

QUARTERLY UPDATE

Business Update: Multikine[®], a Second-Generation Cancer Vaccine

Snapshot

June 21, 2010

CEL-SCI Corp. ("CEL-SCI" or "the Company") develops cancer and infectious disease products that empower immune system defenses. CEL-SCI's lead product candidate is Multikine[®], a non-toxic, second-generation cancer immunotherapy. The immunotherapy field recently gained momentum with the launch of Dendreon Corp.'s (DNDN-NASDAQ) Provenge[®], which in April 2010 became the first FDA-approved therapeutic cancer vaccine. Provenge[®], a treatment for prostate cancer, validated the possibility of harnessing the human immune system against a patient's own cancer. CEL-SCI's Multikine[®] immunotherapy, designated as an Orphan Drug by the FDA, is poised to enter a global Phase III trial in the second half of 2010 for advanced primary head and neck cancer. Multikine[®] has several novel characteristics that may differentiate it from the present generation of cancer vaccines: (1) in contrast to many autologous approaches, which must be made specific to each patient, Multikine[®] can be used off-the-shelf, thus large-scale manufacturing is possible; (2) Multikine[®] offers both active and passive immunity, indicating that no outside antigen is needed; and (3) Multikine[®] is administered to patients when the immune system is strongest (before surgery, radiation, or chemotherapy), which CEL-SCI has found to be an optimal time for inducing an effective anti-tumor immune response. Multikine[®] has been shown to kill ~50% of tumor cells before standard treatments commence. As well, it renders residual cancer cells that survive treatment more susceptible to radiation and chemotherapy.



CEL-SCI Corp.
8229 Boone Blvd., Suite 802
Vienna, VA 22182
Phone: (703) 506-9460
Fax: (703) 506-9471
www.cel-sci.com

Recent Financial Data

Ticker (Exchange)	CVM (NYSE Amex)
Recent Price (06/21/2010)	\$0.51
52-week Range	\$0.37 - \$2.10
Shares Outstanding*	~204.7 million
Market Capitalization	~\$104.4 million
Average 3-month Volume	~1.2 million
Insider Owners +5%	11.0%
Institutional Owners	6.8%
EPS (Qtr. ended 03/31/2010)	(\$0.01)
Employees	42



* As of May 10, 2010.

Key Points

- In over 220 patients treated to date, Multikine[®] has been reported to be safe and well tolerated, improving overall survival by 33% at a median of 3.5 years following surgery versus that attained using the standard of care without Multikine[®]. CEL-SCI believes that positive outcomes in the upcoming Phase III trial may allow Multikine[®] to be routinely included as part of the standard of care for all advanced primary head and neck cancer patients.
- Multikine[®] is designed to be injected in the period between diagnosis and surgery; thus, it does not delay surgery. Due to lengthy manufacturing processes, CEL-SCI believes that many alternative cancer vaccine technologies are not able to be administered before the standard of care as they would delay surgery. To the Company's knowledge, no other comprehensive anticancer immunotherapies are being developed for first-line treatment in this manner.
- CEL-SCI has built and validated a 73,000 ft² current Good Manufacturing Practices (cGMP) facility to produce Multikine[®] for Phase III trials and commercial sales. The Company intends to use the facility for contract manufacturing as well, as it includes cold 4°C Aseptic Filling—an important production component for many biodefense and biologic products. CEL-SCI is not aware of any other U.S. facility that can provide cold 4°C finish and fill services on a contract basis.
- Additionally, in November 2009, CEL-SCI began the first stage of a clinical study using an H1N1 LEAPS[™] conjugate technology at the Johns Hopkins University Hospital. This study is designed to develop *in vitro* data to justify moving forward into the clinic with the development of a treatment for hospitalized H1N1 patients.
- CEL-SCI's leadership is highly experienced in the pharmaceutical industry. Most of the management has been with the Company for over 15 years. At March 31, 2010, CEL-SCI's cash position was over \$34 million.

PLEASE REFER TO THE EXECUTIVE INFORMATIONAL OVERVIEW[®] (EIO[®]), 01/21/2010, FOR A FULL COMPANY REPORT.

Recent Events and Financial Results

Recent Events

Within the past 12 months, CEL-SCI achieved the following: (1) completed and validated the manufacturing facility for Multikine[®], a critical step before being able to manufacture Multikine[®] for the Phase III clinical trial; (2) furthered development of a treatment for H1N1-hospitalized patients by launching a clinical trial of the treatment at Johns Hopkins University; (3) raised over \$40 million in new capital; and (4) added a new marketing partner, Byron Biopharma, for Multikine[®] in South Africa. An overview of the Company's recent news is provided below, referring the reader to CEL-SCI's website for complete press releases (www.cel-sci.com).

