to broadly applicable 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 provides 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;

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federal civil and criminal false claims laws, including the federal False Claims Act, which impose criminal and civil penalties, including civil whistleblower actions, 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 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 imposed 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 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 the 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 the business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws. If CEL-SCI's operations are found to be in violation of any of these laws or any other governmental regulations, CEL-SCI 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 the operations, all of which could significantly harm CEL-SCI's business. If any of the physicians or other healthcare providers or entities with whom CEL-SCI expects to do business, including 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 CEL-SCI's business.

Failure to obtain or maintain adequate coverage and reimbursement for the product candidates, if approved, could limit the ability to market those products and decrease CEL-SCI's ability to generate revenue.

Sales of CEL-SCI's product candidates will depend substantially, both domestically and abroad, on the extent to which the costs of the 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. CEL-SCI anticipates 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, CEL-SCI may not be able to successfully commercialize its product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow CEL-SCI to establish or maintain pricing sufficient to realize a return on its investment. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for the product candidates.

Healthcare legislative reform measures may have a material adverse effect on CEL-SCI's 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 CEL-SCI may otherwise receive for its 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. CEL-SCI expects 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 its product candidates or additional pricing pressures.

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. Coverage and reimbursement decisions in one foreign jurisdiction may impact decisions in other countries. To obtain reimbursement or pricing approval in some countries, CEL-SCI may be required to conduct clinical trials that demonstrate the 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, 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 its 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 product candidates from the compounds, compositions and processes, through research financed by CEL-SCI, or as a result of possible third-party licensing arrangements with pharmaceutical or other companies, is not assured. CEL-SCI 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 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. The future market share of Multikine or the other product candidates, if approved, will be reduced or eliminated if the competitors develop and obtain approval for products that are safer or more effective than CEL-SCI'S 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, CEL-SCI does not know whether:

CEL-SCI was the first to make the inventions covered by each of its issued patents and pending patent applications;

CEL-SCI was the first to file patent applications for these inventions;

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

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

any of the patents will be valid or enforceable;

any patents issued to CEL-SCI or the collaboration partners will provide CEL-SCI with any competitive advantages, or will be challenged by third parties;

CEL-SCI will be able to develop additional proprietary technologies that are patentable;

the U.S. government will exercise any of its statutory rights to CEL-SCI's intellectual property that was developed with government funding; or

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

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

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

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 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 CEL-SCI. CEL-SCI is 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 CEL-SCI's intellectual property is protected as trade secrets or confidential know-how, not as a patent.

CEL-SCI considers proprietary trade secrets and/or confidential know-how and unpatented know-how to be important to its business. Much of the intellectual property pertains to CEL-SCI'S 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 CEL-SCI to protect its disclosure to competitors, since legal protections after disclosure may be minimal or non-existent. Accordingly, much of the value of this intellectual property is dependent upon the ability of CEL-SCI to keep the trade secrets and know-how confidential.

To protect this type of information against disclosure or appropriation by competitors, CEL-SCI's policy is to require its employees, consultants, contractors and advisors to enter into confidentiality agreements with CEL-SCI. However, current or former employees, consultants, contractors and advisers may unintentionally or willfully disclose the 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 the application for product candidate approval may require the disclosure of some or all of the 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 product candidates in key countries, CEL-SCI's opportunities and value may suffer.

Failure to obtain or maintain trade secrets and/or confidential know-how trade protection could adversely affect CEL-SCI'S competitive position. Moreover, 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, competitors could limit the use of such trade secrets and/or confidential know-how.

CEL-SCI may be subject to claims challenging the inventorship or ownership of its patents and other intellectual property.

CEL-SCI may also be subject to claims that former employees, collaborators or other third parties have an ownership interest in its patents or other intellectual property. CEL-SCI may be subject to ownership disputes in the future arising, for example, from conflicting obligations of consultants or others who are involved in developing the product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If CEL-SCI fails in defending any such claims, in addition to paying monetary damages, CEL-SCI 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 its business. Even if CEL-SCI is successful in defending against such claims, litigation could result in substantial costs and be a distraction to CEL-SCI's management and employees.

Risks Related to CEL-SCI's common stock

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

CEL-SCI expects that significant additional capital will be needed in the future to continue its planned operations. To raise additional capital, CEL-SCI may in the future offer additional shares of its common stock or other securities convertible into or exchangeable for the common stock. To the extent CEL-SCI raises additional capital by issuing equity securities, the stockholders may experience substantial dilution. These sales may result in material dilution to CEL-SCI's existing stockholders and new investors could gain rights superior to existing stockholders.

CEL-SCI's outstanding options and warrants may adversely affect the trading price of its common stock.

As of September 30, 2016, there were outstanding warrants and options which allow the holders to purchase 3,442,383 shares that may be issued upon the exercise of outstanding warrants, with a weighted average exercise price of $24.25 per share, and 343,571 shares that may be issued upon the exercise of outstanding options, with a weighted average exercise price of $59.25 per share. The outstanding options and warrants could adversely affect the ability of CEL-SCI 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 and warrants, the holders have the opportunity to profit from a rise in the market price of its common stock without assuming the risk of ownership. The issuance of shares upon the exercise of outstanding options and warrants will also dilute the ownership interests of CEL-SCI's existing stockholders.

CEL-SCI's ability to utilize its 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 the public offerings and other transactions, CEL-SCI may have triggered an "ownership change" limitation. In addition, CEL-SCI may experience ownership changes in the future as a result of subsequent shifts in its stock ownership, some of which are outside its control. As a result, the ability to use the 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 CEL-SCI.

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 its 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 its board of directors, no common stock dividends have been declared or paid by CEL-SCI and it has 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 CEL-SCI's common stock. Any return to CEL-SCI's shareholders will therefore be limited to appreciation in the price of its common stock, which may never occur. If CEL-SCI's stock price does not increase, CEL-SCI'S shareholders are unlikely to receive any return on their investments in CEL-SCI's common stock.

The price of CEL-SCI's common stock has been volatile and is likely to continue to be volatile, which could result in substantial losses for CEL-SCI's shareholders.

CEL-SCI's stock price has been, and is likely to continue to be, volatile. As a result of this volatility, CEL-SCI's shareholders may not be able to sell their shares at or above its current market price. The market price for CEL-SCI's common stock may be influenced by many factors, including:

actual or anticipated fluctuations in CEL-SCI's financial condition and operating results;

actual or anticipated changes in CEL-SCI's growth rate relative to competitors;

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

development of new technologies that may address the markets and may make CEL-SCI's technology less attractive;

changes in physician, hospital or healthcare provider practices that may make CEL-SCI's product candidates less useful;

announcements by CEL-SCI, its partners or 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 CEL-SCI provides to the public;

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

variations in its financial results or those of companies that are perceived to be similar to CEL-SCI;

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.

