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CEL SCI CORP  
Form 10-K  
December 13, 2010

FORM 10-K

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

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

For the fiscal year ended September 30, 2010.

OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_.

Commission file number 1-11889

CEL-SCI CORPORATION

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

COLORADO

84-0916344

-----  
(State or other jurisdiction  
of incorporation or organization)

-----  
(I.R.S. Employer Identification No.)

8229 Boone Blvd., Suite 802  
Vienna, Virginia

22182

-----  
(Address of principal executive offices)

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(Zip Code)

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

Common Stock, \$.01 par value  
(Title of Class)

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

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

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

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

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

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

Large accelerated filer  Accelerated filer

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

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

The aggregate market value of the voting stock held by non-affiliates of the Registrant, based upon the closing sale price of the common stock on March 31, 2010, as quoted on the NYSE Amex, was \$128,872,039.

As of November 30, 2010, the Registrant had 205,098,121 issued and outstanding shares of common stock.

Documents Incorporated by Reference: None

### PART I

#### ITEM 1. BUSINESS

CEL-SCI Corporation (CEL-SCI) was formed as a Colorado corporation in 1983. CEL-SCI's principal office is located at 8229 Boone Boulevard, Suite 802, Vienna, VA 22182. CEL-SCI's telephone number is 703-506-9460 and its web site is [www.cel-sci.com](http://www.cel-sci.com). CEL-SCI makes its electronic filings with the Securities and Exchange Commission (SEC), including its annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to these reports available on its website free of charge as soon as practicable after they are filed or furnished to the SEC.

#### OVERVIEW

CEL-SCI's business consists of the following:

- 1) Multikine(R) cancer therapy;
- 2) New "cold fill" manufacturing service to the pharmaceutical industry; and
- 3) LEAPS technology, with two products, H1N1 swine flu treatment for H1N1 hospitalized patients and CEL-2000, a rheumatoid arthritis treatment vaccine.

#### MULTIKINE

CEL-SCI's lead product, Multikine, is being developed for the treatment of cancer. It is the first of a new class of cancer immunotherapy drugs called Combination Immunotherapy because it combines active and passive immunity in one product. It simulates the activities of a healthy person's immune system, which battles cancer every day. Multikine is multi-targeted; it is the only cancer

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immunotherapy that both kills cancer cells in a targeted fashion and activates the general immune system to destroy the cancer. CEL-SCI believes Multikine is the first immunotherapeutic agent being developed as a first-line standard of care treatment for cancer and it is cleared for a global Phase III clinical trial in advanced primary (previously untreated) head and neck cancer patients.

Multikine is a new type of immunotherapy in that it is a combination immunotherapy, incorporating both active and passive immune activity. A combination immunotherapy most closely resembles the workings of the natural immune system in the sense that it works on multiple fronts in the battle against cancer. A combination immunotherapy causes a direct and targeted killing of the tumor cells and activates the immune system to produce a more robust and sustainable anti-tumor response.

Multikine is designed to target the tumor micro-metastases that are mostly responsible for treatment failure. The basic concept is to add Multikine to the current cancer treatments with the goal of making the overall cancer treatment more successful. Phase II data indicated that Multikine treatment resulted in a substantial increase in the survival of patients. The lead indication is

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advanced primary (previously untreated) head & neck cancer (about 600,000 new cases per annum). Since Multikine is not tumor specific, it may also be applicable in many other solid tumors.

The following results were seen in CEL-SCI's last Phase II study conducted with Multikine. This study used the same treatment protocol as will be used in CEL-SCI's Phase III study:

- o 33% improvement in median overall survival: In the last Phase II study a 33% improvement in median overall survival, at a median of 3.5 years post surgery, was seen in patients with locally advanced disease treated with Multikine as first-line therapy (absolute survival rate 63%) as compared to the 3.5 year median overall survival rates of the same cancer patient population determined from a review of 55 clinical trials reported in the scientific literature that were conducted between 1987 and 2007. CEL-SCI's Phase III clinical trial will need to demonstrate a 10% improvement in overall survival for Multikine to be successful.
- o Average of 50% reduction in tumor cells: The three week Multikine treatment regimen used in the last Phase II study killed, on average, approximately half of the cancer cells before the start of standard therapy such as surgery, radiation and chemotherapy (as determined by histopathology).
- o 12% complete response: In 12% of patients the tumor was completely eliminated after only a three week treatment with Multikine (as determined by histopathology).

In January 2007, the US Food and Drug Administration (FDA) concurred with the initiation of a global Phase III clinical trial in head and neck cancer patients using Multikine. The Canadian regulatory agency, the Biologics and Genetic Therapies Directorate, had previously concurred with the initiation of a global Phase III clinical trial in head and neck cancer patients using Multikine.