- *On May 27, 2010*, CEL-SCI announced that Dr. Eyal Talor, the Company's chief scientific officer, was delivering a featured presentation titled "Latest Clinical Results Using Multikine[®] Immunotherapy for Cancer" at the "Targeted Cancer Therapies" conference in London, UK. The presentation highlighted the role of Multikine[®] as a potential treatment for head and neck cancer, and included a discussion of Phase II clinical results and details on the Company's upcoming Phase III pivotal study.
- *On May 17, 2010*, the Company reported financial results for the quarter ended March 31, 2010, which are detailed on page 3.
- *On May 5, 2010*, CEL-SCI provided an update on its planned Phase III clinical trial of Multikine[®]. The Company, together with its development partners Teva Pharmaceuticals Industries Ltd. (TEVA-NASDAQ) and Orient Europharma Co., Ltd. (4120-TPO), had selected 40 of the 50 global medical centers planned to conduct the trial. In addition, all major vendors for the study had been chosen. CEL-SCI expects to enroll the first patient in the study during the second half of 2010.
- *On March 10, 2010*, the Company announced that it received a \$125,000 payment from Byron Biopharma LLC under its licensing agreement where CEL-SCI granted Byron an exclusive license to market and distribute Multikine[®] in the Republic of South Africa. CEL-SCI plans to keep the European and U.S. marketing rights for the head and neck cancer indication in-house.
- *On February 22, 2010*, CEL-SCI and its scientific collaborators announced that the Company's CEL-2000 vaccine demonstrated that it could block the progression of rheumatoid arthritis (RA) in a mouse model. The results were published in the peer-reviewed *Journal of International Immunopharmacology* (online edition) in an article titled "CEL-2000: A Therapeutic Vaccine for Rheumatoid Arthritis Arrests Disease Development and Alters Serum Cytokine/Chemokine Patterns in the Bovine Collagen Type II Induced Arthritis in the DBA Mouse Model" with lead author Dr. Daniel Zimmerman. The study was co-authored by scientists from CEL-SCI, Washington Biotech, Northeastern Ohio Universities Colleges of Medicine and Pharmacy (NEOUCOM), and Boulder BioPath.
- *On February 17, 2010*, CEL-SCI released a letter to its shareholders detailing the milestones reached over the prior year as well as updating shareholders on the status of the development programs for Multikine[®] and the H1N1 treatment.
- *On February 16, 2010*, the Company reported financial results for the quarter ended December 31, 2009. CEL-SCI reported that net income available to shareholders for the quarter ended December 31, 2009, was \$19,159,517, or \$0.10 per share (basic), versus a loss of \$2,173,513, or \$0.02 per share, during the same quarter in fiscal year 2009.

Three-Month Financial Results for the Quarter Ended March 31, 2010

On May 17, 2010, CEL-SCI reported financial results for its fiscal second quarter ended March 31, 2010. The Company's fiscal year ends on September 30.

For the three months ended March 31, 2010, CEL-SCI had research and development (R&D) expenses of \$3.3 million versus \$1.2 million for the year-ago period due to continuing expenses relating to preparation for the upcoming Phase III clinical trial of Multikine[®]. CEL-SCI plans to initiate a pivotal Phase III trial of this candidate during the second half of 2010. General and administrative expenses for the second quarter FY 2010 were nearly \$1.9 million versus \$1 million for the second quarter FY 2009.

CEL-SCI's net loss for the quarter was \$0.7 million, or (\$0.01) per share (basic), versus a loss of \$2.1 million, or (\$0.02) per share, for the same quarter of fiscal year 2009. The second quarter FY 2010 loss was reduced by a gain on derivative instruments of \$4.5 million.

Six-Month Financial Results

On May 17, 2010, CEL-SCI also reported financial results for the six months ended March 31, 2010.

For the six months ended March 31, 2010, CEL-SCI's R&D expenses were \$6.1 million versus \$2.7 million for the year-ago period. General and administrative expenses for the six months were \$3.2 million versus \$2.1 million for the first six months of FY 2009.

Net income available to shareholders for the six months was approximately \$17 million, or \$0.09 per share (basic), versus a net loss of \$4.3 million, or (\$0.03) per share, during the same six months in fiscal year 2009. The gain on net income for the six months ended March 31, 2010, was due to a gain on derivative instruments of over \$27.8 million during the period.

As of March 31, 2010, CEL-SCI had cash and cash equivalents of approximately \$34 million versus over \$36 million in cash and cash equivalents at December 31, 2009. The Company believes that it has sufficient funds to support its operations for more than the next 12 months.

The Company is able to self-fund its upcoming Phase III study of Multikine[®], which may rank among the largest head and neck cancer Phase III trials ever conducted, and is working closely with its partners Teva and Orient Europharma for a successful launch. The net cost of the clinical trial is estimated to be \$25 million. CEL-SCI entered into licensing agreements with Teva and Orient Europharma to help facilitate and fund the Phase III trials.