CEL-SCI has been advised that it is not in compliance with certain continued listing standards of the NYSE MKT.

On December 9, 2016, CEL-SCI received a letter from the NYSE MKT, its current listing exchange, which advised CEL-SCI that, based upon its June 30, 2016 10-Q report, CEL-SCI was noncompliant with certain continued listing standards of the NYSE MKT. CEL-SCI can maintain its listing by submitting a plan of compliance by January 9, 2017. This plan must advise of actions CEL-SCI has taken or will take to regain compliance with the continued listing standards by June 11, 2018. CEL-SCI intends to submit such a plan by January 9, 2017. If the plan is not acceptable,

or CEL-SCI does not make sufficient progress under the plan to reestablish compliance by June 11, 2018, the staff of the exchange may initiate proceedings to delist CEL-SCI's securities from the NYSE MKT. CEL-SCI may appeal a delisting determination in accordance with the rules of the exchange.

In addition, the NYSE MKT will not normally remove the securities of an issuer which is otherwise below the stockholders' equity criteria noted above if the issuer has a market capitalization of at least $50 million.

The letter from the NYSE MKT has no current effect on the listing of CEL-SCI's securities on the exchange.

Under its amended bylaws, stockholders 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 stockholder claims. Article X provides that in the event any stockholder 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 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 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 the 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 provision contained in Article X of the 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 the ability to invoke the 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 stockholder must obtain a judgment that substantially achieves, in substance and amount, the full remedy sought. The application of the fee-shifting bylaw in connection with such claims, if any, will depend in part on future developments of the law. CEL-SCI cannot assure its shareholders that CEL-SCI will or will not invoke the 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 its 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 CEL-SCI or its directors and officers. In addition, it may impact the fees, contingency or otherwise, required by potential plaintiffs’ attorneys to represent the stockholders or otherwise discourage plaintiffs’ attorneys from representing the 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 the 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 stockholder claims brought against CEL-SCI, or its officers or directors, including any derivative claim or claim purportedly filed on CEL-SCI’s 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 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 the stockholders.

ITEM 1B. UNRESOLVED SEC COMMENTS

None

ITEM 2. PROPERTIES

CEL-SCI leases office space at 8229 Boone Blvd., Suite 802, Vienna, Virginia at a monthly rental of approximately $8,000. The lease on the office space expires on June 30, 2020. CEL-SCI believes this arrangement is adequate for the conduct of its present business.

CEL-SCI has a 17,900 square foot laboratory located in Baltimore, Maryland. The laboratory is leased by CEL-SCI at a cost of approximately $11,000 per month. The laboratory lease expires on February 28, 2022.

In August 2007, CEL-SCI leased a building near Baltimore, Maryland (the San Tomas lease). The building, which consists of approximately 73,000 square feet, has been remodeled in accordance with CEL-SCI's specifications so that it can be used by CEL-SCI to manufacture Multikine for CEL-SCI's Phase 3 clinical trial and sales of the drug if approved by the FDA. The lease expires on October 31, 2028 and required annual base rent payments of approximately $1.6 million during the twelve months ending September 30, 2016. The annual base rent escalates each year at 3% beginning on November 1st. CEL-SCI is also required to pay all real and personal property taxes, insurance premiums, maintenance expenses, repair costs and utilities, which were approximately $42,000 per month as of September 30, 2016. The lease allows CEL-SCI, at its election, to extend the lease for two ten-year periods or to purchase the building at the end of the 20-year lease. The Company is not the legal owner of the manufacturing building, but is deemed to be the owner for the accounting purposes based on the accounting guidance for build-to-suit leases under ASC 840-40-55. The lease required CEL-SCI to pay $3,150,000 towards the remodeling costs, which is being recouped by reductions in the annual base rent of $303,228 beginning in fiscal year 2014. In August 2011, CEL-SCI was required to deposit $1,670,917, the equivalent of one year of base rent. The $1,670,917 was required to be deposited when the amount of CEL-SCI's cash had dropped below the amount stipulated in the lease and is included in non-current assets at September 30, 2016.

ITEM 3. LEGAL PROCEEDINGS

CEL-SCI is 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). CEL-SCI initiated the proceedings against inVentiv Health Clinical LLC, or inVentiv, CEL-SCI's former third-party CRO, and is seeking payment for damages related to inVentiv's prior involvement in the Phase 3 clinical trial of Multikine. The arbitration claim, initiated under the Commercial Rules of the American Arbitration Association, alleges (i) breach of contract, (ii) fraud in the inducement, and (iii) common law fraud. Currently, CEL-SCI seeks at least $50 million in damages in its amended statement of claim.

In an amended statement of claim, CEL-SCI asserted the claims set forth above as well as an additional claim for professional malpractice. The arbitrator subsequently granted inVentiv's motion to dismiss the professional malpractice claim based on the "economic loss doctrine" which, under New Jersey law, is a legal doctrine that, under certain circumstances, prohibits bringing a negligence-based claim alongside a claim for breach of contract. The arbitrator denied the remainder of inVentiv's motion, which had sought to dismiss certain other aspects of the amended statement of claim. In particular, the arbitrator rejected inVentiv's argument that several aspects of the amended statement of claim were beyond the arbitrator's jurisdiction.

In connection with the pending arbitration proceedings, inVentiv has asserted counterclaims against CEL-SCI 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 CEL-SCI's 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 CEL-SCI 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. CEL-SCI believes inVentiv's counterclaims are meritless. However, if inVentiv successfully asserts any of its counterclaims, such an adverse determination could have a material adverse effect on CEL-SCI's business, results, financial condition and liquidity.

In October 2015, CEL-SCI signed an arbitration funding agreement with a company established by Lake Whillans Litigation Finance, LLC, a firm specializing in funding litigation expenses. Pursuant to the agreement, an affiliate of Lake Whillans provides CEL-SCI with funding for litigation expenses to support its arbitration claims against inVentiv. The funding is available to CEL-SCI to fund the expenses of the ongoing arbitration and will only be repaid when CEL-SCI receives proceeds from the arbitration.

The arbitration hearing on the merits (the "trial") began on September 26, 2016.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. MARKET FOR CEL-SCI'S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS.