The protocol is designed to develop conclusive evidence of the efficacy of Multikine in the treatment of advanced primary (previously untreated) squamous

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cell carcinoma of the oral cavity (head and neck cancer). A successful outcome from this trial should enable CEL-SCI to apply for a Biologics License to market Multikine for the treatment of this patient population.

The trial will test the hypothesis that Multikine treatment administered prior to the current standard therapy for head and neck cancer patients (surgical resection of the tumor and involved lymph nodes followed by radiotherapy or radiotherapy and concurrent chemotherapy) will extend the overall survival, enhance the local/regional control of the disease and reduce the rate of disease progression in patients with advanced oral squamous cell carcinoma.

However, before starting the Phase III trial, CEL-SCI needed to build a dedicated manufacturing facility to produce Multikine. CEL-SCI estimates the 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 \$25 - \$26 million. Since CEL-SCI has obtained substantial financing, CEL-SCI is moving forward rapidly to launch its global Phase III clinical trial.

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CEL-SCI, together with its development partners Teva Pharmaceutical Industries and Orient Europharma, has plans to run the study in about 48 medical centers in 9 countries.

Multikine is the first immunotherapeutic agent being developed as a first-line treatment for cancer. It is administered prior to any other cancer therapy because that is the period when the anti-tumor immune response can still be fully activated. Once the patient has had surgery or has received radiation and/or chemotherapy, the immune system is severely weakened and is less able to mount an effective anti-tumor immune response. To date, other immunotherapies have been administered later in cancer therapy (i.e., after radiation, chemotherapy, surgery).

Clinical trials in over 200 patients have been completed with Multikine with the following results:

1. It has been demonstrated to be safe and non-toxic.
2. It has been shown to render cancer cells much more susceptible to radiation therapy (The Laryngoscope, December 2003, Vol.113 Issue 12).
3. A publication in the Journal of Clinical Oncology (Timar et al, JCO, 23(15): May 2005), revealed the following:
  - (i) Multikine induced anti-tumor immune responses through the combined activity of the different cytokines present in Multikine following local administration of Multikine for only three weeks.
  - (ii) The combination of the different cytokines caused the induction, recruitment into the tumor bed, and proliferation of anti-tumor T-cells and other anti-tumor inflammatory cells, leading to a massive anti-tumor immune response.
  - (iii) Multikine induced a reversal of the CD4/CD8 ratio in the tumor infiltrating cells, leading to a marked increase of CD4 T-cells in the tumor, which resulted in the prolongation of the

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anti-tumor immune response and tumor cell destruction.

- (iv) The anti-tumor immune-mediated processes continued long after the cessation of Multikine administration.
- (v) A three-week Multikine treatment of patients with advanced primary oral squamous cell carcinoma resulted in an overall response rate of 42% prior to standard therapy, with 12% of the patients having a complete response.
- (vi) A histopathology study showed that the tumor load in Multikine treated patients was reduced by nearly 50% as compared to tumors from control patients in the same pathology study.

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- (vii) The tumors of all of the patients in this Phase II trial who responded to Multikine treatment were devoid of the cell surface marker for HLA Class II. This finding, if confirmed in this global Phase III clinical trial, may lead to the establishment of a marker for selecting the patient population best suited for treatment with Multikine.
- (viii) In a Phase II study, using the same drug regimen as will be used in the Phase III study, the addition of Multikine as first-line treatment prior to the standard of care treatment resulted in a 33% improvement in the median overall survival at 3 1/2 years post-surgery, when compared to the results of 55 OSCC clinical trials published in the scientific literature between 1987 and 2007.

Multikine works in a comprehensive way to marshal an effective killing of the tumor:

1. Multikine attacks multiple antigens on the cancer cells.
2. Multikine directly kills cancer cells:
  - o The various cytokines present in Multikine, such as TNF, IL-1, along with other cytokines, are responsible for this activity.
3. Multikine signals the immune system to mount an effective and sustainable anti-tumor immune response:
  - o Multikine changes the type of cells that infiltrate and attack the tumor from the 'usual' CD-8 cells to CD-4 cells. These CD-4 cells bring about a more robust anti-tumor response.
    - This is extremely important because the tumor is able to shut down the infiltrating CD-8 cells, but is unable to shut down the CD-4 cell attack. In addition, CD-4 cells help break "tumor tolerance," thereby allowing the immune system to recognize, attack, and destroy the tumor. The normal immune system is 'blind' to tumor cells because the tumor cells are derived from the body's own cells, and thus the body 'thinks' of the tumor as 'self', a phenomenon also known as 'tumor tolerance'.
4. Multikine renders the remaining cancer cells potentially much more susceptible to radiation and chemotherapy treatment, thereby making these treatments much more effective.