Head and Neck Cancer

Head and neck cancer ranks among the most frequently occurring cancers worldwide. Several hundred thousand individuals are newly diagnosed with the disease each year. In the U.S., head and neck cancer accounts for between 3% and 5% of malignancies (Source: American Society of Clinical Oncology 2009). This group of cancers includes tumors in the cheeks, lips, gums, tongue, mouth floor, salivary glands, paranasal sinuses and nasal cavity, larynx (voice box), and lymph nodes. In total, there are more than 30 locations in the head and neck where these cancers can develop.

It is estimated that more than half of the patients diagnosed with head and neck cancer globally die of the disease (Source: *Science Centric* November 2008). The high mortality rate is largely due to metastasis (spread) and recurrence, even after the tumor has been surgically removed and the patient has received follow-up treatment. Between 10% and 40% of patients whose oral cancer is considered “cured” are likely to be diagnosed with cancer of the oral cavity again or with cancer of a nearby organ, such as the larynx, esophagus, or lung (Source: the American Cancer Society [ACS]).

For head and neck cancer patients, the standard of care (the accepted level of care that physicians are expected to routinely administer to all patients after diagnosis) is surgery followed by radiation. If patients exhibit micrometastases (cancer resulting from the spread of the original tumor) around where the tumor was removed or in the nearby lymph nodes after surgery, they receive concurrent radiation and chemotherapy instead of only radiation. After surgery, patients have a variety of options for secondary follow-on treatments that may accompany radiation and chemotherapy, such as immunotherapy.

Cancer Market

In the U.S., men have slightly less than a 1 in 2 risk of developing cancer over their lifetime. For women, the risk is a little more than 1 in 3 (Source: *Cancer Facts & Figures 2009*). Thus, the oncology market is one of the largest pharmaceutical markets. With the introduction of improved treatments, it is expected to continue to expand. The global market for cancer therapies was estimated at \$47.3 billion in 2008, which could increase to \$110.6 billion by 2013 (Source: BBC Research and Consulting’s *Cancer Therapies: Technologies and Global Markets* May 2008). In particular, treatment of head and neck cancer in the U.S. is valued at approximately \$3.2 billion annually (Source: *Med Ad News* February 2008).

Immunotherapy

The oncology market encompasses four key segments: (1) targeted therapy, including both small molecules and antibodies; (2) chemotherapy; (3) hormone therapy; and (4) immunotherapy, the segment where Multikine[®] is positioned. Immunotherapy utilizes the body’s immune system to fight invading microorganisms and cancers while trying not to harm the surrounding healthy cells. There are a variety of available immunotherapies that can be classified as either passive agents, which are immune system components (e.g., antibodies) created outside the body and then administered to a patient, or active agents, which directly trigger the immune system *in vivo* to attack cancer cells. CEL-SCI’s Multikine[®] is a novel comprehensive immunotherapy that possesses both passive and active anticancer immune response characteristics. To CEL-SCI’s knowledge, it is the only entity presently seeking to commercialize a comprehensive immunotherapy that could be administered in the intervening time between diagnosis and when patients undergo surgery.

CEL-SCI believes that the low rate of long-term survival for head and neck cancer patients is due in part to inadequacies within the current standard of care and limitations, including the design of available immunotherapies, as summarized below and on page 6.

- It is not always possible to entirely remove a tumor and its surrounding metastases by surgery alone.
- Concurrent radiation and chemotherapy can be highly toxic to patients, causing severe side effects and potentially death in many individuals—effects that are amplified when other treatments that have their own toxicities are added to these procedures and given to the same patient.

- Presently, immunotherapies are administered after the immune system is already weakened by surgery, radiation, and chemotherapy or, at earliest, in conjunction with radiation or chemotherapy.
- Many immunotherapies only target one cancer-related antigen (e.g., monoclonal antibodies [MAbs]). Since cancer cells and their antigens can mutate both as tumors grow and in response to treatment, they are able to evade subsequent attack by the same agent. In addition, for any given type of cancer, the same antigen is not always guaranteed to be present on every patient's tumor. This limits the usefulness of a monospecific immunotherapy to only those patients whose tumor expresses the antigen against which the immunotherapy is directed.

Conversely, CEL-SCI's multi-targeted therapy, Multikine[®], is directed at several targets on the cancer cell and activates multiple cellular components of the immune system in order to more effectively fight cancer. The compound kills tumor cells and at the same time activates a robust anti-tumor immune response.