As of September 30, 2016 there were approximately 1,000 record holders of CEL-SCI's common stock. CEL-SCI's common stock is traded on the NYSE American under the symbol "CVM".

Shown below are the range of high and low quotations for CEL-SCI's common stock for the periods indicated as reported on the NYSE American. The market quotations have been adjusted for a 1 for 25 reverse stock split which became effective on the NYSE American on June 15, 2017 reflect inter-dealer prices, without retail mark-up, mark-down or commissions and may not necessarily represent actual transactions.

| Quarter Ending | High | Low |
|---|---|---|
| 12/31/14 | $ 22.75 | $ 13.50 |
| 3/31/15 | $ 30.75 | $ 14.75 |
| 6/30/15 | $ 27.25 | $ 14.75 |
| 9/30/15 | $ 20.00 | $ 12.00 |
| 12/31/15 | $ 18.75 | $ 9.00 |
| 3/31/16 | $ 16.50 | $ 9.00 |
| 6/30/16 | $ 15.00 | $ 11.00 |
| 9/30/16 | $ 13.50 | $ 6.00 |

Holders of common stock are entitled to receive dividends as may be declared by CEL-SCI's 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. CEL-SCI's 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.

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.

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 which may be 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.

The graph below matches the cumulative 5-year total return of holders of CEL-SCI's common stock with the cumulative total returns of the NYSE MTK Composite index and the RDG MicroCap Biotechnology index. The graph assumes that the value of an investment in CEL-SCI's common stock and in each of the indexes (including

reinvestment of dividends) was $100 on September 30, 2011 and tracks it through September 30, 2016.
The stock price performance included in this graph is not necessarily indicative of future stock price performance.

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| | 9/11 | 9/12 | 9/13 | 9/14 | 9/15 | 9/16 |
|---|---|---|---|---|---|---|
| CEL-SCI Corporation | 100.00 | 94.52 | 46.58 | 24.98 | 16.44 | 8.36 |
| NYSE MKT Composite | 100.00 | 123.99 | 127.59 | 148.86 | 129.94 | 145.53 |
| RDG MicroCap Biotechnology | 100.00 | 166.25 | 182.33 | 136.22 | 97.34 | 52.30 |

ITEM 6. SELECTED FINANCIAL DATA

The following selected historical consolidated financial data:

reflect a 1 for 25 reverse stock split which became effective on the NYSE American on June 15, 2017,

reflect the restatement to the Company's financial statements as further explained in Note 17, in the financial statements enclosed herein, and

are qualified by reference to, and should be read in conjunction with the consolidated financial statements and the related notes thereto, appearing elsewhere in this report, as well as Item 7 of this report.

| | (Restated) | | | | |
|---|---|---|---|---|---|
| Statements of Operations | 2016 | 2015 | 2014 | 2013 | 2012 |
| Grant revenue and other | $ 285,055 | $ 657,377 | $ 264,033 | $ 159,583 | $ 254,610 |
| Operating expenses: | | | | | |
| Research and development | 17,445,382 | 19,191,750 | 15,266,189 | 11,027,724 | 8,908,007 |
| General and administrative | 6,486,501 | 13,855,775 | 10,665,558 | 7,093,738 | 6,683,045 |
| Gain on derivative instruments | 14,013,726 | 282,616 | 248,767 | 10,750,666 | 1,911,683 |
| Loss on debt extinguishment | - | (620,457) | - | - | - |
| Interest income (expense), net | (1,879,390) | (1,964,221) | (1,933,732) | (1,932,272) | (2,017,719) |
| Net loss | (11,512,492) | (34,692,210) | (27,352,679) | (9,143,485) | (15,442,478) |
| Issuance of additional shares due to reset provision | | | (1,117,447) | - | (250,000) |
| Modification of warrants | | | | (59,531) | (325,620) |
| Inducement warrants | - | - | - | - | (1,593,000) |
| Net loss available to common shareholders | $ (11,512,492) | $ (34,692,210) | $ (28,470,126) | $ (9,203,016) | $ (17,611,098) |
| | | | | | |
| Net loss per common share | | | | | |
| Basic | $ (2.37) | $ (10.51) | $ (12.10) | $ (7.60) | $ (17.48) |
| Diluted | $ (2.37) | $ (10.51) | $ (12.21) | $ (16.47) | $ (19.38) |
| Weighted average common shares outstanding | | | | | |
| Basic and diluted | 4,866,204 | 3,300,761 | 2,352,185 | 1,211,178 | 1,007,346 |

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| Balance Sheets | 2016 | 2015 | 2014 | 2013 | 2012 |
|---|---|---|---|---|---|
| Working capital (deficit) | $ 1,446,053 | $ 1,639,920 | $ 7,952,002 | $ (1,632,087) | $ 4,877,670 |
| Total assets | $ 24,886,125 | $ 28,553,702 | $ 32,104,603 | $ 23,457,326 | $ 28,655,921 |
| Derivative instruments (a) | $ 8,394,934 | $ 13,686,587 | $ 5,505,246 | $ 433,024 | $ 6,983,690 |
| Total liabilities | $ 25,565,338 | $ 33,315,972 | $ 21,320,790 | $ 16,430,409 | $ 21,329,124 |
| Stockholders' (deficit) equity | $ (679,213) | $ (4,762,270) | $ 10,783,813 | $ 7,026,917 | $ 7,326,797 |

(a)
Included in total liabilities.

CEL-SCI's net loss available to common shareholders for each fiscal quarter during the two years ended September 30, 2016 were:

| | | Net income (loss) per share | |
|---|---|---|---|
| Quarter- (Restated) | Net income (loss) | Basic | Diluted |
| 12/31/15 | $2,332,734 | $0.53 | $0.53 |
| 3/31/16 | $(8,855,530) | $(1.87) | $(1.87) |
| 6/30/16 | $(3,861,606) | $(0.78) | $(0.78) |
| 9/30/16 | $(1,128,090) | $(0.21) | $(0.21) |
| 12/31/14 | $(7,846,983) | $(2.68) | $(3.42) |
| 3/31/2015 | $(12,559,695) | $(4.14) | $(4.14) |
| 6/30/2015 | $(4,413,593) | $(1.32) | $(1.62) |
| 9/30/2015 | $(9,871,939) | $(2.54) | $(2.54) |

Variances in quarterly gains and losses for the quarters presented are caused by the changes in the fair value of outstanding warrants accounted for as derivatives each quarter. These changes in the fair value of the warrants are recorded on the statements of operations.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion should be read in conjunction with the financial statements and the related notes thereto appearing elsewhere in this report.

