

CEL-SCI Corporation (CVM - \$ 0.28)

Initiating Coverage with BUY Rating

We are initiating coverage on CEL-SCI with a BUY rating and a 12-month price target of \$0.75. We believe that Multikine, the company's lead product, has blockbuster potential. Multikine, a defined mixture of 14 cytokines, is in Phase III development for the treatment of head and neck cancer.

- Initiating Coverage With a BUY Rating.** Our 12-month price target for CEL-SCI is \$0.75, which is based on the NPV of our probability-adjusted forecasts for Multikine and a small value for the company's manufacturing plant. We have assigned no value to the LEAPS program due to its preclinical status. Any success in the LEAPS platform could lead to potential upside to our price target. We note that this recommendation is speculative in nature due to the company's current stock price (under \$1.00 per share) and our opinion that the large majority of the value of the stock is hinged on a binary event, the approval of Multikine for the treatment of head and neck cancer.
- Multikine has Blockbuster Potential.** Multikine is in Phase III for the treatment of head and neck cancer. Worldwide there are an estimated 600,000 new cases of head and neck cancer diagnosed each year, which represents about 5% - 6% of all newly diagnosed cancers. There are about 40,000 new cases in the U.S. and 100,000 new cases in Europe diagnosed annually. If the drug can penetrate 25% of the market in the U.S. and Europe at its peak that would be 35,000 treatments per year. We have assumed a price of \$50,000 per course of therapy. This would imply peak sales potential of \$1.75 billion.
- Positive Phase III Data Expected.** The Multikine Phase III trial is an event-driven, open-label, randomized, controlled, multi-center head and neck cancer study with a median three-year follow-up. The primary endpoint is 10% improvement in overall survival (OS). A Phase II study had an OS of 63.2% at 3.5 years from surgery. Current literature suggests an approximate survival rate of 47.5% at 3.5 years with current SOC. HPV-positive patients have higher levels of survival and the literature number contained both HPV-positive and negative patients while the patients in the Phase II trial were primarily HPV-negative. Thus the 33% of OS improvement in Phase II was more remarkable, in our opinion, due to the patient population. The Phase III trial is comprised primarily of HPV-negative patients. If approved, we expect Multikine could reach the market in the 2018 – 2020 timeframe.

Earnings Estimates: (per share)

(Sept.)	1Q	2Q	3Q	4Q	FY	P/E
FY_14E	NA	NA	NA	NA	-0.05	NA
FY_13E	-0.02	-0.02	-0.01	-0.01	-0.06	NA
FY_12A	-0.02	-0.04	0.00	-0.01	-0.07	NA
FY_11A	-0.03	-0.07	-0.01	-0.01	-0.13	NA

Source: Laidlaw & Company estimates

Healthcare / Biotechnology

Ticker:	CVM
Rating:	Buy
Price Target:	\$ 0.75

Trading Data:

Last Price (01/14/2013)	\$ 0.28
52-Week High (3/22/2012)	\$ 0.65
52-Week Low (12/31/2012)	\$ 0.26
Market Cap. (MM)	\$ 77
Shares Out. (MM)	273

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Investment Conclusions

Our 12-month price target of \$0.75 is based on the NPV of our probability-adjusted forecasts for Multikine and a small value for the company's manufacturing facility

Our risk-adjusted total sales estimate for Multikine is \$456 million in 2023

Phase II data were encouraging as patients had an overall response rate of 42% and overall survival of 63.2% at 3.5 years from surgery.

- **Initiating Coverage with a Buy Rating.** CEL-SCI's lead product is Multikine, which is in Phase III for the treatment of head and neck cancer. We believe that Multikine has substantial blockbuster potential, which is currently undervalued by the market. The peak market potential for Multikine in head and neck cancer is approximately \$1.75 billion, in our opinion. Our 12-month price target for CEL-SCI is \$0.75, which is based on the NPV of our probability-adjusted forecasts for Multikine and a small value for the company's manufacturing plant. We have assigned no value to the LEAPS program due to its preclinical status. Any success in the LEAPS platform could lead to potential upside to our price target. We are initiating coverage on CEL-SCI with a BUY rating and note that this recommendation is speculative in nature due to the company's current stock price (under \$1.00 per share) and our opinion that the large majority of the value of the stock is hinged on a binary event, the approval of Multikine for the treatment of head and neck cancer.
- **Multikine Has Blockbuster Potential, In Our Opinion.** We believe the peak market potential for Multikine in head and neck cancer is approximately \$1.75 billion. Head and neck cancer is the sixth most frequently occurring cancer worldwide and the disease accounts for about 2% of all cancer deaths annually. The disease is difficult to treat and can be debilitating and disfiguring. Worldwide there are an estimated 600,000 new cases of head and neck cancer diagnosed each year, which represents about 5% - 6% of all newly diagnosed cancers. About two-thirds of these cases occur in developing countries. The American Cancer Society estimated that in 2012 there were 40,250 new cases of head and neck cancer in the U.S. and 7,850 estimated deaths from the disease. In the European Union about 100,000 people are diagnosed with head and neck cancer every year and about 40,000 die from the disease. If the drug can penetrate 25% of the market in the U.S. and Europe at its peak that would imply 35,000 treatments per year. We have assumed a price of \$50,000 per course of therapy. Our risk-adjusted mean (the mean of our best and worst case expectations) projections for total sales of Multikine are \$15 million in 2018 growing to \$456 million by 2023.
- **We Expect Positive Phase III Data.** Phase II data were encouraging as patients had an overall response rate of 42% and overall survival of 63.2% at 3.5 years from surgery. Current literature suggests an approximate survival rate of 47.5% at 3.5 years with current standard of care (SOC). Patients with HPV have less invasive head and neck cancer. HPV is closely correlated with expression of p16. In a study published in the Journal of Clinical Oncology, tumor-positivity for p16 was significantly correlated with improved locoregional tumor control

Current literature suggests an approximate survival rate of 47.5% at 3.5 years with current standard of care (SOC).

versus p16 negative tumors (5-year actuarial values 58% versus 28%; $P = .0005$), improved disease-specific survival (72% versus 34%; $P = .0006$) and improved overall survival (62% versus 26%; $P = .0003$). Thus, the expression of p16 has a major impact on treatment response and survival in patients with head and neck cancer. CEL-SCI compared its Phase II overall survival results to that of studies published in the literature that contained both HPV-positive and HPV-negative patients while the Multikine study had a largely HPV-negative population. This implies that the overall survival finding in the Phase II Multikine study has an even greater importance. We believe that if the overall survival data from Multikine's Phase II trial was compared with an only HPV-negative population in the literature, Multikine would have shown an improvement even greater than the 33% improvement that was observed. The Multikine Phase III trial is an event-driven study with a median three-year follow-up. The primary endpoint is 10% improvement in overall survival (80% power, 95% confidence) in the Multikine treatment arm plus the current SOC, over that which can be achieved in the SOC arm alone. Due to the anatomy of patients in the study, the Phase III study is expected to have 84% - 97% of its patients HPV-negative. As the primary endpoint of the study is 10% improvement in overall survival and the Phase II study showed a 33% improvement in overall survival versus a mixed HPV population (HPV-positive and negative) in literature and the Phase III study should be overwhelmingly composed of HPV-negative patients, we have confidence that the Phase III Multikine trial will meet its primary endpoint.

With over 220 patients treated so far, no serious adverse events were reported by the clinical investigators as being expressly due to administration of Multikine

- No Safety Issues So Far.** In Phase I and Phase II clinical trials, a total of over 220 patients received Multikine in daily doses of 200 – 3,200 IU as IL-2 (over 2-3 weeks in Phase II and up to a few months in early Phase I). No serious adverse events were reported by the clinical investigators as being expressly due to administration of Multikine. Adverse events that were reported included pain at the injection site, local minor bleeding and edema at the injection site, diarrhea, headache, nausea, and constipation. No abnormal laboratory results were reported following Multikine treatment - other than those commonly seen by treating physicians in this patient population regardless of Multikine administration. Similarly, in these early-phase clinical studies in patients, there were no reported increased toxicity of follow-on treatments as a result of Multikine administration. No complications following surgery (such as increased time for wound healing) were reported. In the recent interim review of the safety data from the Phase III study, an Independent Data Monitoring Committee (IDMC) raised no safety concerns. The IDMC also indicated that no safety signals were found that would call into question the benefit/risk of continuing the study. The members of the IDMC are all key opinion leaders in cancer from the U.S., Europe and Asia. The results of the IDMC review are important since studies have shown that up to 30% of Phase III trials fail due to safety considerations and the IDMC's safety findings from this interim review were similar to those reported by investigators during CEL-SCI's Phase I and II trials.
- Dedicated Manufacturing Facilities Reduce Risk, In Our Opinion.** Before starting the Phase III trial, CEL-SCI's management determined

CEL-SCI's facility can manufacture about 20,000 courses of treatment annually

that it needed to build a dedicated manufacturing facility to produce Multikine. This facility has been completed and validated, and has produced several clinical lots that have been used for the Phase III clinical trial. CEL-SCI produces Multikine from white blood cells it sources from the American Red Cross. Currently, CEL-SCI's facility can manufacture about 20,000 courses of treatment annually (a course of treatment is 15 vials). The plant can be increased to three times its current size at its current location, building out its annual capacity to about 60,000 treatments annually from the current facility. CEL-SCI completed validation of its new manufacturing facility in January 2010. Its manufacturing and laboratory operations were deemed compliant with GMP requirements following an audit by European Union Qualified Person for Pharmacovigilance in the fall of 2010. With its huge potential sources for raw material (WBC) and its ability to seamlessly increase its manufacturing capacity at its current facility, we believe manufacturing risk for CEL-SCI is lower than at most of its similarly sized peers that contract out manufacturing.