CEL-SCI believes that the successful outcome of Dendreon Corp.'s study with Provenge[®], which has become the first vaccine approved to treat prostate cancer, validated the cancer immunotherapy field by demonstrating the possibility of harnessing the human immune system against a patient's own cancer. In its pivotal Phase III IMPACT study, Dendreon found that administering Provenge[®] to men with advanced prostate cancer improved their overall survival versus a placebo control. Subsequently, on April 29, 2010, the U.S. Food and Drug Administration (FDA) approved Provenge[®] for the treatment of men with advanced prostate cancer. Dendreon's success has renewed the investment community's interest in cancer immunotherapy companies. As of June 21, 2010, Dendreon's 52-week range was \$21.25 to \$57.67, with a closing share price of \$36.83 on June 21st.

Multikine[®] Versus Autologous Manufacture

A significant limitation of immunotherapy technologies is that many are autologous in nature, indicating that they are made from the cancer patient's own tissues and are intended to treat only that patient. This can be a costly, labor-intensive process that does not easily lend itself to mass production. For instance, treatment with Provenge[®] requires that cells be removed from the patient, transported to Dendreon's facilities where they are treated with Provenge[®] and tested for purity and potency, and then returned back to the physician for infusion into the patient. Because each dose is unique to the patient, Dendreon cannot warehouse drugs. Dendreon is expected to be able to provide only approximately 2,000 doses of Provenge[®] within the first year, for which a full course of therapy is estimated to cost patients as much as \$93,000.

In contrast, Multikine[®] is not an autologous therapy. It is composed of a patented and reproducible mixture of cytokines—regulatory proteins produced by the immune system that affect cell behavior and communication. Multikine[®] can be mass produced like other pharmaceuticals to exact specifications under cGMP, and is an “off-the-shelf” product that can be readily and immediately available for use by physicians. CEL-SCI estimates that it presently has the manufacturing capacity for as many as 20,000 treatments annually, with the ability to ramp-up to approximately 60,000 treatments within a year.

Multikine[®]: An Immune Simulator

Multikine[®] (Leukocyte Interleukin, Injection) is the first immunotherapeutic agent in a new class of drugs called immune simulators, which closely imitate the behavior of a healthy person's immune system. It is a multi-targeted combination of immune components that simultaneously initiates a direct and targeted killing of specific tumor cells while the immune system develops a solid, multifaceted attack. Multikine[®] is the first immunotherapeutic agent designed to be administered to patients before surgery as a first-line standard of care, when the immune system is still intact and capable of launching its most effective anti-tumor immune response.

CEL-SCI has conducted a series of Phase I and Phase II clinical trials in over 220 patients throughout the U.S., Europe, Canada, and Israel, which have demonstrated that Multikine[®] is safe and well tolerated, with significant clinical impact. Importantly, there have been no reported severe adverse events associated with the use of Multikine[®] in the Company's trials. In the most recently completed Phase II trial, patients treated with Multikine[®] plus the standard of care had an average 33% improvement in their 3.5 year median overall survival versus the average survival of a historical control group. The control data was derived from 55 publications in peer-reviewed medical journals between 1987 and 2007 for patients who were given only the standard of care. Moreover, 12% of Multikine[®]-treated oral squamous cell carcinoma patients in Phase II had a complete response (CR) as determined by clinical examination and histopathology of surgical specimens. Not only was there was no clinical evidence of cancer remaining after three weeks of treatment with Multikine[®] but there was also no microscopic evidence of the disease (Source: *Journal of Clinical Oncology* 2005).

Researchers have found that Multikine[®] kills an average of 50% of tumor cells before the standard of care treatments (including surgery) are even initiated. As such, CEL-SCI believes that Multikine[®] is aligned with recent healthcare trends, which have emphasized increasing cost effectiveness. Through administration as a first-line therapy, Multikine[®] is designed to increase the effectiveness of the standard-of-care treatments and decrease the risk of tumor recurrence. CEL-SCI hopes to use the results of its upcoming Phase III trial to establish a new standard of care that includes Multikine[®]. The Company's goal is for every head and neck cancer surgeon to prescribe Multikine[®] prior to surgery.

Multikine[®] was featured in *Med Ad News*' Eighth Annual Future Blockbusters Report as one of 10 medicines *Med Ad News* expects to eventually receive FDA approval, in addition to surpassing \$1 billion in annual sales. *Med Ad News* anticipated the included potential blockbusters to emerge in the 2009 to 2011 period (Source: *Med Ad News* February 2008).

Upcoming Phase III Trial

In June 2007, the FDA granted Multikine[®] Orphan Drug status as a neoadjuvant therapy in patients with squamous cell carcinoma of the head and neck, which may enable an accelerated approval process, among other significant benefits (detailed on page 32 of the base EIO[®]). In addition, Multikine[®] has been cleared by the FDA and Canadian regulators for a global Phase III clinical trial designed to support marketing approval in newly diagnosed head and neck cancer. In early 2010, CEL-SCI completed the construction and validation of a dedicated manufacturing facility for Multikine[®] (as described on pages 39-40 of the EIO[®]), which is intended to produce quantities of the compound for Phase III trials as well as for subsequent commercialization.