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Multikine is currently being developed as an adjunct (additive) therapy to the existing treatment of previously untreated head and neck cancer patients with the goal of killing cancer cells and activating the general immune system to destroy the cancer. CEL-SCI scientists believe that patients with previously untreated disease would most likely benefit more from Multikine treatment as

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their immune systems are still capable of proper immune response. Head and neck cancer represents a clear unmet medical need. The recurrence rate is high and about one out of every two patients die within three years. Currently used therapies (surgery followed by radiation, chemotherapy or radio-chemotherapy) fail to completely arrest the disease because they are unable to completely remove or kill all of the cancer cells. The persistence of these residual cells is responsible for the cancer's recurrence or metastasis. Multikine is injected five times a week for three weeks around the tumor (peri-tumorally) as well as in the vicinity of the local lymph nodes (peri-lymphatically) prior to the patient's tumor being removed surgically and the patient receiving any other therapy because these are the areas in which most of the cancer will recur and from which metastases will develop. Multikine unleashes and then harnesses and enhances the immune system's ability to target and kill those tumor cells before they can cause recurrence or metastasize. Since Multikine may be potentially useful in treating many tumor types, it is expected that multiple indications will be pursued over time since it is the same principle for different cancers.

Proof of efficacy for anti-cancer drugs is a lengthy and complex process. At this stage of clinical investigation, it remains to be proven that Multikine will be effective against any form of cancer. Even if some form of Multikine is found to be effective in the treatment of cancer, commercial use of Multikine may be several years away due to extensive safety and effectiveness tests that would be necessary before required government approvals are obtained. It should be noted that other companies and research teams are actively involved in developing treatments and/or cures for cancer, and accordingly, there can be no assurance that CEL-SCI's research efforts, even if successful from a medical standpoint, can be completed before those of its competitors.

### Development, Supply and Distribution Agreements

CEL-SCI has a development, supply and distribution agreement with Orient Europharma of Taiwan. The agreement gave Orient Europharma the exclusive marketing rights to Multikine for all cancer indications in Taiwan, Singapore, Hong Kong and Malaysia. On November 3, 2008, CEL-SCI expanded its exclusive licensing agreement for Multikine with Orient Europharma. The new agreement extends the Multikine collaboration to also cover South Korea, the Philippines, Australia and New Zealand. As part of this new agreement, Orient Europharma invested an additional \$500,000 in CEL-SCI. The agreement provides for 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, which are very prevalent in Far East Asia. CEL-SCI may use the clinical data generated in these trials to support applications for marketing approvals for Multikine in other parts of the world. Orient Europharma will participate in and pay for part of CEL-SCI's head and neck Phase III clinical trial.

Under the agreement, CEL-SCI will manufacture and supply Multikine to Orient Europharma for distribution in the territory. Both parties will share in the revenue from the sale of Multikine. Orient Europharma will participate in the upcoming Phase III clinical trial by enrolling and paying for a substantial number of patients in its territory. Orient Europharma will also purchase Multikine for the Phase III trial from CEL-SCI for these patients at a rate

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established in the November 2000 agreement.

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Pursuant to an agreement dated May 2003, Eastern Biotech is due a royalty equal to 2% of CEL-SCI's net sales worldwide of Multikine and CEL-1000 prior to May 30, 2033.

On August 19, 2008, CEL-SCI entered into an agreement with Teva Pharmaceutical Industries Ltd. (Teva), a leading global pharmaceutical company, under which CEL-SCI granted Teva an exclusive license to market and distribute CEL-SCI's cancer drug Multikine in Israel and Turkey (the "Territory"). Although the licensing agreement is initially restricted to the areas of head and neck cancer, Teva has the right, subject to certain conditions, to include other cancers during the term of the agreement.

Pursuant to the agreement, Teva will participate in CEL-SCI's upcoming global Phase III clinical trial. Teva will fund a portion of the Phase III clinical study and Teva's clinical group will conduct part of the clinical study in Israel under the auspices of CEL-SCI and its Clinical Research Organization. Teva will also be responsible for registering Multikine in the Territory. If Multikine is approved, CEL-SCI will be responsible for manufacturing the product, while Teva will be responsible for sales in the Territory. Revenues will be divided equally between CEL-SCI and Teva.

Effective March 6, 2009, CEL-SCI entered into a licensing agreement with Byron Biopharma LLC ("Byron") under which CEL-SCI granted Byron an exclusive license to market and distribute Multikine in the Republic of South Africa.

Pursuant to the agreement, Byron will be responsible for registering the product in South Africa. Once Multikine has been approved for sale, CEL-SCI will be responsible for manufacturing the product, while Byron will be responsible for sales in South Africa. Revenues will be divided equally between CEL-SCI and Byron. To maintain the license Byron, among other requirements, made a payment to CEL-SCI in the amount of \$125,000 on March 8, 2010.