Cash burn of approximately \$1.1 million per month

- **CEL-SCI May Have To Raise Funds.** CEL-SCI estimates the total cost of the Phase III trial, with the exception of the parts that will be paid by its licensees, to be approximately \$32 million of which approximately \$7 million has been paid as of September 30, 2012. The company's cash burn is about \$1.1 million per month. At the end of its Fiscal Year 2012, CEL-SCI had cash and equivalents of \$3.9 million. We estimate CEL-SCI realized about \$9.8 million from its December offering. We project that after its December 2012 stock offering, CEL-SCI has cash on its balance sheet of about \$13.7 million. With a cash burn of approximately \$1.1 million per month, we would expect CEL-SCI to announce another stock offering in late 2013. In calculating our price target, we have assumed two stock offerings similar to the one in December 2012 to occur before Multikine is submitted for regulatory approval. Despite potentially revisiting the capital markets, we believe CEL-SCI's stock could trade up to \$0.75 in the next 12 months.

Company Description

CEL-SCI's lead investigational therapy is Multikine, currently in a pivotal Phase III clinical trial for head and neck cancer

Multikine is a defined mixture of 14 cytokines

Phase I and Phase II clinical trials suggest that Multikine simulates the activities of a healthy person's immune system

CEL-SCI Corporation is a small cap biotech company focused on developing drugs that utilize the immune system to improve cancer treatment and infectious disease. Its lead investigational therapy is Multikine (Leukocyte Interleukin, Injection), currently in a pivotal Phase III clinical trial. CEL-SCI is also developing its LEAPS technology platform as an immunotherapy for possible treatment for H1N1 hospitalized patients (LEAPS-H1N1-DC) and as a vaccine (CEL-2000) for Rheumatoid Arthritis (currently in preclinical testing). The immunotherapy LEAPS-H1N1-DC treatment involves non-changing regions of H1N1 Pandemic Flu, Avian Flu (H5N1), and the Spanish Flu. Most of the company's resources are dedicated to the development of Multikine. This is the area of the company that we believe investors should focus. CEL-SCI has operations in Vienna, Virginia, and in and near Baltimore, Maryland. The company was formed as a Colorado corporation in 1983.

CEL-SCI's lead pipeline drug, Multikine, is currently being developed as a potential therapeutic agent for the treatment of head and neck cancer. It uses the immune system to produce an anti-tumor immune response. Multikine is a defined mixture of 14 cytokines. It is a combination immunotherapy, possessing both active and passive properties. Immunotherapy is one of the more recent approaches to cancer therapy. It is based on the generally-accepted hypothesis that the immune system is the best tool humans have for fighting disease. Immunotherapies have the potential to be used to fight cancer by either applying an external stimulus to the immune system to make it have a stronger response, or by providing the immune system with man-made or naturally-derived tumor specific proteins made outside of the body so that the immune system can recognize the tumor as foreign and destroy it. Immunotherapy is sometimes used by itself to treat cancer, but it is most often used in combination with traditional treatments like radiation, chemotherapy, and surgery in order to enhance their effects. One of the possible benefits of immunotherapy is that it has the potential not to be as toxic as radiation, chemotherapy, and surgery. It also may offer a different mode of attack on the tumor.

Data from Phase I and Phase II clinical trials suggest that Multikine simulates the activities of a healthy person's immune system, enabling it to use the body's own anti-tumor immune response. To achieve a meaningful immunotherapeutic effect when treating cancer, immunotherapy should be used early in the treatment of the disease. It should be used before any potential adverse effect on the immune system that might be caused by radiation, chemotherapy and surgery, and before the cancer has possibly become tolerated by the affected individual's immune system. In Phase I and Phase II clinical trials, and in the ongoing Phase III clinical trial, Multikine is administered prior to any other cancer therapy because CEL-SCI believes that this is the period when there is a greater potential of activating an anti-tumor immune response. Once the patient has had surgery or has received radiation with or without chemotherapy, the immune system may be weakened and may be less able to mount an anti-tumor immune response. Multikine is injected around the tumor and in the vicinity of

the draining local lymph nodes because these are the areas in which metastases are believed to be most likely develop and where the cancer may recur in most cancer patients with this disease.

Multikine is protected in the U.S. under a composition of matter and method of use patent that was issued on May 24, 2005 and expires in 2024

Multikine is protected under U.S. patent 6896879, a composition of matter and method of use patent that was issued on May 24, 2005 and expires in 2024. Multikine has similar patent coverage in Europe, China and Japan. Much of CEL-SCI's intellectual property pertains to its manufacturing system, certain aspects of which may not be suitable for patent filing and must be protected as a trade secret. CEL-SCI has a number of new patent applications pending.

Head and neck cancer refers to a group of biologically similar cancers that start in the lip, oral cavity (mouth), paranasal sinuses, pharynx, and larynx. About 90% of head and neck cancers are squamous cell carcinomas (SCCHN), originating from the mucosal lining (epithelium) of these regions. Head and neck cancers often spread to the lymph nodes of the neck, and this is often the first (and sometimes only) sign of the disease at the time of diagnosis. Head and neck cancer is strongly associated with certain environmental and lifestyle risk factors, including tobacco smoking, alcohol consumption, UV light, particular chemicals used in certain workplaces, and certain strains of viruses, such as human papillomavirus (HPV). HPV causes cancers located in certain areas of the head and neck and is usually associated with less aggressive cancer. Recent increases in incidence and survival of head and neck cancers in the U.S. have been attributed to HPV infection as HPV status is a strong and independent prognostic factor for survival among patients with head and neck cancer. This is important for reasons we will discuss later in this report.

The American Cancer Society estimated that in 2012 there were 40,250 new cases of head and neck cancer in the U.S. and 7,850 estimated deaths from the disease

Head and neck cancers are frequently aggressive in their biologic behavior; patients with these types of cancer are at a higher risk of developing another cancer in the head and neck area. The American Cancer Society estimated that in 2012 there were 40,250 new cases of head and neck cancer in the U.S. and 7,850 estimated deaths from the disease. In the European Union about 100,000 people are diagnosed with head and neck cancer every year and about 40,000 die from the disease (a 2010 study by Jean Lacau St. Guily published in *Head & Neck Oncology* stated that there were 143,000 new cases of head and neck cancer diagnosed in Europe in 2007 responsible for more than 68,000 deaths, but we use the more often cited number of 100,000 new cases in our European forecasts). Advanced primary (not yet treated) head and neck cancer represents an unmet medical need. About 50% of the patients with head and neck cancer die within three years following treatment. The current standard of care (SOC) for head and neck cancer as defined by the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology is surgery followed by radiation therapy, with or without chemotherapy. Minimal progress has been made in the treatment of head and neck cancer over the last 50 years.

LEAPS is designed to stimulate the human immune system to more effectively fight bacterial, viral and parasitic infections

CEL-SCI is also developing its LEAPS (Ligand Epitope Antigen Presentation System) technology. CEL-SCI's patented T-cell Modulation Process LEAPS technology 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. While CEL-SCI's 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 animal models, which may indicate that the LEAPS technology might translate to humans. The LEAPS

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candidates have demonstrated protection against lethal herpes simplex virus (HSV1) and H1N1 influenza infection, as a prophylactic or therapeutic agent in animals. They have also shown efficacy in animals in two autoimmune conditions, curtailing and sometimes preventing disease progression in arthritis and myocarditis animal models. Ultimately, the LEAPS technology may be a significant alternative to the therapies currently available on the market today for these diseases, but a LEAPS based drug likely won't be available in this decade, in our opinion, as CEL-SCI devotes the majority of its resources to the development of Multikine.

Clinical Pipeline

Multikine

CEL-SCI produces Multikine, a defined mixture of cytokines, from white blood cells it sources from the American Red Cross

Phase II data in head and neck cancer were encouraging as patients had an overall response rate of 42% and overall survival of 63.2% at 3.5 years from surgery

Patients with HPV have less invasive head and neck cancer

Multikine, CEL-SCI's lead investigational drug is in Phase III for the treatment of head and neck cancer. Multikine is a different kind of cancer therapy; it is an immunotherapy that is a defined mixture of cytokines. CEL-SCI produces this defined mixture of 14 cytokines from white blood cells it sources from the American Red Cross and can source from other FDA approved blood donation organizations in the U.S. Phase I and II clinical data suggest the potential for Multikine to demonstrate a possible improvement in the clinical outcome for patients with head and neck cancer. It is a combination immunotherapy, possessing both active and passive properties. The various cytokines present in the Multikine investigational therapy, such as IL-2, TNF, IL-1, along with other cytokines, could be responsible for this potential activity. Early-phase clinical data is encouraging, suggesting the potential that approximately 60% - 66% of head and neck cancer patients with primary disease could be candidates for this therapy. Phase II data were encouraging as patients had an overall response rate of 42% and overall survival of 63.2% at 3.5 years from surgery (Multikine is given about 3 weeks before surgery). Current literature suggests an approximate survival rate of 47.5% at 3.5 years with current standard of care (SOC), which is surgery and radiation, with or without chemotherapy. The Phase II data implies a 33% improvement. It is important to note when looking at that comparison that the 47.5% seen in literature includes patients with HPV while the Multikine studies likely have low numbers of HPV positive patients due to the anatomical distribution of the tumors.

According to a 2009 Journal of Clinical Oncology article by Pernille, patients with HPV have less invasive head and neck cancer. HPV is closely correlated with expression of p16. Tumor positivity for p16 was significantly correlated with improved locoregional tumor control versus p16 negative tumors (5-year actuarial values 58% versus 28%; $P = .0005$), improved disease-specific survival (72% versus 34%; $P = .0006$) and improved overall survival (62% versus 26%; $P = .0003$). Thus, the expression of p16 has a major impact on treatment response and survival in patients with head and neck cancer treated with conventional radiotherapy. This implies that the overall survival finding in the Phase II Multikine study has an even greater importance. CEL-SCI compared its Phase II overall survival results to that of studies published in the literature that contained both HPV-positive and HPV-negative patients while the Multikine study had a largely HPV-negative population. We believe that if the overall survival data from Multikine's Phase II trial was compared with an only HPV-negative population in the literature, Multikine would have shown an even greater than the 33% improvement that was observed.