CEL-SCI is poised to initiate a global, open-label, well-controlled Phase III clinical study to examine the potential benefits of adding Multikine[®] to the first-line standard of care for advanced primary head and neck cancer. CEL-SCI plans to conduct the Phase III trial at multiple centers throughout North America, the European Union (EU), and Asia, and intends to enroll the first patient during the second half of 2010. By early May 2010, the Company reported that 40 of the 50 global medical centers anticipated to serve as trial sites had been selected. In addition, all major vendors for the study have been chosen.

The study has a targeted enrollment of approximately 880 participants in order to have approximately 780 patients available for complete follow-up. The Company believes this represents a sufficient number of patients to support a statistical finding that treating advanced primary head and neck cancer patients with Multikine[®] prior to surgery and follow-on therapies increases overall survival in this patient population. To avoid confounding results in the Phase III data, CEL-SCI has designed its Phase III study of Multikine[®] so that the drug is administered at the same time (prior to surgical removal of the patient's tumor) and in the exact same dose, route, and frequency of administration as it was during the final proof-of-concept Phase II study. The Company expects this to increase the likelihood of the Phase III results mirroring the Phase II data and the Phase III endpoint being met.

To CEL-SCI's knowledge, this trial may be the first Phase III study worldwide in which cancer immunotherapy is given to treatment-naïve patients—before surgery, radiation, or chemotherapy. This technique is designed to stimulate a stronger anti-tumor immune response, as the immune system is still competent.

Strategic Collaborations

The Phase III trial for Multikine[®] is being launched in collaboration with Teva and Orient Europharma, two of the Company's strategic partners. CEL-SCI has outlicensed rights for marketing and distributing Multikine[®] in emerging markets to Teva, Orient Europharma, and Byron Biopharma, and continues to pursue additional licensees. Teva holds an exclusive license to market and distribute Multikine[®] for head and neck cancer in Israel and Turkey. Orient Europharma's license agreement pertains to Taiwan, Singapore, Hong Kong, Malaysia, South Korea, the Philippines, Australia, and New Zealand. Byron holds an exclusive license to market and distribute Multikine[®] in the Republic of South Africa. Greater details of these relationships and the Company's licensing strategy are provided on page 9 of the base EIO[®].

Treatment Vaccines Using LEAPS[™] Technology

CEL-SCI's LEAPS[™] technology aims to more effectively fight bacterial, viral, and parasitic infections as well as malignant and autoimmune diseases by selectively stimulating the immune system against these ailments. LEAPS[™] conjoins a patented T-cell binding ligand with a small, disease-associated peptide antigen. In this way, CEL-SCI is attempting to imitate the cell-to-cell interactions that typically occur on the surface of the T-cell when a disease-associated peptide antigen is presented to the T-cell. In addition, LEAPS[™] conjugates may overcome viral mutations by focusing on more conserved and common epitopes for critical viral function. The Company believes that any disease for which an antigenic sequence has been identified, such as infectious, parasitic, malignant, or autoimmune diseases and allergies, are potential therapeutic or preventive sites for the application of LEAPS[™] technology.

Protection in various animal challenge models has been shown against a variety of diseases, such as herpes simplex virus, viral encephalitis, and malaria, among others. At present, the Company is conducting a clinical study of a potential treatment for H1N1 hospitalized patients using a LEAPS[™] construct and is also performing preclinical research on a number of disease targets, most notably a treatment vaccine for rheumatoid arthritis (RA) called CEL-2000.

The Company's Investigational H1N1 Treatment

A new strain of the flu known as H1N1 swine influenza emerged in Mexico in early 2009 and reached pandemic status in June 2009. Currently, the majority of patients infected with swine-origin H1N1 experience mild symptoms and are treatable with Roche Laboratories' Tamiflu[®] or GlaxoSmithKline plc's (GSK-NYSE) Relenza[®]. However, for a subset of patients, H1N1 is a very severe, potentially fatal illness. This pandemic has been responsible for over 18,100 laboratory-confirmed deaths worldwide and was predicted to cause many more deaths. President Barack Obama's advisory group on science and technology released a report in August 2009 noting that as many as 300,000 people in the U.S. may be sickened severely enough to require hospitalization in the intensive care unit (ICU).

Additionally, 67 cases of Tamiflu[®]-resistant H1N1 have been identified in the U.S. (and nearly 300 worldwide) as of May 28, 2010 (Source: the U.S. Centers for Disease Control and Prevention [CDC]). Moreover, antivirals are considerably less effective if they are not initiated within two days of the onset of flu symptoms. A study conducted by the CDC from April 2009 to June 2009 found that 90% of the U.S. patients who died from H1N1 during this time had received antivirals and antibiotics, but did not begin treatment until an average of a week after flu onset (Source: *New England Journal of Medicine* October 2009). As such, CEL-SCI is aggressively pursuing the development of therapeutic vaccine approaches that its scientists have pioneered. The Company is focused on the victims of H1N1 who have been hospitalized and are fighting for their lives.