As of November 30, 2010, neither Orient Europharma nor Teva had started any clinical trials.

### New Manufacturing Facility

CEL-SCI's new, state-of-the-art manufacturing facility will be used to manufacture Multikine for CEL-SCI's Phase III clinical trial. Located near Baltimore, MD, it was designed over several years, and was built out to CEL-SCI's specifications. CEL-SCI leased this specially designed and built out facility, rather than having Multikine produced by a third party on a contract basis, since regulatory agencies prefer that the same facility be used to manufacture Multikine for both the Phase III trials and commercial sales, assuming the Phase III trial is successful. As is customary with large, complex construction projects, the manufacturing facility required a number of construction, utility and equipment adjustments as well as "punch list" items that required additional time to complete. This resulted in a gap between the time when CEL-SCI took over the facility and the time when validations and other CEL-SCI specific activities could commence. In addition to using this facility to manufacture Multikine, CEL-SCI will offer the use of the facility as a service to pharmaceutical companies and others, particularly those that need to

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"fill and finish" their drugs in a cold environment (4 degrees Celsius, or approximately 39 degrees Fahrenheit). Fill and finish is the process of filling injectable drugs in a sterile manner and is a key part of the manufacturing process for many medicines. However, this service will only be offered when CEL-SCI has the time and resources available, with priority always given to Multikine.

The fastest area of growth in the biopharmaceutical and pharmaceutical markets is biologics, and most recently stem cell products. These compounds and therapies are derived from or mimic human cells or proteins and other molecules (e.g., hormones, etc.). Nearly all of the major drugs developed for unmet medical needs (e.g., Avastin(R), Erbitux(R), Rituxan(R), Herceptin(R), Copaxon(R), etc.) are biologics. 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.

See Item 2 of this report for information concerning the terms of the lease on the manufacturing facility.

### LEAPS

CEL-SCI's patented T-cell Modulation Process uses "heteroconjugates" to direct the body to choose a specific immune response. The heteroconjugate technology, referred to as LEAPS (Ligand Epitope Antigen Presentation System), is intended to selectively stimulate the human immune system to more effectively fight bacterial, viral and parasitic infections as well as autoimmune, allergies, transplantation rejection and cancer, when it cannot do so on its own. Administered like vaccines, 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.



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treatment for H1N1 (swine flu) hospitalized patients. This LEAPS flu treatment is designed to focus on the conserved, non-changing epitopes of the different strains of Type A Influenza viruses (H1N1, H5N1, H3N1, etc.), including "swine", "avian or bird", and "Spanish Influenza", in order to minimize the chance of viral "escape by mutations" from immune recognition. CEL-SCI's LEAPS flu treatment contains epitopes known to be associated with immune protection against influenza in animal models.

On September 16, 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.

On November 6, 2009, CEL-SCI announced that The Johns Hopkins University School of Medicine had given clearance for CEL-SCI's first clinical study to proceed using LEAPS-H1N1. This study started one week later. Since the disease disappeared about one month later, the study has been unable to enroll many patients.

To fully consider a next-stage clinical trial to evaluate LEAPS-H1N1 treatment of hospitalized patients with laboratory-confirmed H1N1 Pandemic Flu under an Exploratory IND, the FDA has asked CEL-SCI to submit a detailed follow-up regulatory filing with extensive additional data. Thus, in parallel with preparing for this first study, CEL-SCI is proceeding on an expedited basis to complete this next submission. Recognizing that it cannot proceed with its next-stage clinical trial without the FDA's concurrence, CEL-SCI anticipates engaging in a detailed dialogue with the FDA regarding the proposed LEAPS-H1N1 clinical-development program following this future filing.

With its LEAPS technology, CEL-SCI also discovered a second peptide named CEL-2000, a potential rheumatoid arthritis vaccine. The data from animal studies of rheumatoid arthritis using the CEL-2000 treatment vaccine demonstrated that CEL-2000 is an effective treatment against arthritis with fewer administrations than those required by other anti-rheumatoid arthritis treatments, including Enbrel(R). CEL-2000 is also potentially a more disease type-specific therapy, is calculated to be significantly less expensive and may be useful in patients unable to tolerate or who may not be responsive to existing anti-arthritis therapies.

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

None of the products or vaccines which are in development using the LEAPS technology have been approved by the FDA or any other government agency. Before

obtaining marketing approval from the FDA in the United States, and by comparable agencies in most foreign countries, these product candidates must undergo rigorous preclinical and clinical testing which is costly and time consuming and subject to unanticipated delays. There can be no assurance that these approvals will be granted.