The Phase III Multikine clinical trial is thought to be the first Phase III study in the world in which immunotherapy is given to cancer patients first, prior to their receiving any conventional treatment for cancer, including surgery, radiation and/or chemotherapy. This could be shown to be important because

The Multikine Phase III study is expected to have 84% - 97% of its patients HPV-negative

The Phase III trial is event driven, so setting a definitive timeline to completion is impossible

In preclinical studies, LEAPS has been shown to protect animals from infection or disease by a number of viruses and parasitic agents

The LEAPS technology has produced a potential peptide treatment for H1N1 (swine flu) hospitalized patients

conventional therapy may weaken the immune system, and may compromise the potential effect of immunotherapy. CEL-SCI is testing patients for HPV. Due to the anatomy of patients in the study, the Phase III study is expected to have 84% - 97% of its patients HPV-negative. The Phase III study will have three arms, one arm treated with SOC only, one with Multikine 5 times per week for 3 weeks plus CIZ (Cyclophosphamide 300mg/m² (x1,IV, day-3); Indomethacin 25mg t.i.d., p.o. (day 1 to 24 hrs prior to surgery) + 15-45mg Zinc (as Multivitamin) i.d., p.o.) and one with Multikine 5 times per week for 3 weeks without CIZ. The primary purpose of the “No CIZ” arm is to gain more information on the mechanism of action of Multikine. CIZ is added to decrease tumor suppressor mechanisms and thereby increase Multikine effectiveness. The first patient entered the study at the end of 2010/early 2011 but the first real bolus of patients entered the study in July – September 2011. It is a global study, conducted in 8 countries on 3 continents that will match global distribution of the disease (note that there are about 250,000 patients diagnosed annually with the disease in India, about 40,000 in the U.S. and 100,000 in the EU). This is an event driven trial, so setting a definitive timeline to completion is impossible, however, we estimate Multikine could be on the market sometime between 2018 – 2020 or possibly sooner.

LEAPS Technology

CEL-SCI's other investigational immunotherapy products (LEAPS conjugates) are currently in various stages of preclinical development. LEAPS (Ligand Epitope Antigen Presentation System), uses “heteroconjugates” to direct the body to choose a specific immune response. In preclinical studies, LEAPS has been shown to protect animals from infection or disease by a number of viruses and parasitic agents. LEAPS is designed to stimulate the 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, since in general, current vaccine technology is unable to “force” the immune system to pre-select the “appropriate” immune response that would likely offer “protection.”

The LEAPS technology has produced a potential peptide treatment for H1N1 (swine flu) hospitalized patients. This possible treatment is not really just an H1N1 treatment, but a pandemic flu treatment. The 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. CEL-SCI's LEAPS flu treatment contains epitopes known to be associated with immune protection against influenza in animal models. In September 2009, the U.S. Food and Drug Administration advised CEL-SCI that it could proceed with its first clinical trial to evaluate the effect of LEAPS-H1N1 treatment on the white

blood cells of hospitalized H1N1 patients. This followed an expedited initial review of CEL-SCI's regulatory submission for this study proposal.

In November 2009, CEL-SCI announced that The Johns Hopkins University School of Medicine had given clearance for CEL-SCI's 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 work is being pursued in collaboration with the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health. 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.

Utilizing its LEAPS technology, CEL-SCI also developed a second peptide, CEL-2000, as a potential rheumatoid arthritis vaccine

Utilizing its LEAPS technology, CEL-SCI also developed a second peptide, CEL-2000, as a potential rheumatoid arthritis vaccine. The data from animal studies of rheumatoid arthritis using the CEL-2000 treatment vaccine demonstrated that CEL-2000 is an effective treatment against arthritis with fewer administrations than those required by other anti-rheumatoid arthritis treatments, including Enbrel. CEL-2000, potentially a more disease type-specific therapy, is calculated to be significantly less expensive and may be useful in patients unable to tolerate or who may not be responsive to existing anti-arthritis therapies. In February 2010, CEL-SCI announced that its CEL-2000 vaccine demonstrated that it was able to block the progression of rheumatoid arthritis in a mouse model. The results were published in the scientific peer-reviewed Journal of International Immunopharmacology (online edition) in an article titled "CEL-2000: A Therapeutic Vaccine for Rheumatoid Arthritis Arrests Disease Development and Alters Serum Cytokine/Chemokine Patterns in the Bovine Collagen Type II Induced Arthritis in the DBA Mouse Model." 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 effects. 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., IL-12 and IFN- γ) and their action on reducing TNF- α and other inflammatory cytokines as well regulation of antibodies to these disease associated antigens. This was also illustrated by a schematic model showing how these pathways interact and result in the overall effect of protection and regulation of cytokines in a beneficial manner.

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

devotes most of its resources to the development of Multikine. We do not expect any drugs utilizing CEL-SCI's LEAPS technology to be commercially available in this decade.

Multikine Phase I and II Trials

In Phase I and II trials, no serious adverse events were reported by the clinical investigators as being expressly due to administration of Multikine

Multikine is given prior to the current SOC - surgery, radiation and then either chemotherapy or no chemotherapy

Phase II studies suggest that Multikine could change the type of cells that infiltrate and attack the tumor from CD-8 cells to predominantly CD-4 cells

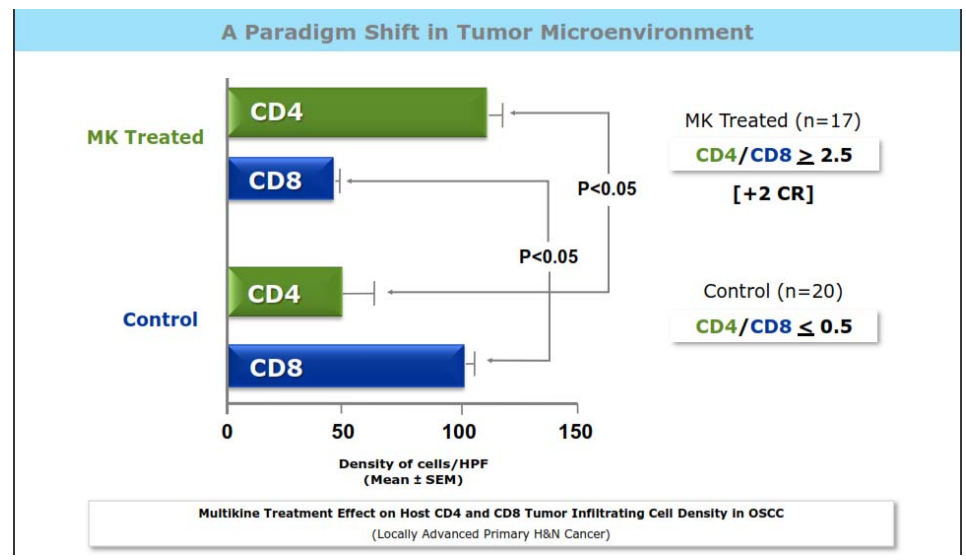
Clinical investigators have reported that Multikine studies thus far have shown that the drug is safe and suggest that it may be highly beneficial to patients with head and neck cancer. Clinical and pathology data from Phase I and Phase II clinical trials with the Multikine investigational therapy published in peer reviewed scientific journals (Timar et al 2003 and 2005) suggest that Multikine has the potential to produce an anti-tumor response. Prior to the start of the phase III trial, over 220 patients were exposed to daily Multikine doses of 200 to 3200 IU as IL-2 (over 2-3 weeks in Phase II and up to a few months in early-Phase I), no serious adverse events were reported by the clinical investigators as being expressly due to administration of Multikine. Adverse events that were reported included pain at the injection site, local minor bleeding and edema at the injection site, diarrhea, headache, nausea, and constipation. No abnormal laboratory results were reported following Multikine treatment - other than those commonly seen by treating physicians in this patient population regardless of Multikine administration. Similarly, in these early-phase clinical studies in patients, there was no reported increased toxicity of follow-on treatments as a result of Multikine administration. No complications following surgery (such as increased time for wound healing) were reported. The data indicate that Multikine appears to be able to activate the patient's own anti-tumor immune response. Additionally, Multikine has the potential to directly affect/kill the tumor cells.

The Multikine is injected around the tumor and in the vicinity of the draining local lymph nodes because these are the areas in which metastases are believed to be most likely developed and where the cancer may recur in most cancer patients with this disease. Multikine is given prior to the current SOC - surgery, radiation and then either chemotherapy or no chemotherapy.

Preliminary data from early-phase clinical studies on the Multikine investigational therapy suggest that it may have the potential to act on multiple fronts: 1) It is thought to have the potential to act on the cancer cell, 2) It is thought to have the potential to cause a direct effect on the tumor cells, 3) It is thought to have the potential to activate the immune system to produce an anti-tumor immune response and 4) It is thought to have the potential to possibly render residual tumor cells more susceptible to radiation and/or chemotherapy.

Clinical data reported from Phase II studies suggest that Multikine could change the type of cells that infiltrate and attack the tumor from CD-8 cells to predominantly CD-4 cells. These CD-4 cells have the potential to bring about an anti-tumor immune response. In this Phase II study (published in the Journal of Clinical Oncology in 2005), Multikine treated head and neck cancer patients were characterized by a markedly altered composition of tumor-infiltrating mononuclear cells, increased CD-4:CD-8 ratio, and increased tumor stroma to epithelial ratio, all of which were distinct from controls.

Figure 1 Phase II Trial Immune Cell Infiltrate Changes the Tumor Microenvironment



Source: Company reports

Phase II studies reported that Multikine administration appeared to have caused, on average, a 50% reduction in tumor cells present at surgery and...