CEL-SCI's lead investigational therapy, Multikine, is cleared for a Phase 3 clinical trial in advanced primary head and neck cancer. It has received a go-ahead by the U.S. FDA as well as twenty-three other countries.

On September 26, 2016, CEL-SCI received verbal notice from the FDA that the Phase 3 clinical trial in advanced primary head and neck cancer has been placed on clinical hold. Pursuant to this communication from FDA, patients currently receiving study treatments can continue to receive treatment, and patients already enrolled in the study will continue to be followed.

On October 21, 2016, CEL-SCI issued a press release stating the following: "following up on our press release issued on September 26, 2016, we have received the Partial Clinical Hold letter from the U.S. Food and Drug Administration (FDA). On November 21, 2016, CEL-SCI announced that it had submitted a response to FDA's Partial Clinical Hold letter referenced above.

CEL-SCI also owns and is developing a pre-clinical technology called LEAPS.

All of CEL-SCI's projects are under development. As a result, CEL-SCI cannot predict when it will be able to generate any revenue from the sale of any of its products.

Since inception, CEL-SCI has financed its operations through the issuance of equity securities, convertible notes, loans and certain research grants. CEL-SCI's expenses will likely exceed its revenues as it continues the development of Multikine and brings other drug candidates into clinical trials. Until such time as CEL-SCI becomes profitable, any or all of these financing vehicles or others may be utilized to assist CEL-SCI's capital requirements.

Correction of an Error

The historical financial information in this report have been restated. In November 2017, the Company discovered an error in the way it accounted for the operating lease for its manufacturing facility. In October 2008, the Company entered into a lease arrangement whereby the Company leased a building owned by a third party, but to which the owner made tenant-directed improvements. Upon commencement of the lease, the Company accounted for the arrangement as an operating lease under ASC 840, Accounting for Leases, whereby the total minimum lease payment obligations under the leases were recognized as monthly rent expense on a straight-line basis over the term of the lease. The cost of the tenant improvements incurred were capitalized as deferred rent and amortized over the 20-year lease term.

In November 2017, it was determined that because the terms of the original lease agreement required the Company to be responsible for possible cost overruns, if there were any, but of which there were none, the Company was deemed to be the owner of the leased building for accounting purposes only under ASC 840-40-55. In addition to the costs it incurred and capitalized for the tenant improvements, the Company should have reflected an asset on its balance sheet for the costs paid by the lessor to purchase the building and improve it, as well as a corresponding liability. Upon completion of the improvements, the Company did not meet the "sale-leaseback" criteria under ASC 840-40-25, Accounting for Leases, Sale-Leaseback Transactions due to the Company's significant continuing involvement with the facility which is considered to be other than a normal leaseback as defined in ASC 840-40-25 and therefore should have treated the lease as a financing obligation and the asset and corresponding liability should not be derecognized.

The correction to the historical financial statements to apply ASC 840-40-25 does not affect the total cash payments the Company has made or is obligated to make under the lease agreement, nor does it change the total expense to be recognized over the lease term. However, the timing and nature of expense is different under this treatment as compared to operating lease treatment. Specifically, the Company should have recognized depreciation, expense on the asset it is deemed to own and interest expense on the associated lease financing obligation, instead of rental expense.

The accompanying Management's Discussion and Analysis of Financial Condition and Results of Operations gives effect to the restatement adjustments made to the previously reported financial statements for the years ended September 30, 2016, 2015, and 2014. For additional information and a detailed discussion of the restatement, see Note 17 of the financial statements included in this Report.

Results of Operations

Fiscal 2016

During the year ended September 30, 2016, grant and other income decreased by approximately $372,000 compared to the year ended September 30, 2015. The decrease is primarily due to the timing of drug shipments to supply the Company’s partner in Taiwan and the grant income earned by the Company’s Small Business Innovation Research (SBIR) grant during fiscal year 2016 compared to fiscal year 2015.

During the year ended September 30, 2016, research and development expenses decreased by approximately $1.7 million compared to the year ended September 30, 2015. The Company is continuing the Phase 3 clinical trial subject to the partial clinical hold and research and development fluctuates based on the activity level of the clinical trial.

During the year ended September 30, 2016, general and administrative expenses decreased by approximately $7.4 million, compared to the year ended September 30, 2015. Major components of the decrease are 1) Lake Whillans Litigation Finance took over payment of legal fees which were about $4.4 million in fiscal year 2015 in the arbitrations against the former CRO that used to run the Company's Phase 3 trial, 2) a $2.8 million decrease in share-based employee compensation costs, which relates to the timing vesting for the incentive stock bonus plan and 3) other miscellaneous decreases netting to approximately $200,000.

During the years ended September 30, 2016 and 2015, CEL-SCI recorded a derivative gain of approximately $14.0 million and $283,000, respectively. This variation was the result of the change in fair value of the derivative liabilities during the period which was caused by fluctuations in the share price of CEL-SCI’s common stock.

Net interest income (expense) decreased approximately $85,000 during the year ended September 30, 2016 compared to the year ended September 30, 2015, primarily due to an approximate $124,000 reduction in interest expense on the related party loan, which was paid off in January 2016, offset by an approximate $35,000 increase in interest expense on the lease liability.

Fiscal 2015

During the year ended September 30, 2015, grant and other income increased by approximately $393,000 compared to the year ended September 30, 2014. The increase is primarily due to the timing of drug shipments to supply the Company’s partner in Taiwan and the grant income earned by the Company’s Small Business Innovation Research (SBIR) grant during fiscal year 2015 compared to fiscal year 2014.

During the year ended September 30, 2015, research and development expenses increased by approximately $3.9 million compared to the year ended September 30, 2014. CEL-SCI is continuing the Phase 3 clinical trial and research and development fluctuates based on the activity level of the clinical trial. In fiscal year 2015, CEL-SCI received clearance from seven new countries for the Phase 3 clinical trial, and enrolled 305 patients in fiscal year 2015 vs 142 in fiscal year 2014.

During the year ended September 30, 2015, general and administrative expenses increased by approximately $3.2 million, compared to the year ended September 30, 2014. This increase is primarily due to an increase of approximately $2.0 million of equity based compensation costs for restricted stock granted, increased legal fees of approximately $1.8 million relating to arbitration with the Company’s former CRO, as discussed in Item 3 above, and an increase of approximately $220,000 in fees for professional services. These increases were offset by a decrease of approximately $788,000 in employee compensation, primarily due to a decrease in the number of stock options issued and vested in 2015 compared to 2014.