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### PATENTS

CEL-SCI currently has six patents issued in the United States and twenty-two patent applications pending in Europe, Japan, China, India, Hong Kong, Canada and the United States. One patent covers certain aspects of Multikine and will expire in 2023. The remaining five patents cover CEL-SCI's LEAPS technology and will expire between December 2014 and April 2022. CEL-SCI believes that the greatest level of protection for Multikine is not based on patents but from the confidential and proprietary process relating to the manufacture of Multikine.

### RESEARCH AND DEVELOPMENT

Since 1983, and through September 30, 2010, approximately \$77,243,000 has been spent on CEL-SCI-sponsored research and development, including \$11,911,600, \$6,011,800, and \$4,101,600 respectively during the years ended September 30, 2010, 2009 and 2008.

The costs associated with the clinical trials relating to CEL-SCI's technologies, research expenditures and CEL-SCI's administrative expenses have been funded with the public and private sales of CEL-SCI's securities and borrowings from third parties, including affiliates of CEL-SCI. The extent of CEL-SCI's clinical trials and research programs is primarily based upon the amount of capital available to CEL-SCI and the extent to which CEL-SCI has received regulatory approvals for clinical trials.

### GOVERNMENT REGULATION

#### New drug development and approval process

Regulation by governmental authorities in the United States and other countries is a significant factor in the manufacture and marketing of biological and other drug products and in ongoing research and product development activities. CEL-SCI's products will require regulatory approval by governmental agencies prior to commercialization. In particular, these products are subject to rigorous preclinical and clinical testing and other premarket approval requirements by the FDA and regulatory authorities in other countries. In the United States, various statutes and regulations also govern or influence the manufacturing, safety, labeling, storage, record keeping and marketing of pharmaceutical and biological drug products. The lengthy process of seeking these approvals, and the subsequent compliance with applicable statutes and regulations, require the expenditure of substantial resources. CEL-SCI believes that it is currently in compliance with applicable statutes and regulations that are relevant to its operations. CEL-SCI has no control, however, over the compliance of its partners.

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The FDA's statutes, regulations, or policies may change and additional statutes or government regulations may be enacted which could prevent or delay regulatory approvals of biological or other drug products. CEL-SCI cannot predict the likelihood, nature or extent of adverse governmental regulation that might arise from future legislative or administrative action, either in the U.S. or abroad.

Regulatory approval, when and if obtained, may be limited in scope. In particular, regulatory approvals will restrict the marketing of a product to specific uses. Further, approved biological and other drugs, as well as their manufacturers, are subject to ongoing review. Discovery of previously unknown problems with these products may result in restrictions on their manufacture,

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sale or use or in their withdrawal from the market. Failure to comply with regulatory requirements may result in criminal prosecution, civil penalties, recall or seizure of products, total or partial suspension of production or injunction, as well as other actions affecting CEL-SCI. Any failure by CEL-SCI or its partners to obtain and maintain, or any delay in obtaining, regulatory approvals could materially adversely affect CEL-SCI's business.

The process for new drug approval has many steps, including:

### Preclinical testing

Once a biological or other drug candidate is identified for development, the drug candidate enters the preclinical testing stage. During preclinical studies, laboratory and animal studies are conducted to show biological activity of the drug candidate in animals, both healthy and with the targeted disease. Also, preclinical tests evaluate the safety of drug candidates. These tests typically take approximately two years to complete. Preclinical tests must be conducted in compliance with good laboratory practice regulations. In some cases, long-term preclinical studies are conducted while clinical studies are ongoing.

### Investigational new drug application

When the preclinical testing is considered adequate by the sponsor to demonstrate the safety and the scientific rationale for initial human studies, an investigational new drug application (IND) is filed with the FDA to seek authorization to begin human testing of the biological or other drug candidate. The IND becomes effective if not rejected by the FDA within 30 days after filing. The IND must provide data on previous experiments, how, where and by whom the new studies will be conducted, the chemical structure of the compound, the method by which it is believed to work in the human body, any toxic effects of the compound found in the animal studies and how the compound is manufactured. All clinical trials must be conducted under the supervision of a qualified investigator in accordance with good clinical practice regulations. These regulations include the requirement that all subjects provide informed consent. In addition, an institutional review board (IRB), comprised primarily of physicians and other qualified experts at the hospital or clinic where the proposed studies will be conducted, must review and approve each human study. The IRB also continues to monitor the study and must be kept aware of the study's progress, particularly as to adverse events and changes in the research. Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if adverse events occur. In

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addition, the FDA may, at any time during the 30-day period after filing an IND or at any future time, impose a clinical hold on proposed or ongoing clinical trials. If the FDA imposes a clinical hold, clinical trials cannot commence or recommence without FDA authorization, and then only under terms authorized by the FDA. In some instances, the IND process can result in substantial delay and expense.