...the tumor apparently was no longer present (as determined by histopathology) in approximately 12% of patients

In a Phase II trial, Multikine as first-line investigational therapy followed by surgery and radiotherapy had a 63.2% overall survival (OS) rate at 3.5 years from surgery

The clinical investigators who administered the three week Multikine treatment regimen used in Phase II studies reported that Multikine administration appeared to have caused, on average, a 50% reduction in tumor cells present at surgery (as determined by histopathology assessing the area of Stroma/Tumor (Mean±/Standard Error of the Mean of the number of cells counted per filed)) even before the start of standard therapy such as radiation and chemotherapy. The investigators reported a 12% complete response (100% tumor reduction) in the trial -- the final Phase II study reported that, as was determined in a controlled pathology study, the tumor apparently was no longer present (as determined by histopathology) in approximately 12% of patients (2 of 17 evaluable by pathology). This determination was made by three pathologists blinded to the study from the surgical specimen. In two other Multikine-treated patients, there was more than 50% tumor volume reduction (considered a partial or major response) and in four patients, the volume reduction was proven to be more than 30%, which was considered a minor response. Progressive disease (greater than or equal to 40% tumor volume increase) occurred in only one patient whereas stable disease was detected in the rest of the patients. The objective response rate was 21%, with an overall response of 42%. CEL-SCI's final Phase II study conducted with Multikine used the same treatment protocol as is being used in CEL-SCI's Phase III study.

In this last Phase II clinical study, head and neck cancer patients with locally advanced primary disease who received Multikine as first-line investigational therapy followed by surgery and radiotherapy had a 63.2% overall survival (OS) rate at 3.5 years from surgery. This percentage OS was arrived at as follows: of the 22 subjects enrolled in this final Phase II study, the consent for the survival follow-up portion of the study was received from 19 subjects. One subject did not consent to the follow-up portion of the study. The other 2 subjects did not have squamous cell carcinoma of the oral cavity and were thus not evaluable per the protocol. The overall survival rate of subjects receiving the investigational therapy in this study was compared to the overall survival rate that was calculated based upon a review of 55 clinical trials conducted in the same cancer population (with a total of 7,294 patients studied), and reported in the peer reviewed scientific literature between 1987 and 2007. Review of this literature

The results of CEL-SCI's final Phase II study were considered to be potentially favorable in terms of overall survival

showed an approximate survival rate of 47.5% at 3.5 year from treatment. Therefore, the results of CEL-SCI's final Phase II study were considered to be potentially favorable in terms of overall survival recognizing the limitations of this early-phase study. The goal of the Phase III trial currently underway is to confirm these findings.

As noted earlier in this report, according to a Journal of Clinical Oncology article, patients with HPV have less invasive head and neck cancer. HPV is closely correlated with expression of p16. Tumor -positivity for p16 was significantly correlated with improved locoregional tumor control (5-year actuarial values 58% versus 28%; $P = .0005$), improved disease-specific survival (72% versus 34%; $P = .0006$) and improved overall survival (62% versus 26%; $P = .0003$). Thus, the expression of p16 has a major impact on treatment response and survival in patients with head and neck cancer treated with conventional radiotherapy. This implies that the overall survival finding in the Phase II Multikine study has an even greater importance. CEL-SCI compared its Phase II overall survival results to that of studies published in the literature that contained both HPV-positive and HPV-negative patients while the Multikine study had a largely HPV-negative population. We believe that if the overall survival data from Multikine's Phase II trial was compared with an only HPV-negative population in the literature, Multikine would have shown an even greater than the 33% improvement that was observed.

Multikine Phase III Trial

Multikine has been cleared by the regulators in eight countries on three continents for a global Phase III clinical trial in head and neck cancer

Multikine has been cleared by the regulators in eight countries on three continents, including the U.S. FDA, for a global Phase III clinical trial in head and neck cancer patients with advanced disease who are treatment naïve (i.e., have received no prior treatment). The current recommendation for initial treatment of these patients according to the NCCN guidelines (published by the National Comprehensive Cancer Network) is surgery followed by radiotherapy (or surgery followed by combined radiochemotherapy) - depending on pathology assessment of the resected tumor following surgery. In CEL-SCI's ongoing study, patients receiving Multikine have it administered before these other treatments are given. This clinical trial is thought to be the first Phase III study in the world in which immunotherapy is given to cancer patients first, prior to their receiving any conventional treatment for cancer, including surgery, radiation and/or chemotherapy. This could be shown to be important because conventional therapy may weaken the immune system, and may compromise the potential effect of immunotherapy. Because Multikine is given before conventional cancer therapy, when the immune system may be more intact, CEL-SCI believes the possibility exists for it to have a greater likelihood of activating an anti-tumor immune response under these conditions.

Multikine has orphan drug status in the U.S.

Because of Multikine's orphan drug status in the U.S., it currently is anticipated that only one pivotal study is expected to be necessary for Multikine's approval. Advanced primary (not yet treated) head and neck cancer represents a recognized unmet medical need (since about 50% of the patients diagnosed with the disease will die within three years following treatment) with minimal progress made in the treatment of the disease over the last 50 years.

The Multikine Phase III trial is expected to be the largest head and neck cancer clinical study ever conducted with planned enrollment of 880 patients

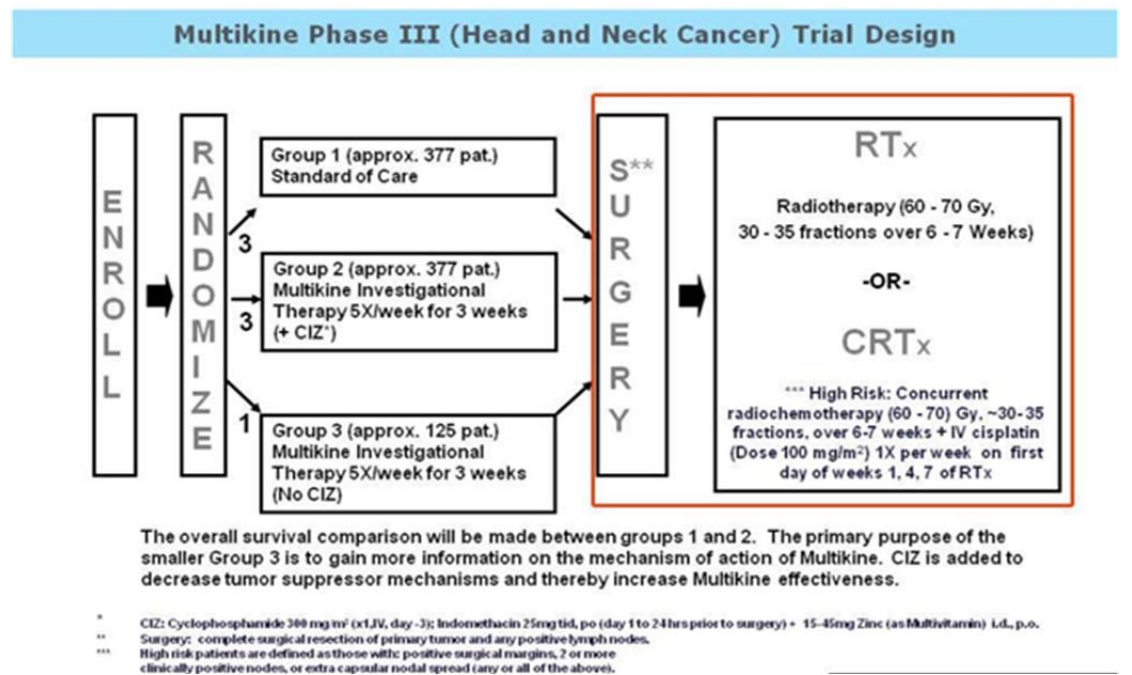
The Multikine Phase III trial is expected to be the largest head and neck cancer clinical study ever conducted with planned enrollment of 880 patients (in order to have approximately 784 evaluable subjects). The Phase III study is an open-label, randomized, controlled, multi-center study. To date, 36 centers have passed SIV (Site Initiation Visit) and are screening/acquiring patients with a goal of about 50 centers in total. This is an event-driven study with a median three-year follow-up. The primary endpoint is 10% improvement in overall survival (80% power, 95% confidence) in the Multikine treatment arm (Multikine 5 times per week for 3 weeks plus CIZ (Cyclophosphamide 300mg/m² (x1,IV, day-3); Indomethacin 25mg tid, po (day 1 to 24 hrs prior to surgery) + 15-45mg Zinc (as Multivitamin) i.d., p.o.), plus the current standard of care (SOC - consisting of surgery + radiotherapy or surgery + radiochemotherapy), over that which can be achieved in the SOC arm alone. These trial arms will have about 377 patients each. The third arm of the trial will have about 125 patients. This arm will treat patients with Multikine 5 times per week for 3 weeks and SOC but without CIZ. The primary purpose of the "No CIZ" arm is to gain more information on the mechanism of action of Multikine and to show Multikine toxicity alone. CIZ is added to decrease tumor suppressor mechanisms and thereby increase Multikine effectiveness. Due to the anatomy of patients in the

The primary endpoint is 10% improvement in overall survival (80% power, 95% confidence) in the Multikine treatment arm

study, the Phase III study is expected to have 84%-97% of its patients HPV-negative (the significance of this was discussed earlier in this report).

Based on what is presently known about the current survival statistics for this population, CEL-SCI believes that achievement of its Phase III endpoint should enable CEL-SCI, subject to further consultations with FDA, to move forward, prepare and submit a Biologic License Application to FDA for Multikine. The secondary objectives are to evaluate the effects of the investigational Multikine therapy on the cumulative incidence of local-regional control, progression-free survival, tumor histopathology, and quality of life, while also seeking to confirm Multikine safety. Tumor response is a tertiary outcome in this immunotherapy study.

Figure 2 Multikine Phase III (Head and Neck Cancer) Trial Design



Source: Company reports

In the recent interim review of the safety data from the Phase III study, an Independent Data Monitoring Committee (IDMC) raised no safety concerns

In the recent interim review of the safety data from the Phase III study, an Independent Data Monitoring Committee (IDMC) raised no safety concerns. The IDMC also indicated that no safety signals were found that would call into question the benefit/risk of continuing the study. The members of the IDMC are all key opinion leaders in cancer from the U.S., Europe and Asia. The results of the IDMC review are important since studies have shown that up to 30% of Phase III trials fail due to safety considerations and the IDMC's safety findings from this interim review were similar to those reported by investigators during CEL-SCI's Phase I and II trials.