During the years ended September 30, 2015 and 2014, CEL-SCI recorded a derivative gain of approximately $283,000 and $249,000, respectively. This variation was the result of the change in fair value of the derivative liabilities during the period which resulted from relative consistencies in the share price of CEL-SCI's common stock.

Interest expense increased by approximately $30,000 during the year ended September 30, 2015 compared to the year ended September 30, 2014, and consisted primarily of approximately $37,000 in increased interest expense on the lease liability, offset by a reduction of the interest on the loan from CEL-SCI's former president. Effective July 7, 2015, the interest rate on the related party loan was reduced from 15% to 9%. Additionally, the modifications of the loan from de Clara Trust were determined to be substantive, resulting in an extinguishment loss of approximately $620,000 during 2015.

Research and Development Expenses

During the five years ended September 30, 2016, CEL-SCI's research and development efforts involved Multikine and LEAPS. The table below shows the research and development expenses associated with each project during this five-year period.

| | (Restated) 2016 | 2015 | 2014 | 2013 | 2012 |
|---|---|---|---|---|---|
| MULTIKINE | $ 17,054,474 | $ 18,697,940 | $ 14,891,411 | $ 10,650,239 | $ 8,516,929 |
| LEAPS | 390,908 | 493,810 | 374,778 | 377,485 | 391,078 |
| TOTAL | $ 17,445,382 | $ 19,191,750 | $ 15,266,189 | $ 11,027,724 | $ 8,908,007 |

In January 2007, CEL-SCI received a "no objection" letter from the FDA indicating that it could proceed with Phase 3 trials with Multikine in head and neck cancer patients. CEL-SCI had previously received a "no objection" letter from the Canadian Biologics and Genetic Therapies Directorate which enabled CEL-SCI to begin its Phase 3 clinical trial in Canada. Subsequently, CEL-SCI received similar authorizations from twenty-three other regulators.

CEL-SCI's Phase 3 clinical trial began in December 2010 after the completion and validation of CEL-SCI's dedicated manufacturing facility.

As explained in Item 1 of this report, as of November 30, 2016, CEL-SCI was involved in pre-clinical studies with respect to its LEAPS technology. As with Multikine, CEL-SCI does not know what obstacles it will encounter in future pre-clinical and clinical studies involving its LEAPS technology. Consequently, CEL-SCI cannot predict with any certainty the funds required for future research and clinical trials and the timing of future research and development projects.

Clinical and other studies necessary to obtain regulatory approval of a new drug involve significant costs and require several years to complete. 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 CEL-SCI has received regulatory approvals for clinical trials. The inability of CEL-SCI to conduct clinical trials or research, whether due to a lack of capital or regulatory approval, will prevent CEL-SCI from completing the studies and research required to obtain regulatory approval for any products which CEL-SCI is developing. Without regulatory approval, CEL-SCI will be unable to sell any of its products.

On September 26, 2016, CEL-SCI received verbal notice from the FDA that the Phase 3 clinical trial in advanced primary head and neck cancer has been placed on clinical hold. Pursuant to this communication from FDA, patients currently receiving study treatments can continue to receive treatment, and patients already enrolled in the study will continue to be followed.

On October 21, 2016, CEL-SCI issued a press release stating the following: “following up on our press release issued on September 26, 2016, we have received the Partial Clinical Hold letter from the U.S. Food and Drug Administration (FDA). On November 21, 2016, CEL-SCI announced that it had submitted a response to FDA’s Partial Clinical Hold letter referenced above.

Liquidity and Capital Resources

CEL-SCI has had only limited revenues from operations since its inception in March 1983. CEL-SCI has relied upon capital generated from the public and private offerings of its common stock and convertible notes. In addition, CEL-SCI has utilized short-term loans to meet its capital requirements. Capital raised by CEL-SCI has been used to acquire an exclusive worldwide license to use, and later purchase, certain patented and unpatented proprietary technology and know-how relating to the human immunological defense system and for clinical trials. Capital has also been used for patent applications, debt repayment, research and development, administrative costs, and the construction of CEL-SCI’s laboratory facilities. CEL-SCI does not anticipate realizing significant revenues until it enters into licensing arrangements regarding its technology and know-how or until it receives regulatory approval to sell its products (which could take a number of years). As a result, CEL-SCI has been dependent upon the proceeds from the sale of its securities to meet all of its liquidity and capital requirements and anticipates having to do so in the future. During fiscal year 2016 and 2015, CEL-SCI raised net proceeds of approximately $21.4 million and $21.1 million, respectively, through the sale of stock.

CEL-SCI estimates the total cash cost of the Phase 3 clinical trial, with the exception of the parts that will be paid by its licensees, Teva Pharmaceuticals and Orient Europharma, to be approximately $12.1 million going forward.

In August 2007, CEL-SCI leased a building near Baltimore, Maryland. The building, which consists of approximately 73,000 square feet, has been remodeled in accordance with CEL-SCI’s specifications so that it can be used by CEL-SCI to manufacture Multikine for CEL-SCI’s Phase III clinical trials and sales of the drug if approved by the FDA. The lease expires on October 31, 2028, and required annual base rent payments of approximately $1.6 million during the twelve months ended September 30, 2016. See Item 2 of this report for more information concerning the terms of this lease.

In January 2014, CEL-SCI offered to the investors to extend the outstanding 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. In March 2014, 4,272 Series N Warrants were exercised. On October 28, 2014, the remaining Series N warrants were transferred to the de Clara Trust, of which the Company’s CEO, Geert Kersten, is the trustee and a beneficiary. On June 29, 2015, concurrently with the modification of the note payable held by the de Clara Trust, CEL-SCI extended the expiration date of the Series N warrants to August 18, 2017. As of September 30, 2016, the remaining 113,785 Series N warrants entitle the holders to purchase one share of CEL-SCI's common stock at a price of $13.18 per share at any time prior to August 18, 2017.

On January 13, 2016, CEL-SCI repaid the note payable to the de Clara Trust, the balance of which was $1,105,989, including principal and interest. At the same time the Company sold 120,000 shares of its common stock and 120,000 Series X warrants to the de Clara Trust for $1,110,000. Each warrant allows the de Clara Trust to purchase one share of the Company's common stock at a price of $9.25 per share at any time on or before January 13, 2021.