Some limited human clinical testing may also be done under a physician's IND that allows a single individual to receive the drug, particularly where the individual has not responded to other available therapies. A physician's IND does not replace the more formal IND process, but can provide a preliminary indication as to whether further clinical trials are warranted, and can, on occasion, facilitate the more formal IND process.

Clinical trials are typically conducted in three sequential phases, but the phases may overlap.

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### Phase I clinical trials

Phase I human clinical trials usually involve between 20 and 80 healthy volunteers or patients and typically take one to two years to complete. The tests study a biological or other drug's safety profile, and may seek to establish the safe dosage range. The Phase I clinical trials also determine how a drug candidate is absorbed, distributed, metabolized and excreted by the body, and the duration of its action.

### Phase II clinical trials

In Phase II clinical trials, controlled studies are conducted on an expanded population of patients with the targeted disease. The primary purpose of these tests is to evaluate the effectiveness of the drug candidate on the volunteer patients as well as to determine if there are any side effects or other risks associated with the drug. These studies generally take several years and may be conducted concurrently with Phase I clinical trials. In addition, Phase I/II clinical trials may be conducted to evaluate not only the efficacy of the drug candidate on the patient population, but also its safety.

### Phase III clinical trials

This phase typically lasts several years and involves an even larger patient population, often with several hundred or even several thousand patients depending on the use for which the drug is being studied. Phase III trials are intended to establish the overall risk-benefit ratio of the drug and provide, if appropriate, an adequate basis for product labeling. During the Phase III clinical trials, physicians monitor the patients to determine efficacy and to observe and report any reactions or other safety risks that may result from use of the drug candidate.

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### Chemical and formulation development

Concurrent with clinical trials and preclinical studies, companies also must develop information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the product in accordance with current good manufacturing practice requirements (cGMPs). The manufacturing process must be capable of consistently producing quality batches of the product and the manufacturer must develop methods for testing the quality, purity, and potency of the final drugs. Additionally, appropriate packaging must be selected and tested and chemistry stability studies must be conducted to demonstrate that the product does not undergo unacceptable deterioration over its shelf-life.

### New drug application or biological license application

After the completion of the clinical trial phases of development, if the sponsor concludes that there is substantial evidence that the biological or other drug candidate is effective and that the drug is safe for its intended use, a new drug application (NDA) or biologics license application (BLA) may be submitted to the FDA. The application must contain all of the information on the biological or other drug candidate gathered to that date, including data from the clinical trials.

The FDA reviews all NDAs and BLAs submitted before it accepts them for filing. It may request additional information rather than accepting an application for filing. In this event, the application must be resubmitted with

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the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth review of the application. The FDA may refer the application to an appropriate advisory committee, typically a panel of clinicians, for review, evaluation and a recommendation. The FDA is not bound by the recommendation of an advisory committee. If FDA evaluations of the NDA or BLA and the manufacturing facilities are favorable, the FDA may issue an approval letter authorizing commercial marketing of the drug or biological candidate for specified indications. The FDA could also issue an approvable letter, which usually contains a number of conditions that must be met in order to secure final approval of the NDA or BLA. When and if those conditions have been met to the FDA's satisfaction, the FDA will issue an approval letter. On the other hand, if the FDA's evaluation of the NDA or BLA or manufacturing facilities is not favorable, the FDA may refuse to approve the application or issue a non-approvable letter.

Among the conditions for NDA or BLA approval is the requirement that each prospective manufacturer's quality control and manufacturing procedures conform to current good manufacturing practice standards and requirements (cGMPs). Manufacturing establishments are subject to periodic inspections by the FDA and by other federal, state or local agencies.

Some of the clinical trials funded to date by CEL-SCI have not been approved by the FDA, but rather have been conducted pursuant to approvals obtained from certain states and foreign countries. Conducting clinical studies in foreign countries is normal industry practice since these studies can often be completed in less time and are less expensive than studies conducted in the U.S. Conducting clinical studies in foreign countries is also beneficial since

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CEL-SCI will need the approval from a foreign country prior to the time CEL-SCI can market any of its drugs in the foreign country. However, since the results of these clinical trials may not be accepted by the FDA, competitors conducting clinical trials approved by the FDA may have an advantage in that the products of such competitors are further advanced in the regulatory process than those of CEL-SCI. CEL-SCI is conducting its trials in compliance with internationally recognized standards. By following these standards, CEL-SCI anticipates obtaining acceptance from world regulatory bodies, including the FDA.

CEL-SCI has selected a Clinical Research Organization (CRO) for the Phase III trial with Multikine. The expected start date for the clinical trial is at the end of 2010 or early in 2011. The expected net cost of the clinical trial is approximately \$25 - \$26 million (excluding the costs that will be paid by CEL-SCI's partners).