In November 2009, following an FDA review of CEL-SCI's submission, the Company launched its initial clinical study of its treatment for hospitalized H1N1 patients at the Johns Hopkins University Hospital. CEL-SCI intends to use the LEAPS[™] vaccine technology to convert the white blood cells of individuals infected with the H1N1 influenza virus into cells that are targeted for killing the patient's influenza-infected cells. By employing its LEAPS-H1N1 construct, the Company hopes to be able to increase the likelihood of survival for hospitalized H1N1-infected patients in situations where antivirals (e.g., Tamiflu[®] or Relenza[®]) have been administered too late in the disease process to be effective as well as in cases where the virus has become resistant to antivirals or in patients for whom the antivirals do not seem to be

effective in eliminating the virus. The Company believes that showing promise as well as safety in its first trial could lead to accelerated review and Emergency Use Authorization or product approval.

While at present H1N1 cases appear to be greatly reduced, the Company believes that the virus will likely return in a mutated form, potentially recombined with the deadly Avian Flu virus.

Combating a Potentially Fatal Cytokine Storm

A group of Brazilian researchers who have been performing autopsies of H1N1 swine influenza victims have found that some patients showed traces of a “cytokine storm” in their lung tissue that led to acute lung injury and fatal respiratory failure (Source: Medical News Today [www.medicalnewstoday.com] December 23, 2009). Cytokine storm entails a potentially fatal pro-inflammatory cytokine response that can follow the natural response to infection. In essence, it occurs when the immune system’s response to an infection is too strong, causing more detriment to bodily tissue at the infection site than the virus. One of the main characteristics of the LEAPS™ technology is that it seeks to induce a potent immune response while avoiding the administration of regions of H1N1 and other viruses that may exacerbate cytokine storm. In November 2009, CEL-SCI’s collaborators at the Northeastern Ohio Universities Colleges of Medicine and Pharmacy (NEOUCOM) presented data at GTCbio’s 7th Annual Vaccines: “All Things Considered” conference demonstrating that LEAPS™ converts precursor murine or human cells into dendritic immune cells, which then produce the cytokine interleukin (IL)-12 without stimulating over-production of cytokines (i.e., avoiding cytokine storm).

CEL-2000

In June 2008, CEL-SCI announced the discovery of a novel peptide to treat RA called CEL-2000. The peptide was discovered as part of the Company’s ongoing LEAPS™ technology research and development. Data results of a LEAPS™ construct for RA have shown that LEAPS™ reduces the production of pro-inflammatory cytokines in order to block the progression of RA in mouse models. The peptide has been compared to Enbrel®, an RA treatment, and was tested in a well-established animal model of RA. The research suggests that CEL-2000 may be equivalent or even superior to Enbrel® in symptom suppression and slowing disease progression in mice. In addition, CEL-2000 has been shown to be safe and well tolerated without any adverse effects. The Company believes that CEL-2000 has the potential to be less invasive, require fewer and smaller doses, have lower toxicity, be more disease-specific, be less costly, and be applicable to patients who are not able to take or who are unresponsive to existing anti-arthritis therapies.

In February 2010, data was published in the online edition of the *Journal of International Immunopharmacology* demonstrating that CEL-2000 appeared to block the progression of RA in a mouse model. The research was conducted by scientists from CEL-SCI, Washington Biotech, NEOUCOM, and Boulder BioPath. CEL-2000, administered after disease symptoms commenced, had statistical significance at preventing the further development of arthritic conditions, including joint swelling and deformation, bone and cartilage changes, and was accompanied by serum cytokine alterations over the CEL-2000 treatment period with comparable or better activity than Enbrel®. CEL-SCI believes that this data is encouraging both for the RA vaccine as well as in support of the Company’s H1N1 treatment currently under development.

Contract Manufacturing Services

To produce quantities of its head and neck cancer candidate, Multikine®, for use in Phase III trials and for possible subsequent commercial sale, CEL-SCI built out a \$22 million, cGMP production facility in a 73,000-square foot building near Baltimore, Maryland. The facility was specially designed for Multikine® production and includes cold 4°C Aseptic Filling, which the Company believes is not available for contract manufacturing elsewhere. A “True cold-fill” suite cools the fill room environment to the desired temperature prior to aseptic filling and packaging to allow the maintenance of the finished product at the desired temperature. CEL-SCI’s True cold-fill can be operated at temperatures between 4°C and room temperatures and includes humidity control.