In October 2013, CEL-SCI sold 713,043 shares of its common stock, plus 819,000 Series S warrants, in an underwritten offering. The net proceeds to CEL-SCI from the sale of the shares and warrants were approximately $16.4 million, after deducting the underwriting discount. The Series S warrants may be exercised at any time on or before October 11, 2018 at a price of $31.25 per share.

In December 2013, CEL-SCI sold 209,524 shares of its common stock and Series S warrants, in an underwritten offering. The net proceeds to CEL-SCI from the sale of the shares and Series S warrants were approximately $2.7 million, after deducting the underwriting discount. The Series S warrants may be exercised at any time on or before October 11, 2018 at a price of $31.25 per share.

In February 2014, the S warrants began trading on the NYSE MKT under the ticker symbol “CVM WS”. As of September 30, 2016, 83,551 Series S Warrants had been exercised. The remaining 1,037,120 Series S warrants entitle the holders to purchase one share of CEL-SCI's common stock at a price of $31.25 per share.

In April 2014, CEL-SCI sold 285,129 shares of common stock, plus 71,282 Series T warrants, in an underwritten offering. The net proceeds to CEL-SCI from the sale of the stock and warrants were approximately $9.23 million. The Series T warrants had an exercise price of $39.50 and expired on October 17, 2014. CEL-SCI also issued 17,821 Series U warrants to the underwriters for this offering. The Series U warrants may be exercised beginning October 17, 2014 at a price of $43.75 per share and expire on October 17, 2017. As of September 30, 2016, none of the Series U warrants had been exercised.

In October 2014, CEL-SCI sold 315,789 shares of common stock, plus 78,947 Series S warrants in an underwritten public offering. The net proceeds to CEL-SCI from the sale of the stock and warrants were approximately $5.5 million. The warrants are immediately exercisable, expire October 11, 2018 and have an exercise price of $31.25.

Additionally, in October 2014, CEL-SCI sold 52,800 shares of common stock, plus 13,200 Series S warrants in a registered direct offering. The net proceeds to CEL-SCI from the sale of the stock and warrants were approximately $941,000. The warrants are immediately exercisable, expire October 11, 2018 and have an exercise price of $31.25.

On May 28, 2015, CEL-SCI sold 810,127 shares of common stock, plus 810,127 Series V warrants, in an underwritten public offering. The common stock and Series V warrants were sold at a combined per unit price of $19.75 for net proceeds of approximately $14.7 million. The Series V warrants are immediately exercisable at a price of $19.75 and expire on May 28, 2020. As of September 30, 2016, none of the Series V warrants had been exercised.

On October 28, 2015, the Company closed an underwritten public offering of 688,930 shares of common stock and 688,930 Series W warrants to purchase shares of common stock. The common stock and warrants were sold at a combined per unit price of $16.75 for net proceeds of approximately $10.5 million, net of underwriting discounts and commissions and offering expenses. The Series W warrants are immediately exercisable at a price of $16.75 and expire on October 28, 2020. As of September 30, 2016, none of the Series W warrants had been exercised.

In January 2016, the Company sold 120,000 shares of its common stock and 120,000 Series X warrants to the de Clara Trust for approximately $1.1 million, as noted above. The de Clara Trust is controlled by Geert Kersten, the Company's Chief Executive Officer and a director. Each Series X warrant allows the de Clara Trust to purchase one share of the Company's common stock at a price of $9.25 per share at any time on or before January 13, 2021. As of September 30, 2016, none of the Series X warrants had been exercised.

In February 2016, the Company sold 52,000 shares of its common stock and 26,000 Series Y warrants to a private investor for $624,000. Each Series Y warrant allows the holder to purchase one share of the Company's common stock at a price of $12.00 per share at any time on or before February 15, 2021. As of September 30, 2016, none of the Series Y warrants had been exercised.

On May 23, 2016, the Company closed a registered direct offering of 400,000 shares of common stock and 264,000 Series Z warrants to purchase shares of common stock. The common stock and warrants were sold at a combined per unit price of $12.50 for net proceeds of approximately $4.6 million, net of placement agent’s commissions and offering expenses. The Series Z warrants may be exercised at any time on or after November 23, 2016 and on or before November 23, 2021 at a price of $13.75 per share. The Company also issued 20,000 Series ZZ warrants to the placement agent as part of its compensation. The Series ZZ warrants may be exercised at any time on or after November 23, 2016 and on or before May 18, 2021 at a price of $13.75 per share. As of September 30, 2016, none of the Series Z and ZZ warrants had been exercised.

On August 26, 2016, the Company closed a registered direct offering of 400,000 shares of common stock and Series AA warrants to purchase up to 40,000 shares of common stock. Each share of common stock was sold together with a Series AA warrant to purchase one-half of a share of common stock for the combined purchase price of $12.50. Each warrant can be exercised at any time after February 22, 2017 and on or before February 22, 2022 at a price of $13.75 per share. The Company also issued 16,000 Series BB warrants to the placement agent as part of its compensation. The Series BB warrants may be exercised at any time on or after February 22, 2017 and on or before August 22, 2021 at a price of $13.75 per share. The Company received proceeds from the sale of Series AA and Series BB shares and warrants of approximately $4.5 million, net of placement agent’s commissions and offering expenses. As of September 30, 2016, none of the Series AA and BB warrants had been exercised.

On December 8, 2016, the Company sold 1,360,960 shares of common stock and warrants to purchase common stock at a price of $3.13 in a public offering. The warrants consist of 680,480 Series CC warrants to purchase 680,480 shares of common stock, 1,360,960 Series DD warrants to purchase 1,360,960 shares of common stock and 1,360,960 Series EE warrants to purchase 1,360,960 shares of common stock. The Series CC warrants are immediately exercisable, expire in five-years and have an exercise price of $5.00 per share. The Series DD warrants are immediately exercisable, expire in six-months and have an exercise price of $4.50 per share. The Series EE warrants are immediately exercisable, expire in nine-months and have an exercise price of $4.50 per share. In addition, the Company issued 68,048 Series FF warrants to purchase 68,048 shares of common stock to the placement agent. The FF warrants are exercisable at any time on or after June 8, 2017 and expire on December 1, 2021 and have an exercise price $3.91. The net proceeds to CEL-SCI from this offering was approximately $3.8 million, excluding any future proceeds that may be received from the exercise of the warrants.

Inventory decreased by approximately $393,000 at September 30, 2016 as compared to September 30, 2015, due to the timing of supplies purchased and used in the manufacturing of Multikine for the Phase 3 clinical trial. In addition, receivables increased by approximately $307,000, primarily due to the timing of payments reimbursed under the litigation funding arrangement noted above.