Development/Marketing Agreements

CEL-SCI has agreements with Teva Pharmaceutical for Israel, Turkey, Serbia and Croatia...

CEL-SCI has an agreement with Teva Pharmaceutical Industries, Ltd., which provides Teva with the exclusive license to market and distribute Multikine in Israel, Turkey, and in August 2011, the companies added Serbia and Croatia. Pursuant to the agreement, Teva will participate in CEL-SCI's Phase III clinical trial and will fund a portion of the Phase III trial in Israel.

...Orient Europharma of Taiwan for Taiwan, Singapore, Hong Kong, Malaysia, South Korea, the Philippines, Australia and New Zealand...

CEL-SCI has an agreement with Orient Europharma of Taiwan which provides Orient Europharma with the exclusive marketing rights to Multikine for all cancer indications in Taiwan, Singapore, Hong Kong, Malaysia, South Korea, the Philippines, Australia and New Zealand. The agreement requires Orient Europharma to fund the clinical trials needed to obtain marketing approvals in these countries for head and neck cancer, naso-pharyngeal cancer and potentially cervical cancer.

...Byron Biopharma LLC for the Republic of South Africa...

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

...and IDC-GP Pharm for Argentina and Venezuela

In August 2011, CEL-SCI entered into an exclusive Sales, Marketing and Distribution agreement with IDC-GP Pharm LLC under which CEL-SCI has granted IDC-GP Pharm an exclusive license to market Multikine in the countries of Argentina and Venezuela. IDC-GP Pharm is a joint venture between two groups of experienced pharmaceutical entrepreneurs with expertise in the registration and commercialization of pharmaceutical products in South America, among other regions. One of these two groups represents former employees of a large pharmaceutical company, while the other group is GP Pharm, headquartered in Barcelona, Spain, with operations in each major country in Latin America either directly or through local partners. Pursuant to the agreement, IDC-GP Pharm will be responsible for receiving regulatory approval to use Multikine in the territory. Once Multikine has been approved in any of the two countries, CEL-SCI will be responsible for manufacturing the product, while IDC-GP Pharm will be responsible for sales in the Territory. Revenues will be split 50/50 between CEL-SCI and IDC-GP Pharm after payment to CEL-SCI for the manufacturing costs of Multikine. If IDC-GP Pharma does not receive governmental permission to distribute Multikine in Argentina or Venezuela by August 31, 2013, CEL-SCI has the right to cancel the agreement.

Manufacturing

Multikine is manufactured in CEL-SCI's state-of-the-art "Cold-Fill" manufacturing facility outside of Baltimore

Currently, CEL-SCI's facility can manufacture about 20,000 courses of treatment annually

"Fill and finish" could be an additional revenue source for the company, though we have not modeled for any revenue from an endeavor of this sort

CEL-SCI produces Multikine from white blood cells it sources from the American Red Cross and can source from other FDA approved blood donation organizations in the U.S. These white blood cells are the same as those used in hospitals, but CEL-SCI still puts them through its viral removal technology, as is required for all biologic manufacturers regardless if there is a "real" need. Multikine is manufactured in CEL-SCI's state-of-the-art "Cold-Fill" manufacturing facility outside of Baltimore. The white blood cells from only about 100 blood donations can produce approximately 10,000 2.2ml vials (one vial is a daily dose) of Multikine. Currently, CEL-SCI's facility can manufacture about 20,000 courses of treatment annually (a course of treatment is 15 vials). The plant can be increased to three times its current size at its current location, building out its annual capacity to about 60,000 treatments annually from the current facility.

Before starting the Phase III trial, CEL-SCI's management determined that it needed to build a dedicated manufacturing facility to produce Multikine. This facility has been completed and validated, and has produced several clinical lots that have been used for the Phase III clinical trial. CEL-SCI completed validation of its new manufacturing facility in January 2010. In addition to using this facility to manufacture Multikine, CEL-SCI, only if the facility is not being used for Multikine, may offer the use of the facility as a service to pharmaceutical companies and others, particularly those that need to "fill and finish" their drugs in a cold environment (4 degrees Celsius, or approximately 39 degrees Fahrenheit). However, priority will always be given to Multikine. 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. CEL-SCI currently does not have any contracts to "fill and finish" for other companies. However, this could be an additional revenue source for the company, though we have not modeled for any revenue from an endeavor of this sort.

Biologics are usually very sensitive to heat and quickly lose their biological activity if exposed to room or elevated temperature. Room or elevated temperatures may also affect the shelf-life of a biologic with the result that the product cannot be stored for as long as desired. However, these products do not generally lose activity when kept at 4 degrees Celsius. The FDA and other regulatory agencies require a drug developer to demonstrate the safety, purity and potency of a drug being produced for use in humans. When filling a product at 4 degrees Celsius, minimal to no biological losses occur and therefore the potency of the drug is maintained throughout the final critical step of the drug's manufacturing process. If the same temperature sensitive drug is instead aseptically filled at room temperature, expensive and time-consuming validation studies must be conducted, first, to be able to obtain a complete understanding of the product's potency loss during the room temperature fill process, and second, to create solutions to the drug's potency losses, which require further testing and validation. CEL-SCI's unique, cold aseptic filling suite can be operated at temperatures between 2 degrees Celsius and room temperatures, and

at various humidity levels. CEL-SCI's aseptic filling suites are maintained at FDA and EU ISO classifications of 5/6. CEL-SCI also has the capability to formulate, inspect, label and package biologic products at cold temperatures.

*We believe supply
disruption risk for CEL-SCI
is lower than at most of its
similarly sized peers*

With its huge potential sources for raw material (WBC) and its ability to seamlessly increase its manufacturing capacity at its current facility, we believe supply disruption risk for CEL-SCI is lower than at most of its similarly sized peers.

Market Opportunity

Head and neck cancer is strongly associated with certain environmental and lifestyle risk factors

Head and neck cancer refers to a group of biologically similar cancers that start in the lip, oral cavity (mouth), paranasal sinuses, pharynx, and larynx. About 90% of head and neck cancers are squamous cell carcinomas originating from the mucosal lining (epithelium) of these regions. Head and neck cancers often spread to the lymph nodes of the neck, and this is often the first (and sometimes only) sign of the disease at the time of diagnosis. Head and neck cancer is strongly associated with certain environmental and lifestyle risk factors, including tobacco smoking, alcohol consumption, UV light, particular chemicals used in certain workplaces, and certain strains of viruses, such as human papillomavirus. These cancers are frequently aggressive in their biologic behavior; patients with these types of cancer are at a higher risk of developing another cancer in the head and neck area.

Worldwide there are an estimated 600,000 new cases of head and neck cancer diagnosed each year

Head and neck cancer is the sixth most frequently occurring cancer worldwide and the disease accounts for about 2% of all cancer deaths annually. Almost two-thirds of the cases occur in men. The disease is difficult to treat and can be debilitating and disfiguring. Worldwide there are an estimated 600,000 new cases of head and neck cancer diagnosed each year, which represents about 5 - 6% of all newly diagnosed cancers. About two-thirds of these cases occur in developing countries. The American Cancer Society estimated that in 2012 there were 40,250 new cases of head and neck cancer in the U.S. and 7,850 estimated deaths from the disease. In the European Union about 100,000 people are diagnosed with head and neck cancer every year and about 40,000 die from the disease (a 2010 study by Jean Lacau St. Guily published in *Head & Neck Oncology* stated that there were 143,000 new cases of head and neck cancer diagnosed in Europe in 2007 responsible for more than 68,000 deaths, but we use the more often cited number of 100,000 new cases in our European forecasts).

The affected population is changing from older males to young Caucasian males. Rates are high in men in Western, Southern and Eastern Europe. The disease is more common in men than women in most countries. The risk of developing disease increases with age with the majority of cases occurring in patients over age 50. In some areas of the developing world, however, oral cancer is relatively common in younger people. Rising trends of oral cancer in young and middle aged men and women have been reported in the UK, other European countries, and the USA

Approximately 85% of head and neck cancers are linked to tobacco use

Tobacco (including smokeless tobacco, sometimes called "chewing tobacco" or "snuff") and alcohol use are the most important risk factors for head and neck cancers, particularly those of the oral cavity, oropharynx, hypopharynx, and larynx. Approximately 85% of head and neck cancers are linked to tobacco use. People who use both tobacco and alcohol are at greater risk for developing these cancers than people who use either tobacco or alcohol alone. Other risk factors for cancers of the head and neck include sun exposure (lip) and possibly human papillomavirus (HPV) infection. High-risk strains of the human papillomavirus

(HPV) already are associated with cervical, oral, and anal cancers; however, HPV DNA has been detected in about a third of head and neck malignancies.

We estimate the current market for Multikine would be 40,000 patients annually in the U.S. and 100,000 patients in Europe

Since Multikine is given before any other cancer therapy, it potentially addresses a very large market. We estimate the current market for Multikine would be 40,000 patients annually in the U.S. and 100,000 patients in Europe. If the drug can penetrate 25% of the market in the U.S. and Europe at its peak that would imply 35,000 treatments per year and remember that manufacturing at the current facility can be built out to an annual capacity of 60,000 courses of treatment annually.

Financial Assumptions

CEL-SCI estimates the total cost of the Phase III trial to be about \$32 million

CEL-SCI estimates the total cost of the Phase III trial, with the exception of the parts that will be paid by its licensees, Teva Pharmaceuticals and Orient Europharma, to be approximately \$32 million of which approximately \$7 million has been paid as of September 30, 2012. We estimate that after its December 2012 stock offering, CEL-SCI has cash on its balance sheet of about \$13.7 million. Out of the planned 48 Phase III trial sites, 36 sites have completed their site initiation visits and patients are being screened/enrolled in multiple locations. According to information in the filed SEC documents, it should be noted that the total cost of the Phase III trial is only an estimate based on the information currently available in CEL-SCI's contracts with the Clinical Research Organization responsible for managing the Phase III trial. This estimate can be affected by the speed of enrollment, foreign currency exchange rates and many other factors, some of which cannot be foreseen today. It is therefore possible that the cost of the Phase III trial will be higher than currently estimated.