CEL-SCI expects to capitalize on the benefits of its True cold-fill suite when providing contract manufacturing services at the Baltimore production facility, subject to the work not interfering with the primary project, which is Multikine[®] cancer therapy. Cold-fill is an important production component for many biodefense and biologic products. Biologics represent one of the most rapid areas of growth in the pharmaceutical/biopharmaceutical market. The market for biologic products is currently approximately \$112 billion, and this class of drugs is expected to equal the FDA's new drug approvals for traditional, chemical pharmaceuticals within a few years (Source: *San Francisco Chronicle* December 6, 2009). CEL-SCI's aseptic filling process circumvents the loss of biological activity that is often encountered when an aseptic cold-fill is not available and may accelerate time to market by eliminating complicated, costly, and time-consuming validation studies and tests required when biologic products are filled at room temperature. The Company believes that this process is also likely to save money in the production of follow-on biologics and biosimilars (the general equivalent of generics in the biological arena), which could be approved in the U.S. in the future.

Headquarters and Employees

CEL-SCI was formed as a Colorado corporation in 1983. It is now headquartered in the Washington, D.C. area, in close proximity to the FDA and the National Cancer Institute (NCI). The Company also leases laboratory space in Baltimore, Maryland, and has entered into a 20-year lease (with an option to buy) for the 73,000-square foot manufacturing facility in Baltimore. CEL-SCI trades on the NYSE Amex under the symbol "CVM," and employs 42 individuals.

Key Points to Consider

- CEL-SCI is a biotechnology company developing products to empower immune system defenses. Its primary product candidate is Multikine[®], a second-generation cancer vaccine. Multikine[®] is poised to enter Phase III clinical trials as a first-line treatment for advanced primary head and neck cancer. CEL-SCI intends to initiate the trial at multiple centers globally during 2010.
- Multikine[®] is the first immunotherapeutic agent being developed as a first-line standard of care for cancer patients. CEL-SCI designed Multikine[®] in this manner to capitalize on an intact immune system before it is weakened by surgery, radiation, or chemotherapy. In later cancer stages, the Company believes that the immune system is less likely to wage an effective anti-tumor response.
 - Researchers have found that Multikine[®] kills an average of 50% of tumor cells before the standard of care treatments (including surgery) are even initiated.
 - As such, CEL-SCI believes that Multikine[®] is aligned with recent healthcare trends, which have emphasized increasing cost effectiveness. Through administration as a first-line therapy, Multikine[®] is designed to increase the effectiveness of the standard-of-care treatments and decrease the risk of tumor recurrence.
- In Phase II, Multikine[®]-treated patients had an average 33% improvement in median overall survival versus patients who were given only the current standard of care. In comparison, the majority of cancer blockbusters have received FDA approval after demonstrating only a 10% survival rate increase in Phase III trials. After three weeks of treatment, 12% of Multikine[®] patients experienced a complete response (CR), where the tumor was fully eliminated (as determined by histopathology).
- The Company hopes to use the results of its upcoming Phase III trial to commercialize Multikine[®] as an integral and vital part of the standard of care, where ideally every head and neck cancer surgeon would prescribe Multikine[®] before surgery. Becoming part of the standard of care may provide CEL-SCI with reimbursement coverage and could positively influence the therapy's adoption and usage.
- The composition and distinct modes of action of Multikine[®] cause a direct, multi-targeted killing of tumor cells, produce a robust and sustainable anti-tumor response, impede cancer recurrence, and render residual tumor cells more susceptible to post-surgery treatments. By clearing the tumor metastases, Multikine[®] improves surgeons' abilities to remove the entire tumor and may decrease patients' needs for intensified, highly toxic radiation/chemotherapy regimens after surgery.
- By administering Multikine[®] in the period between diagnosis and surgery, patients can have a proactive approach to treatment instead of only dwelling on their newly diagnosed cancer while waiting for surgery. To CEL-SCI's knowledge, there are no other comprehensive immunotherapies being developed for first-line treatment in this way. Data from Phase II clinical trials suggest that Multikine[®] may also enhance the effectiveness of post-treatment radiation and chemotherapy, if these courses are needed.
- CEL-SCI has conducted a series of Phase I and Phase II clinical trials in over 220 patients throughout the U.S., Europe, Canada, and Israel, which have demonstrated that Multikine[®] is safe and well tolerated, with significant clinical impact. Most importantly, there has not been a single severe adverse event associated with the use of Multikine[®] reported in any of the Company's trials completed to date—an unusual but positive outcome for a cancer treatment.
- In June 2007, the FDA granted Multikine[®] Orphan Drug status as a neoadjuvant therapy in patients with squamous cell carcinoma of the head and neck (head and neck cancer). As an Orphan Drug, Multikine[®] benefits from seven years of market exclusivity in the U.S. after approval, an expedited regulatory process, possibly a high premium, the ability to expand to encompass non-orphan indications, eligibility to be awarded annual grants from the FDA, and tax incentives on clinical trials.