During the year ended September 30, 2016, CEL-SCI's cash decreased by approximately $2.8 million. Significant components of this decrease include: 1) net cash used in operating activities of approximately $23.1 million, 2) expenditures for equipment and patents of approximately $34,000, 3) the approximate $1.1 million repayment of the related party loan, and 4) the payment of approximately $8,000 in capital lease obligations offset by approximately $21.4 in proceeds from the sale of stock and warrants.

Future Capital Requirements

Other than funding operating losses, funding its research and development program, and making required lease payments, CEL-SCI does not have any material capital commitments. As of September 30, 2016, material contractual obligations, consisting of operating lease payments, excluding payments under the San Tomas lease, are as follows:

| | |
|---|---|
| 2017 | $ 243,000 |
| 2018 | 251,000 |
| 2019 | 258,000 |
| 2020 | 238,000 |
| 2021 | 163,000 |
| Thereafter | 69,000 |
| Total minimum lease payments: | $ 1,222,000 |

Future minimum lease payments under the San Tomas lease as of September 30, 2016 are as follows:

| | |
|---|---|
| Years ending September 30, | |
| 2017 | $ 1,687,000 |
| 2018 | 1,747,000 |
| 2019 | 1,808,000 |
| 2020 | 1,872,000 |
| 2021 | 1,937,000 |
| Thereafter | 15,762,000 |
| Total future minimum lease obligation | 24,813,000 |
| Less imputed interest on financing obligation | (11,802,000) |
| Net present value of lease financing obligation | $ 13,011,000 |

For information on employment contracts, see Item 11 of this report.

Further, CEL-SCI has contingent obligations with vendors for work that will be completed in relation to the Phase 3 trial. The timing of these obligations cannot be determined at this time. CEL-SCI estimates that the total remaining cash cost of the Phase 3 clinical trial, excluding any costs that will be paid by CEL-SCI's partners, would be approximately $12.1 million after September 30, 2016. This ís based on the executed contract costs with the CROs only and does not include other related costs, e.g. the manufacturing of the drug.

CEL-SCI will need to raise additional funds, either through the exercise of outstanding warrants/options, through a debt or equity financing or a partnering arrangement, to complete the Phase 3 trial and bring Multikine to market. The ability of CEL-SCI to complete the necessary clinical trials and obtain FDA approval for the sale of products to be developed on a commercial basis is uncertain. In general, CEL-SCI believes that it will be able to raise sufficient capital in fiscal year 2017 to continue operations through December 2017. However, it is possible that CEL-SCI will not be able to generate enough cash to continue operations at its current level. CEL-SCI's registered independent public accounting firm has issued an audit opinion that includes an explanatory paragraph that expresses substantial doubt about CEL-SCI's ability to continue as a going concern mainly due to continued losses from operations and

future liquidity needs of CEL-SCI. CEL-SCI's management has engaged in fundraising for over 20 years and believes that the manner in which it is proceeding will produce the best possible outcome for the shareholders. There can be no assurances that CEL-SCI will be successful in raising additional funds.

Clinical and other studies necessary to obtain regulatory approval of a new drug involve significant costs and require several years to complete. 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 CEL-SCI has received regulatory approvals for clinical trials. The inability of CEL-SCI to conduct clinical trials or research, whether due to a lack of capital or regulatory approval, will prevent CEL-SCI from completing the studies and research required to obtain regulatory approval for any products which CEL-SCI is developing. Without regulatory approval, CEL-SCI will be unable to sell any of its products.

In the absence of revenues, CEL-SCI will be required to raise additional funds through the sale of securities, debt financing or other arrangements in order to continue with its research efforts. However, there can be no assurance that such financing will be available or be available on favorable terms. Ultimately, CEL-SCI must complete the development of its products, obtain appropriate regulatory approvals and obtain sufficient revenues to support its cost structure.

Since all of CEL-SCI’s projects are under development, CEL-SCI cannot predict with any certainty the funds required for future research and clinical trials, the timing of future research and development projects, or when it will be able to generate any revenue from the sale of any of its products.

CEL-SCI's cash flow and earnings are subject to fluctuations due to changes in interest rates on its bank accounts, and, to an immaterial extent, foreign currency exchange rates.

Critical Accounting Policies

CEL-SCI's significant accounting policies are more fully described in Note 1 to the financial statements included as part of this report. However, certain accounting policies are particularly important to the portrayal of CEL-SCI’s financial position and results of operations and require the application of significant judgments by management. As a result, the financial statements are subject to an inherent degree of uncertainty. In applying those policies, management uses its judgment to determine the appropriate assumptions to be used in the determination of certain estimates. These estimates are based on CEL-SCI's historical experience, terms of existing contracts, observance of trends in the industry and information available from outside sources, as appropriate. CEL-SCI’s significant accounting policies include:

Stock Options and Warrants – Compensation cost is measured at fair value as of the grant date in accordance with the provisions of ASC 718. The fair value of the stock options is calculated using the Black-Scholes option pricing model. The Black-Scholes model requires various judgmental assumptions including volatility, forfeiture rates and expected option life. The stock-based compensation cost is recognized on the accelerated method as expense over the requisite service or vesting period.

Options to non-employees are accounted for in accordance with ASC 505-50, “Equity-Based Payments to Non-Employees.” Accordingly, compensation cost is recognized when goods or services are received and is measured using the Black-Scholes valuation model. The Black-Scholes model requires CEL-SCI’s management to make assumptions regarding the fair value of the options at the date of grant and the expected life of the options.

Asset Valuations and Review for Potential Impairments - CEL-SCI reviews its fixed assets, intangibles and deferred rent every fiscal quarter. This review requires that CEL-SCI make assumptions regarding the value of these assets and the changes in circumstances that would affect the carrying value of these assets. If such analysis indicates that a possible impairment may exist, CEL-SCI is then required to estimate the fair value of the asset and, as deemed appropriate, expense all or a portion of the asset. The determination of fair value includes numerous uncertainties, such as the impact of competition on future value. CEL-SCI believes that it has made reasonable estimates and judgments in determining whether its long-lived assets have been impaired; however, if there is a material change in the assumptions used in its determination of fair values or if there is a material change in economic conditions or circumstances influencing fair value, CEL-SCI could be required to recognize certain impairment charges in the future. As a result of the reviews, no changes in asset values were required.