### COMPETITION AND MARKETING

Many companies, nonprofit organizations and governmental institutions are conducting research on cytokines. Competition in the development of therapeutic agents incorporating cytokines is intense. Large, well-established pharmaceutical companies are engaged in cytokine research and development and have considerably greater resources than CEL-SCI has to develop products. Licensing and other collaborative arrangements between governmental and other nonprofit institutions and commercial enterprises, as well as the seeking of patent protection of inventions by nonprofit institutions and researchers, could result in strong competition for CEL-SCI. Any new developments made by such organizations may render CEL-SCI's licensed technology and know-how obsolete.

Several biotechnology companies are producing compounds that utilize cytokines. However, CEL-SCI believes that its main advantage lies in two areas

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and that those two areas will allow it to be successful: 1) Multikine is given prior to surgery, radiation and/or chemotherapy, a time when the immune system can still be activated effectively. Other companies give their immunotherapy drugs after these cancer treatments. At that time the immune system is already so weakened that it can no longer mount a complete immune response. 2) Multikine simulates the activities of a healthy person's immune system, which battles cancer every day. Multikine is multi-targeted; it is a cancer immunotherapy that both kills cancer cells in a targeted fashion and activates the general immune system to destroy the cancer. In addition, since Multikine is a complex biologic, CEL-SCI believes that it will be extremely difficult for someone to copy Multikine and its manufacturing.

### EMPLOYEES

As of November 30, 2010, CEL-SCI had 42 employees. Eight employees are involved in administration, 31 employees are involved in manufacturing and 3 employees are involved in general research and development with respect to CEL-SCI's products.

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### ITEM 1A. RISK FACTORS

Investors should be aware that the risks described below could adversely affect the price of CEL-SCI's common stock.

#### Risks Related to CEL-SCI

Since CEL-SCI has earned only limited revenues and has a history of losses, CEL-SCI will require additional capital to remain in operation.

CEL-SCI has had only limited revenues since it was formed in 1983. Since the date of its formation and through September 30, 2010 CEL-SCI incurred net losses of approximately \$161,800,000. CEL-SCI has relied principally upon the proceeds of public and private sales of its securities to finance its activities to date. All of CEL-SCI's potential products, with the exception of Multikine, are in the early stages of development, and any commercial sale of these products will be many years away. Even potential product sales from Multikine are many years away as cancer trials can be lengthy. Accordingly, CEL-SCI expects to incur substantial losses for the foreseeable future.

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

At the present time, CEL-SCI intends to use available funds to finance CEL-SCI's operations. Accordingly, while payment of dividends rests within the discretion of the Board of Directors, no common stock dividends have been declared or paid by CEL-SCI and CEL-SCI has no intention of paying any common stock dividends.

If CEL-SCI cannot obtain additional capital, CEL-SCI may have to postpone development and research expenditures which will delay CEL-SCI's ability to produce a competitive product. Delays of this nature may depress the price of CEL-SCI's common stock.

Clinical and other studies necessary to obtain approval of a new drug can be time consuming and costly, especially in the United States, but also in foreign countries. CEL-SCI's estimates of the costs associated with future

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clinical trials and research may be substantially lower than the actual costs of these activities. The different steps necessary to obtain regulatory approval, especially that of the Food and Drug Administration, involve significant costs and may require several years to complete. CEL-SCI expects that it will need substantial additional financing over an extended period of time in order to fund the costs of future clinical trials, related research, and general and administrative expenses. This additional funding may come from the exercise of warrants and options currently outstanding, equity or debt financings or a partnering arrangement with a larger company.

The extent of CEL-SCI's clinical trials and research programs are primarily based upon the amount of capital available to CEL-SCI and the extent to which CEL-SCI has received regulatory approvals for clinical trials.

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In accordance with the terms of the manufacturing facility's lease, CEL-SCI must maintain a certain amount of cash. Should CEL-SCI's cash position fall below the amount stipulated in the lease CEL-SCI will be required to deposit with the landlord the equivalent of one year's base rent. CEL-SCI paid this additional amount of \$1,575,000 in 2008 and, upon meeting the required cash level, received a refund of \$1,575,000 from the landlord in February 2010.

The inability of CEL-SCI to conduct clinical trials or research, whether due to a lack of capital or regulatory approval, will prevent CEL-SCI from completing the studies and research required to obtain regulatory approval for any products which CEL-SCI is developing.

No definite plan for marketing of Multikine has been established.

CEL-SCI has not established a definitive plan for marketing nor has it established a price structure for CEL-SCI's saleable products. However, CEL-SCI intends, if CEL-SCI is in a position to begin commercialization of its products, to sell Multikine itself in certain markets and to enter into written marketing agreements with various major pharmaceutical firms with established sales forces. The sales forces in turn would probably target CEL-SCI's products to cancer centers, physicians and clinics involved in head and neck cancer.