- Whereas many immunotherapy technologies are autologous in nature, which often require costly and time-consuming manufacturing, Multikine[®] can be mass produced like other pharmaceuticals to exact specifications under cGMP. It is an “off-the-shelf” product that can be readily and immediately available for use by physicians.
- In the past, companies have experienced problems gaining FDA approval for commercial pharmaceuticals not manufactured in the same facility as that which was used in the Phase III clinical trial. The Company’s Maryland manufacturing facility is designed to provide tight control over the manufacturing process, which may alleviate concerns over trials and commercial production.
- The Company estimates that the head and neck cancer market for Multikine[®] could be over \$1 billion in the U.S. and \$3 billion in Europe. CEL-SCI’s management believes that it is important that the Company has retained key marketing areas for Multikine[®], potentially enabling a greater upside.
- The oncology market is one of the largest pharmaceutical markets. Globally, the market for cancer therapies was estimated at \$47.3 billion in 2008, which could increase to \$110.6 billion by 2013.
- To generate near-term revenue streams and mitigate risk, CEL-SCI offers contract manufacturing services using its new manufacturing facility, which includes cold 4°C Aseptic Filling—an important production component for many biodefense and biologic products. CEL-SCI is not aware of any other facility in the U.S. that is able to provide cold 4°C finish and fill services on a contract basis.
- In November 2009, CEL-SCI initiated a clinical trial of the Company’s proposed treatment for hospitalized H1N1 patients. CEL-SCI’s H1N1 treatment uses the LEAPS[™] vaccine technology to convert an individual’s white blood cells into cells targeted for killing influenza. LEAPS[™] may be effective against H1N1 as LEAPS[™] conjugates induce a potent immune response without causing excessive amounts of pro-inflammatory cytokines, which may exacerbate illness or become fatal. As hospitalized H1N1 patients are at a risk of death, CEL-SCI believes that any clinical improvement for these patients is important to regulatory agencies and thus may result in an accelerated approval.
- Prior research has been performed on the Company’s LEAPS[™] technology under collaborations with the National Institute of Allergy and Infectious Diseases (NIAID), the U.S. Naval Medical Research Center, the U.S. Army, and the Northeastern Ohio Universities Colleges of Medicine and Pharmacy (NEOUCOM). CEL-SCI believes that its ability to enhance the immune response could benefit patients who typically have a poor response to vaccinations.
- In February 2010, data were published in the *Journal of International Immunopharmacology* (online edition) suggesting that CEL-SCI’s peptide for the treatment of rheumatoid arthritis (RA), CEL-2000, may slow damage caused by RA. These results, which demonstrated a reduction of inflammatory response, also support the H1N1 treatment approach. Based on research thus far, the Company believes that CEL-2000 has the potential to be less invasive, require fewer and smaller doses, have lower toxicity, and be more disease-specific than current treatments.
- CEL-SCI’s intellectual property protection incorporates four measures: (1) a Composition of Matter patent for Multikine[®] until 2024; (2) pending patent applications in the U.S. and under the Patent Cooperation Treaty (PCT); (3) trade secrets, such as quality control; and (4) Orphan Drug status for Multikine[®]. In addition, due to the classification of Multikine[®] as a complex biologic, the Company believes that it may be protected from generic competition.
- CEL-SCI’s leadership is highly experienced in the pharmaceutical industry and most members of management have been with the Company for over 15 years.
- CEL-SCI has raised over \$40 million in new equity since June 24, 2009, and has eliminated its Series K Convertible Notes, which had an initial principal value of \$8.3 million. CEL-SCI’s current financial position allows it to self-fund the Phase III clinical trial, which the Company believes creates advantages for future partnering agreements. As of March 31, 2010, the Company’s cash position was over \$34 million.

Risks

Some of the information in this Quarterly Update relates to future events or future business and financial performance. Such statements can only be predictions and the actual events or results may differ from those discussed due to the risks described in CEL-SCI's statements on Forms 10-K, 10-Q, 8-K, as well as other forms filed from time to time. The content of this report with respect to CEL-SCI has been compiled primarily from information available to the public released by the Company through news releases, Annual Reports, and U.S. Securities and Exchange Commission (SEC) filings. CEL-SCI is solely responsible for the accuracy of this information. Information as to other companies has been prepared from publicly available information and has not been independently verified by the Company. For more complete information about CEL-SCI, please refer to the Company's website at www.cel-sci.com. Additionally, please refer to Crystal Research Associates' base report, the Executive Informational Overview[®] (EIO[®]) dated January 21, 2010, and located on Crystal Research Associates' website at www.crystalra.com for more comprehensive details of CEL-SCI's risk factors.

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Crystal  Research
a s s o c i a t e s

Jeffrey J. Kraws or Karen B. Goldfarb
Phone: (609) 306-2274
Fax: (609) 395-9339
Email: eio@crystalra.com
Web: www.crystalra.com

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