Derivative Instruments—CEL-SCI enters into financing arrangements that consist of freestanding derivative instruments or hybrid instruments that contain embedded derivative features. CEL-SCI accounts for these arrangements in accordance with ASC 815, “Accounting for Derivative Instruments and Hedging Activities, as well as related interpretations of these standards. In accordance with accounting principles generally accepted in the United States (“GAAP”), derivative instruments and hybrid instruments are recognized as either assets or liabilities in the statement of financial position and are measured at fair value with gains or losses recognized in earnings or other comprehensive income depending on the nature of the derivative or hybrid instruments. Embedded derivatives that are not clearly and closely related to the host contract are bifurcated and recognized at fair value with changes in fair value recognized as either a gain or loss in earnings if they can be reliably measured. When the fair value of embedded derivative features cannot be reliably measured, CEL-SCI measures and reports the entire hybrid instrument at fair value with changes in fair value recognized as either a gain or loss in earnings. CEL-SCI determines the fair value of derivative instruments and hybrid instruments based on available market data using appropriate valuation models, giving consideration to all of the rights and obligations of each instrument and precluding the use of “blockage” discounts or premiums in determining the fair value of a large block of financial instruments. Fair value under these conditions does not necessarily represent fair value determined using valuation standards that give consideration to blockage discounts and other factors that may be considered by market participants in establishing fair value.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISKS

Market risk is the potential change in an instrument's value caused by, for example, fluctuations in interest and currency exchange rates. CEL-SCI enters into financing arrangements that are, or include, freestanding derivative instruments or that are, or include, hybrid instruments that contain embedded derivative features. CEL-SCI does not enter into derivative instruments for trading purposes. Additional information is presented in the notes to the financial statements. The fair value of these instruments is affected primarily by volatility of the trading prices of CEL-SCI’s common stock. For three years ended September 30, 2016, CEL-SCI recognized gains of $14,013,726, $282,616, and $248,767, respectively, resulting from changes in fair value of derivative instruments. CEL-SCI has exposure to risks associated with foreign exchange rate changes because some of the expenses related to the Phase 3 trial are transacted in a foreign currency. The interest risk on investments on September 30, 2016 was considered immaterial due to the fact that the interest rates at that time were nominal at best and CEL-SCI keeps its cash and cash equivalents in short term maturities.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

See the financial statements included with this report.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

Not applicable

ITEM 9A. CONTROLS AND PROCEDURES

Under the direction and with the participation of CEL-SCI’s management, including CEL-SCI’s Chief Executive Officer and Chief Financial Officer, CEL-SCI carried out an evaluation of the effectiveness of the design and operation of its disclosure controls and procedures as of September 30, 2016. CEL-SCI maintains disclosure controls and procedures that are designed to ensure that information required to be disclosed in its periodic reports with the Securities and Exchange Commission is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and regulations, and that such information is accumulated and communicated to CEL-SCI’s management, including its principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure. CEL-SCI’s disclosure controls and procedures are designed to provide a reasonable level of assurance of reaching its desired disclosure control objectives. Previously based on this evaluation, CEL-SCI’s Chief Executive and Principal Financial Officer has concluded that CEL-SCI’s disclosure controls were effective as of September 30, 2016. However, due to the material weaknesses in internal control over financial reporting described below, CEl-SCI's Chief Executive Officer and Principal Financial Officer concluded that CEL-SCI's disclosure controls and procedures were not effective as of September 30, 2016.

Management’s Report on Internal Control Over Financial Reporting

CEL-SCI’s management is responsible for establishing and maintaining adequate internal control over financial reporting and for the assessment of the effectiveness of internal control over financial reporting. As defined by the Securities and Exchange Commission, internal control over financial reporting is a process designed by, or under the supervision of CEL-SCI’s principal executive officer and principal financial officer and implemented by CEL-SCI’s Board of Directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of CEL-SCI’s financial statements in accordance with U.S. generally accepted accounting principles.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Geert Kersten, CEL-SCI’s Chief Executive and Principal Financial Officer, evaluated the effectiveness of CEL-SCI’s internal control over financial reporting as of September 30, 2016 based on criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission, or the COSO Framework. Management’s assessment included an evaluation of the design of CEL-SCI’s internal control over financial reporting and testing of the operational effectiveness of those controls.

In November 2017, CEL-SCI discovered an error in the way it accounted for the lease for its manufacturing facility. CEL-SCI initially recorded this lease as an operating lease but later identified that it should have accounted for it as a financing lease and capitalized an asset and related liability. Accordingly, on November 17, 2017, the Audit Committee of the Board of Directors of the Company concluded that CEL-SCI's Management's Report on Internal Control over Financial Reporting and the related Report of independent Registered Public Accounting Firm on internal control over financial reporting included in CEL-SCI's annual Report on Form 10-K for the fiscal year ended September 30, 2016 should no longer be relied upon. Based on this evaluation, Mr. Kersten concluded that CEL-SCI's internal control over financial reporting was not effective as of September 30, 2016.

Management has concluded that the correction of the error for this lease, the lack of impairment assessment for the related asset, and the operating effectiveness of the financial close process are control deficiencies that constitute material weaknesses. In order to remediate these material weaknesses, the Company will change certain control activities over financial reporting to include the following:

All facility leasing activities will be subject to a thorough review of capital versus operating lease classification. Further, leases that include construction activity prior to lease inception will be reviewed against the build-to-suit lease guidance in ASC 840. In addition, the Company will also engage outside financial reporting specialists to assist it in the review process.

The Company will enhance its policy for reviewing long-lived assets for impairments by incorporating additional triggering event factors for consideration as part of its control. This review will be carried out by the Company and also be assisted by an outside financial reporting specialist.

The financial reporting process will be enhanced to include the use of monthly, quarterly and annual closing checklists to capture routine and non-routine transactions that require additional review. Further, the Company will also augment its control process by expanding the use of a financial reporting specialist to assist in the financial close process.

There was no change in CEL-SCI's internal control over financial reporting that occurred during the fiscal year ended September 30, 2016 that has materially affected, or is reasonably likely to materially affect, CEL-SCI's internal control over financial reporting.

CEL-SCI's independent registered public accounting firm BDO USA, LLP has issued an attestation report on CEL-SCI's internal control over financial reporting.

Report of Independent Registered Public Accounting Firm

Board of Directors and Stockholders
CEL-SCI Corporation
Vienna, VA

We have audited CEL-SCI Corporation's (the Company) internal control over financial reporting as of September 30, 2016, based on criteria established in Internal Control – Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying "Item 9A, Management's Report on Internal Control Over Financial Reporting". Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.