CEL-SCI has been required to make monthly base rent payments of \$131,250

CEL-SCI's lease on the manufacturing facility expires on October 31, 2028. Since October 2008, CEL-SCI has been required to make monthly base rent payments of \$131,250. Beginning November 1, 2009, the annual base rent escalates each year at 3%. CEL-SCI is also required to pay all real and personal property taxes, insurance premiums, maintenance expenses, repair costs and utilities associated with the facility, which were approximately \$39,000 per month as of September 30, 2012. In August 2011, CEL-SCI paid a deposit of \$1,670,917 to the landlord since CEL-SCI's cash balances did not meet the minimum amount required by the lease. When CEL-SCI meets the minimum cash balance required by the lease, the deposit will be returned to CEL-SCI. However, we don't expect this will occur until after Multikine is launched.

Including the December 2012 offering, to date, CEL-SCI has raised about \$210 million from investors since 1983

CEL-SCI completed an equity offering in December 2012. Including the December 2012 offering, to date, CEL-SCI has raised about \$210 million from investors since 1983. The net tangible book value of CEL-SCI's common stock on September 30, 2012 was approximately \$5.7 million, or approximately \$0.02 per share, based on 273,213,332 shares of common stock outstanding as of September 30, 2012. As of November 30, 2012, there were outstanding stock options to purchase approximately 37,567,000 shares of common stock, at prices ranging between \$0.16 and \$2.00 per share, and outstanding warrants to purchase approximately 74,431,000 shares of common stock, at prices ranging between \$0.30 and \$1.75 per share. On December 4, 2012, CEL-SCI announced it would raise \$10.5 million by offering 35.0 million shares and 26.25 million Series R warrants that entitle the holder to purchase one share of CEL-SCI's common stock. The Series R warrants may be exercised at any time on or after June 7, 2013 and on or before December 7, 2016 at a price of \$0.40 per share. Following this offering (Laidlaw and Company did not take part in the offering), there were 308,213,332 shares of common stock outstanding and we estimate outstanding stock options to purchase approximately 37,567,000 shares of

common stock and outstanding warrants to purchase approximately 100,681,000 shares of common stock.

The company's cash burn is about \$1.1 million per month

The company's cash burn is about \$1.1 million per month. At the end of its fiscal year 2012, CEL-SCI had cash and equivalents of \$3.9 million. We estimate CEL-SCI realized about \$9.8 million from its December offering. With a cash burn of approximately \$1.1 million per month, we would expect CEL-SCI to announce another stock offering in late 2013. In calculating our price target, we have assumed two stock offerings similar to the one in December 2012 to occur before Multikine is submitted for regulatory approval.

We estimate CEL-SCI will generate \$0.25 million in revenue in each of the next 3 years

Through grant income and "other" we estimate CEL-SCI will generate \$0.25 million in revenue in each of the next 3 years. We project that R&D expenses will rise approximately 12.5% in each of the next 3 years and that SG&A will rise in the low single digits. We estimate CEL-SCI will record a loss of (\$0.06) in FY13 and losses of (\$0.05) in both FY14 and FY15.

We believe that if Phase III results are positive and that if Multikine is approved, a course of Multikine therapy could be priced in the \$50,000 area

We believe that if Phase III results are positive and that if Multikine is approved, a course of Multikine therapy could be priced in the \$50,000 area. Since Multikine is given before any other cancer therapy, it potentially addresses a large market. If the drug can penetrate 25% of the market in the U.S. and Europe at its peak (in many other regions CEL-SCI has signed development/marketing deals as previously mentioned) this would imply potential peak sales in the area of \$1.75 billion. This estimate assumes 35,000 treatments per year and remember that manufacturing at the current facility can be built out to an annual capacity of 60,000 courses of treatment annually. We expect gross margin could be above 90%. Note that we do not expect CEL-SCI will develop its own sales organization to sell Multikine, but rather we expect management will either enter into a marketing agreement or sell the company outright.

Potential peak sales for Multikine is in the area of \$1.75 billion, in our opinion

Management Profiles

Maximilian de Clara

Director and President

Maximilian de Clara has been a Director of CEL-SCI since its inception in March 1983, and has been President of CEL-SCI since July 1983. Prior to his affiliation with CEL-SCI, and since at least 1978, Mr. de Clara was involved in the management of his personal investments and personally funding research in the fields of biotechnology and biomedicine. Mr. de Clara attended the medical school of the University of Munich from 1949 to 1955, but left before he received a medical degree. For his efforts and dedication to research and development in the fight against cancer and AIDS, Mr. de Clara was awarded the "Pour le Merit" honorary medal of the Austrian Military Order "Merito Navale" as well as the honor cross of the Austrian Albert Schweitzer Society. As of November 30, 2012, Mr. de Clara holds 6,707,023 shares and 6,455,789 options or warrants exercisable prior to February 28, 2013 in CEL-SCI.

Geert R. Kersten, Esq.

Director, Chief Executive Officer and Treasurer

Geert Kersten has served in his current leadership role at CEL-SCI since 1995. Mr. Kersten has been with CEL-SCI since 1987. Mr. Kersten also provides CEL-SCI with significant expertise in the fields of finance and law and has a unique vision of how CEL-SCI's Multikine product could potentially change the way cancer is treated. Prior to CEL-SCI, Mr. Kersten worked at the law firm of Finley & Kumble and worked at Source Capital, an investment banking firm located in McLean, VA. He is a native of Germany, graduated from Millfield School in England, and completed his studies in the U.S. Mr. Kersten received his Undergraduate Degree in Accounting, and an M.B.A. from George Washington University, and a law degree (J.D.) from American University in Washington, DC. As of November 30, 2012, Mr. Kersten holds 9,678,103 shares and 6,233,009 options or warrants exercisable prior to February 28, 2013 in CEL-SCI.

Patricia B. Prichep

Senior Vice President of Operations and Secretary

Patricia B. Prichep joined CEL-SCI in 1992 and has been CEL-SCI's Senior Vice President of Operations since March 1994. Between December 1992 and March 1994, Ms. Prichep was CEL-SCI's Director of Operations. Ms. Prichep became CEL-SCI's Corporate Secretary in May 2000. She is responsible for all day-to-day operations of CEL-SCI, including human resources and is the liaison with CEL-SCI's independent registered public accounting firm for financial reporting. From June 1990 to December 1992, Ms. Prichep was the Manager of Quality and Productivity for the NASD's Management, Systems and Support

Department. She was responsible for the internal auditing and work flow analysis of operations. Between 1982 and 1990, Ms. Prichep was Vice President and Operations Manager for Source Capital, Ltd. She handled all operations and compliance for CEL-SCI and was licensed as a securities broker. Ms. Prichep received her B.A. from the University of Bridgeport in Connecticut. As of November 30, 2012, Ms. Prichep holds 3,238,775 shares and 2,352,296 options or warrants exercisable prior to February 28, 2013 in CEL-SCI.

Dr. Eyal Talor

Chief Scientific Officer

Eyal Talor, Ph.D. joined CEL-SCI in October 1993. In October 2009, Dr. Talor was promoted to Chief Scientific Officer. Prior to this promotion he was the Senior Vice President of Research and Manufacturing since March of 1994. He is a clinical immunologist with over 19 years of hands-on management of clinical research and drug development for immunotherapy application; pre-clinical to Phase III, in the biopharmaceutical industry. His expertise includes; biopharmaceutical R&D and Biologics product development, GMP (Good Manufacturing Practices) manufacture, Quality Control testing, and the design and building of GMP manufacturing and testing facilities. He served as Director of Clinical Laboratories (certified by the State of Maryland) and has experience in the design of clinical trials (Phase I – III) and GCP (Good Clinical Practices) requirements. He also has broad experience in the different aspects of biological assay development, analytical methods validation, raw material specifications, and QC (Quality Control) tests development under FDA/GMP, USP, and ICH guidelines. He has extensive experience in the preparation of documentation for IND and other regulatory submissions. His scientific area of expertise encompasses immune response assessment. He is the author of over 25 publications and has published a number of reviews on immune regulations in relation to clinical immunology. Before coming to CEL-SCI, he was Director of R&D and Clinical Development at CBL, Inc., Principal Scientist - Project Director, and Clinical Laboratory Director at SRA Technologies, Inc. Prior to that he was a full time faculty member at The Johns Hopkins University, Medical Intuitions; School of Public Health. He has invented technologies which are covered by two U.S. patents; one on Multikine's composition of matter and method of use in cancer, and one on a platform Peptide technology ('Adapt') for the treatment of autoimmune diseases, asthma, allergy, and transplantation rejection. Dr. Talor also has patents on Multikine in the EU, China and Japan. He also is responsible for numerous product and process inventions as well as a number of pending U.S. and PCT patent applications. He received his Ph.D. in Microbiology and Immunology from the University of Ottawa, Ottawa, Ontario, Canada, and had post-doctoral training in clinical and cellular immunology at The John Hopkins University, Baltimore, Maryland, USA. He holds an Adjunct Associate teaching position at the Johns Hopkins University Medical Institutions. As of November 30, 2012, Dr. Talor holds 2,045,828 shares and 1,552,719 options or warrants exercisable prior to February 28, 2013 in CEL-SCI.

Dr. Daniel H. Zimmerman

Senior Vice President of Research, Cellular Immunology

Daniel H. Zimmerman, Ph.D., was CEL-SCI's Senior Vice President of Cellular Immunology between 1996 and December 2008 and again since November 2009. He joined CEL-SCI in January 1996 as the Vice President of Research,

Cellular Immunology. Dr. Zimmerman founded CELL-MED, Inc. and was its president from 1987-1995. From 1973-1987, Dr. Zimmerman served in various positions at Electronucleonics, Inc. His positions included: Scientist, Senior Scientist, Technical Director and Program Manager. Dr. Zimmerman held various teaching positions at Montgomery College between 1987 and 1995. Dr. Zimmerman has invented technologies which are covered by over a dozen US patents as well as many foreign equivalent patents. He is the author of over 40 scientific publications in the area of immunology and infectious diseases. He has been awarded numerous grants from NIH and DOD. From 1969-1973, Dr. Zimmerman was a Senior Staff Fellow at NIH. For the following 25 years, he continued on at NIH as a guest worker. Dr. Zimmerman received a Ph.D. in Biochemistry and a Masters in Zoology from the University of Florida and a B.S. in Biology from Emory and Henry College. As of November 30, 2012, Dr. Zimmerman holds 1,675,091 shares and 1,284,000 options or warrants exercisable prior to February 28, 2013 in CEL-SCI.

John Cipriano

Senior Vice President of Regulatory Affairs

John Cipriano has been CEL-SCI's Senior Vice President of Regulatory Affairs between March 2004 and December 2008 and again since October 2009. Mr. Cipriano brings to CEL-SCI over 30 years of experience in both biotech and pharmaceutical companies. In addition, he held positions at the Food and Drug Administration as Deputy Director, Division of Biologics Investigational New Drugs, Office of Biologics Research and Review and was the Deputy Director, IND Branch, Division of Biologics Evaluation, Office of Biologics. Mr. Cipriano completed his B.S. in Pharmacy from the Massachusetts College of Pharmacy in Boston, Massachusetts and his M.S. in Pharmaceutical Chemistry from Purdue University in West Lafayette, Indiana. As of November 30, 2012, Mr. Cipriano holds 506,000 shares and 506,000 options or warrants exercisable prior to February 28, 2013 in CEL-SCI.

Valuation

Our valuation for CEL-SCI is based on the NPV of our probability-adjusted forecasts for Multikine

Our risk-adjusted mean projections for total sales of Multikine are \$15 million in 2018 growing to \$456 million by 2023

Our 12-month price target for CEL-SCI is \$0.75

We are initiating coverage on CEL-SCI with a BUY rating

Our valuation for CEL-SCI is based on the NPV of our probability-adjusted forecasts for Multikine. We believe that Multikine has substantial blockbuster potential, which is currently undervalued by the market. Since the Multikine Phase III trial is an event-driven trial, it is difficult to definitively state when the trial will end and the drug will be submitted to regulatory authorities and approved. We do expect a rolling submission in the U.S. We have run two scenarios for the timing of approval, one of which we assume Multikine will be launched in 2018 and the other in 2020. It is possible that, assuming the drug is approved, that it could be on the market prior to our 2018 assumption. We believe there is a 50% chance that the drug is approved. Our risk-adjusted mean (the mean of our best and worst case expectations) projections for total sales of Multikine are \$15 million in 2018 growing to \$456 million by 2023.

Our 12-month price target for CEL-SCI is \$0.75, which includes our risk-adjusted value for Multikine, a small value for the company's manufacturing plant and no value for the LEAPS program, due to its preclinical status. However, we believe the LEAPS program could potentially have substantial value in the future provided at least one drug candidate enters Phase I studies by the end of 2016. We have assumed there will be two more stock offerings similar to the one in December 2012 before Multikine is submitted for regulatory approval. We are initiating coverage on CEL-SCI with a BUY rating and note that this recommendation is speculative in nature due to the company's current stock price (under \$1.00 per share) and our opinion that the majority of the value of the stock is hinged on a binary event, the approval of Multikine for the treatment of head and neck cancer.

Risks to Owning the Stock

There are many standard risks for development stage biotechnology companies that hold true for the entire industry. There are development risks associated with preclinical and clinical studies, and potential delays in the start of trials. There is regulatory risk that the company will be unable to receive regulatory approvals for drugs or that regulatory approval may be delayed. Manufacturing risks are associated with the upgrading of facilities from clinical study production to commercial production. There is also commercial risk for a company to successfully market and sell its drug or drugs. Other risks include financing risk, currency risk, potential governmental price controls, and IP (generic) risks. The stock of biotechnology companies, like all publically traded companies, is subject to market volatility and liquidity risks if there are small trading floats. CEL-SCI is susceptible to all of these risks.

Other downside risks specific to CEL-SCI include the likelihood of the need to sell more stock to raise capital for the continuation for the Multikine Phase III trial, the timing of Multikine regulatory submission and approval, and the ultimate market potential and expectations for Multikine.

Figure 3: Income Statement

CEL-SCI Corp. <i>Income Statement (millions, except per share data)</i>	FY 2011				FY 2012E				FY 2013E				FY_11 Sept	FY_12 Sept	FY_13E Sept	FY_14E Sept	FY_15E Sept
	Q1_11 Dec	Q2_11 Mar	Q3_11 Jun	Q4_11 Sept	Q1_12 Dec	Q2_12 Mar	Q3_12 Jun	Q4_12 Sept	Q1_13E Dec	Q2_13E Mar	Q3_13E Jun	Q4_13E Sept					
	Product Sales, net	-	-	-	-	-	-	-	-	-	-	-					
Grant Income and Other Revenue	0.66	0.04	0.08	0.17	0.01	0.11	0.04	0.11	0.06	0.06	0.06	0.06	0.96	0.25	0.25	0.25	0.25
Revenue	0.66	0.04	0.08	0.17	0.01	0.11	0.04	0.11	0.06	0.06	0.06	0.06	0.96	0.25	0.25	0.25	0.25
Cost of sales	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Gross Profit	0.66	0.04	0.08	0.17	0.01	0.11	0.04	0.11	0.06	0.06	0.06	0.06	0.96	0.25	0.25	0.25	0.25
<i>Operating expenses:</i>																	
Selling, general and administrative	1.57	1.95	1.85	1.29	1.85	1.63	1.67	1.44	1.81	1.67	1.71	1.47	6.66	6.60	6.66	6.82	7.00
Research and development	3.26	3.04	2.92	2.51	2.46	2.59	2.47	2.85	2.76	2.98	2.78	3.13	11.75	10.37	11.66	13.12	14.76
Depreciation and amortization	0.14	0.15	0.15	0.10	0.14	0.14	0.11	0.14	0.14	0.14	0.14	0.14	0.53	0.53	0.57	0.57	0.57
Total Operating Expenses	4.98	5.14	4.92	3.90	4.45	4.37	4.25	4.43	4.71	4.79	4.63	4.75	18.94	17.50	18.88	20.51	22.32
Total Operating Expenses (non-GAAP)	4.98	5.14	4.92	3.90	4.45	4.37	4.25	4.43	4.71	4.79	4.63	4.75	18.94	17.50	18.88	20.51	22.32
Operating Income/(loss)	(4.31)	(5.10)	(4.85)	(3.73)	(4.44)	(4.26)	(4.21)	(4.32)	(4.65)	(4.73)	(4.56)	(4.69)	(17.99)	(17.24)	(18.63)	(20.26)	(22.07)
Operating Income/(loss) non-GAAP	(4.31)	(5.10)	(4.85)	(3.73)	(4.44)	(4.26)	(4.21)	(4.32)	(4.65)	(4.73)	(4.56)	(4.69)	(17.99)	(17.24)	(18.63)	(20.26)	(22.07)
<i>Other Income:</i>																	
Gain on derivative instruments	(1.95)	3.06	1.76	1.55	0.96	(4.20)	3.39	1.77	0.00	0.00	0.00	0.00	4.43	1.91	0.00	0.00	0.00
Interest income	0.05	0.05	0.03	0.03	0.03	0.03	0.03	0.03	0.02	0.02	0.02	0.02	0.16	0.12	0.08	0.08	0.08
Interest expense	(0.04)	(0.04)	(0.07)	(0.17)	(0.12)	(0.06)	(0.04)	(0.04)	(0.04)	(0.04)	(0.04)	(0.04)	(0.32)	(0.26)	(0.16)	(0.16)	(0.16)
Other expenses	0.00	(12.00)	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	(12.00)	0.00	0.00	0.00	0.00
Income (loss) before provision for income taxes (GAAP)	(6.25)	(14.03)	(3.11)	(2.32)	(3.58)	(8.49)	(0.84)	(2.57)	(4.67)	(4.75)	(4.58)	(4.71)	(25.71)	(15.48)	(18.71)	(20.34)	(22.15)
Income (loss) before provision for income taxes (non-GAAP)	(6.25)	(14.03)	(3.11)	(2.32)	(3.58)	(8.49)	(0.84)	(2.57)	(4.67)	(4.75)	(4.58)	(4.71)	(25.71)	(15.48)	(18.71)	(20.34)	(22.15)
<i>Tax: (%) non-GAAP</i>	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Income tax provision GAAP	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Net income (loss) GAAP	(6.25)	(14.03)	(3.11)	(2.32)	(3.58)	(8.49)	(0.84)	(2.57)	(4.67)	(4.75)	(4.58)	(4.71)	(25.7)	(15.5)	(18.7)	(20.3)	(22.1)
Net income (loss) non-GAAP	(6.25)	(14.03)	(3.11)	(2.32)	(3.58)	(8.49)	(0.84)	(2.57)	(4.67)	(4.75)	(4.58)	(4.71)	(25.7)	(15.5)	(18.7)	(20.3)	(22.1)
Modifications of Warrants/Inducement Warrants	0.0	(1.1)	0.0	0.0	(0.6)	(1.6)	0.0	0.0	0.0	0.0	0.0	0.0	(1.07)	(2.17)	0.00	0.00	0.00
Net income (loss) available to common shareholders GAAP	(6.25)	(15.10)	(3.11)	(2.32)	(4.16)	(10.09)	(0.84)	(2.57)	(4.67)	(4.75)	(4.58)	(4.71)	(26.78)	(17.65)	(18.71)	(20.34)	(22.15)
Net income (loss) available to common shareholders non-GAAP	(6.25)	(14.03)	(3.11)	(2.32)	(4.16)	(10.09)	(0.84)	(2.57)	(4.67)	(4.75)	(4.58)	(4.71)	(26.78)	(17.65)	(18.71)	(20.34)	(22.15)
Diluted EPS (GAAP)	(0.03)	(0.07)	(0.01)	(0.01)	(0.02)	(0.04)	(0.00)	(0.01)	(0.02)	(0.02)	(0.01)	(0.01)	(0.13)	(0.07)	(0.06)	(0.05)	(0.05)
Diluted EPS (non-GAAP)	(0.03)	(0.07)	(0.01)	(0.01)	(0.02)	(0.04)	(0.00)	(0.01)	(0.02)	(0.02)	(0.01)	(0.01)	(0.13)	(0.07)	(0.06)	(0.05)	(0.05)
Weighted Diluted Shares outstanding (000s)	205.1	207.1	208.4	213.35	228.6	247.4	258.5	272.9	307.94	308.2	308.6	345.1	208.5	251.8	317.5	383.6	423.3
<i>Weighted Diluted Shares outstanding YOY change (%)</i>					11.4%	19.5%	24.0%	27.9%	34.7%	24.6%	19.4%	26.4%	32.2%	20.8%	26.1%	20.8%	10.4%

Source: Bloomberg LP; Company reports; Laidlaw & Company estimates

Figure 4: Balance Sheet

CEL-SCI Corp.	FY 2012E				FY 2013E				FY_10 Sept	FY_11 Sept	FY_12 Sept	FY_13E Sept	FY_14E Sept	FY_15E Sept
	Q1_12 Dec	Q2_12 Mar	Q3_12 Jun	Q4_12 Sept	Q1_13E Dec	Q2_13E Mar	Q3_13E Jun	Q4_13E Sept						
<i>Balance Sheet (\$ millions, except per share data)</i>														
Assets:														
Cash and cash equivalents	3.5	5.3	7.2	3.9	10.2	6.2	2.4	8.5	26.6	4.3	3.9	8.5	5.9	3.3
Receivables	0.0	0.1	0.0	0.2	0.1	0.1	0.1	0.1	-	0.5	0.2	0.1	0.1	0.1
Prepaid expenses	1.8	1.9	1.8	1.3	1.3	1.3	1.3	1.3	0.3	2.0	1.3	1.3	1.3	1.3
Inventories used for R&D and manufacturing	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.5	1.6	1.4	1.4	1.6	1.9
Deferred rent- current portion	0.7	0.7	0.7	0.7	0.6	0.6	0.6	0.6	0.8	0.7	0.7	0.6	0.6	0.6
Other	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total Current Assets	7.3	9.3	11.0	7.4	13.7	9.7	5.8	11.9	29.1	9.0	7.4	11.9	9.5	7.2
Research and Office equipment and leasehold improvements	0.9	0.8	0.7	0.6	0.5	0.5	0.4	0.3	1.3	1.0	0.6	0.3	0.3	0.3
Patent costs	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.5	0.6
Deferred Rent	6.3	6.2	6.1	5.9	5.8	5.7	5.6	5.5	7.1	6.5	5.9	5.5	5.1	4.7
Deposits	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.7	-	1.7	1.7	1.7	1.7	1.7
Other assets	-	-	-	-	-	-	-	-	0.0	-	-	-	-	-
Total Assets	16.7	18.4	19.9	16.1	22.1	17.9	13.9	19.7	37.8	18.6	16.1	19.7	17.0	14.5
Liabilities & Shareholders' Equity:														
Accounts payable	0.6	0.7	0.7	0.6	0.3	0.3	0.3	0.3	1.5	0.7	0.6	0.3	0.3	0.3
Accrued expenses	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.3	0.2	0.2	0.2	0.2
Due to employees	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Related party loan	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1
Deferred rent - current portion	-	0.0	-	0.0	0.0	0.0	0.0	0.0	-	-	0.0	0.0	0.0	0.0
Convertible note	3.0	-	-	-	-	-	-	-	-	5.0	-	-	-	-
Derivative instruments - current portion	0.0	-	-	-	-	-	-	-	0.4	0.1	-	-	-	-
Total Current Liabilities	4.9	2.0	2.0	1.9	1.7	1.7	1.7	1.7	3.3	7.2	1.9	1.7	1.7	1.7
Derivative instruments - net of current portino	3.5	10.0	8.8	7.0	7.0	7.0	7.0	7.0	6.5	2.2	7.0	7.0	7.0	7.0
Deferred revenue	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Deposits held	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	-	-	0.0	0.0	0.0	0.0
Deferred rent	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Other long-term obligations	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total Liabilities	8.6	12.1	10.9	9.0	8.8	8.8	8.8	8.8	10.0	9.5	9.0	8.8	8.8	8.8
Stockholders' Equity	8.1	6.2	9.0	7.0	13.3	9.1	5.1	11.0	27.9	9.1	7.0	11.0	8.3	5.7
Total Liabilities & Equity	16.7	18.4	19.9	16.1	22.1	17.9	13.9	19.7	37.8	18.6	16.1	19.7	17.0	14.5

Source: Bloomberg LP; Company reports; Laidlaw & Company estimate

Figure 5: Cash Flow Statement

CEL-SCI Corp.	FY_10	FY_11	FY_12	FY_13E	FY_14E	FY_15E
<i>Non-GAAP Cash Flow Cont. Ops. (\$ millions, except per share data)</i>	Sept	Sept	Sept	Sept	Sept	Sept
Cash flows from operating activities:						
Net income	10.5	(25.7)	(15.5)	(18.7)	(20.3)	(22.1)
<i>Adjustments to reconcile net income to net cash provided by operating activities:</i>						
Depreciation and amortization	0.5	0.5	0.5	0.4	0.4	0.5
Issuance of convertible notes and preferred stock in legal settlement	1.2	0.2	-	-	0.8	1.7
Issuance of common stock, warrants and options for services	-	9.0	0.5	-	1.0	2.0
Amortization of loan premium	(0.0)	-	-	-	-	-
Extension of options issued to consultants	0.0	0.0	0.1	-	-	-
Extension of options issued to employees	0.2	0.1	0.0	-	-	-
Employee option cost	1.3	1.5	2.2	2.0	-	-
Common stock contributed to 401 (k) plan	0.1	0.2	0.2	-	-	-
Impairment loss on abandonment of patents	0.0	0.0	0.0	-	-	-
Loss on retired equipment	0.0	0.0	0.0	0.0	-	-
Deferred rent	(0.0)	(0.0)	-	0.4	0.4	0.4
Gain on derivative instruments	(28.8)	(4.4)	(1.9)	-	-	-
Other				-	-	-
Changes in assets and liabilities:						
Decrease (increase) in deposits	1.6	(1.7)	-	-	-	-
Decrease (increase) in receivables	-	(0.5)	0.3	0.1	-	-
Decrease in deferred rent asset	1.0	0.6	0.6	0.4	0.4	0.4
Decrease (increase) in prepaid expenses	(0.3)	(1.7)	0.8	-	-	-
Decrease (increase) in inventory for R&D and manufacturing	(1.1)	(0.1)	0.2	(0.0)	(0.2)	(0.3)
Decrease in accounts payable	0.7	(0.8)	(0.2)	0.2	-	-
(Decrease) increase in accrued expenses	0.1	0.1	(0.1)	-	-	-
Increase in deferred revenue	0.1	-	0.0	-	-	-
Increase (decrease) in due to employees	(0.0)	(0.0)	(0.0)	-	-	-
Increase in deposits held	-	-	0.0	-	-	-
Decrease in deferred rent liability	(0.0)	-	0.0	-	-	-
Net cash provided by (used in) operating activities	(12.8)	(22.6)	(12.2)	(15.2)	(17.5)	(17.5)
Operating Cash Flow per share	(\$0.26)	(\$0.11)	(\$0.05)	(\$0.05)	(\$0.05)	(\$0.04)
Cash flow from investing activities:						
Additional investment in manufacturing facility	(0.0)	-	-	-	-	-
Decrease in restricted cash	0.0	0.0	-	-	-	-
Purchases of equipment	(0.5)	(0.2)	(0.1)	(0.1)	-	-
Expenditures for patent costs	(0.0)	(0.1)	(0.1)	(0.1)	(0.1)	(0.1)
Cash provided by investing activities	(0.5)	(0.3)	(0.1)	(0.1)	(0.1)	(0.1)
Cash flows from financing activities:						
Proceeds from issuance of common stock	-	3.9	14.3	19.9	15.0	15.0
Proceeds from exercise of warrants and stock options	6.3	0.7	2.7	-	-	-
Payments for repurchase of preferred stock	-	(4.1)	-	-	-	-
Payments on convertible debt	-	-	(5.0)	-	-	-
Cash (used in) provided by financing activities	6.3	0.6	12.0	19.9	15.0	15.0
Net (decrease) increase in cash and cash equivalents	-	(7.0)	(0.3)	4.5	(2.6)	(2.6)
Cash and cash equivalents at beginning of the period	33.6	26.6	4.3	3.9	8.5	5.9
Cash and cash equivalents at end of period	-	26.6	4.3	3.9	5.9	3.3

Source: Bloomberg LP; Company reports; Laidlaw & Company estimates

DISCLOSURES:

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Additional information available upon request.

RATINGS INFORMATION

Rating and Price Target Change History



3 Year Rating Change History

Date	Rating	Closing Price (\$)
01/15/2013	Buy (B)	0.28*

3 Year Price Change History

Date	Target Price (\$)	Closing Price (\$)
01/15/2013	0.75	0.28*

* Previous Close 1/14/2013

Source: Laidlaw & Company

Created by: Blue-Compass.net

Laidlaw & Company Rating System*		% of Companies Under Coverage With This Rating	% of Companies for which Laidlaw & Company has performed services for in the last 12 months	
			Investment Banking	Brokerage
Strong Buy (SB)	Expected to significantly outperform the sector over 12 months.	0.00%	0.00%	0.00%
Buy (B)	Expected to outperform the sector average over 12 months.	100.00%	0.00%	0.00%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	0.00%	0.00%	0.00%
Sell (S)	Returns expected to significantly underperform the sector average over 12 months.	0.00%	0.00%	0.00%

ADDITIONAL COMPANIES MENTIONED

Orient Europharma Co. Ltd. (4120 TT, Not Rated)
Teva Pharmaceutical-SP ADR (TEVA, Not Rated)

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