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

### Potential Future Dilution

To raise additional capital CEL-SCI may have to sell shares of its common stock or securities convertible into common stock at prices that may be below the prevailing market price of CEL-SCI's common stock at the time of sale. The issuance of additional shares will have a dilutive impact on other stockholders and could have a negative effect on the market price of CEL-SCI's common stock.

Multikine is made from components of human blood which involves inherent risks that may lead to product destruction or patient injury which could materially harm CEL-SCI's financial results, reputation and stock price.

Multikine is made, in part, from components of human blood. There are inherent risks associated with products that involve human blood such as possible contamination with viruses, including Hepatitis or HIV. Any possible

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

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Although CEL-SCI has product liability insurance for Multikine, the successful prosecution of a product liability case against CEL-SCI could have a materially adverse effect upon its business if the amount of any judgment exceeds CEL-SCI's insurance coverage.

Although no claims have been brought to date, participants in CEL-SCI's clinical trials could bring civil actions against CEL-SCI for any unanticipated harmful effects arising from the use of Multikine or any drug or product that CEL-SCI may try to develop.

CEL-SCI's directors are allowed to issue shares of preferred stock with provisions that could be detrimental to the interests of the holders of CEL-SCI's common stock.

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

### Risks Related to Government Approvals

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

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

CEL-SCI cannot be certain when or under what conditions it will undertake further clinical trials, including the Phase III clinical trial for Multikine. The clinical trials of CEL-SCI's product candidates may not be completed on schedule, the FDA or foreign regulatory agencies may order CEL-SCI to stop or modify its research or these agencies may not ultimately approve any of CEL-SCI's product candidates for commercial sale. Varying interpretations of the data obtained from pre-clinical and clinical testing could delay, limit or prevent regulatory approval of CEL-SCI's product candidates. The data collected from CEL-SCI's clinical trials may not be sufficient to support regulatory approval of its various product candidates, including Multikine. CEL-SCI's failure to adequately demonstrate the safety and efficacy of any of its product candidates would delay or prevent regulatory approval of its product candidates in the United States, which could prevent CEL-SCI from achieving profitability.

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

CEL-SCI has only limited experience in filing and pursuing applications necessary to gain regulatory approvals, which may impede its ability to obtain timely approvals from the FDA or foreign regulatory agencies, if at all. CEL-SCI will not be able to commercialize Multikine and other product candidates until it has obtained regulatory approval, and any delay in obtaining, or inability to obtain, regulatory approval could harm its business. In addition, regulatory authorities may also limit the types of patients to which CEL-SCI or others may market Multikine or CEL-SCI's other products.

Any failure to obtain or any delay in obtaining required regulatory approvals may adversely affect the ability of CEL-SCI or potential licensees to successfully market any products they may develop.

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

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

- o product design, development and manufacture;
- o adverse drug experience;
- o product advertising and promotion;
- o product manufacturing, including good manufacturing practice requirements;
- o record keeping requirements;
- o registration and listing of CEL-SCI's establishments and products with the FDA and certain state agencies;
- o product storage and shipping;
- o drug sampling and distribution requirements;
- o electronic record and signature requirements; and
- o labeling changes or modifications.

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

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

If CEL-SCI does not comply with regulatory requirements at any stage, whether before or after marketing approval is obtained, it may be subject to license suspension or revocation, criminal prosecution, seizure, injunction, fines, or be forced to remove a product from the market or experience other adverse consequences, including restrictions or delays in obtaining regulatory marketing approval, which could materially harm CEL-SCI's financial results, reputation and stock price. Additionally, CEL-SCI may not be able to obtain the labeling claims necessary or desirable for product promotion. CEL-SCI may also be required to undertake post-marketing trials. In addition, if CEL-SCI or other parties identify adverse effects after any of CEL-SCI's products are on the market, or if manufacturing problems occur, regulatory approval may be withdrawn. CEL-SCI may be required to reformulate its products, conduct additional clinical trials, make changes in its product's labeling or indications of use, or submit additional marketing applications to support these changes. If CEL-SCI encounters any of the foregoing problems, its business and results of operations will be harmed and the market price of its common stock may decline.

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

### Risks Related to Intellectual Property

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

The biomedical field in which CEL-SCI is involved is undergoing rapid and significant technological change. The successful development of therapeutic agents from CEL-SCI's compounds, compositions and processes through CEL-SCI-financed research, or as a result of possible licensing arrangements with pharmaceutical or other companies, will depend on its ability to be in the technological forefront of this field.

Many companies are working on drugs designed to treat cancer and have substantial financial, research and development, and marketing resources and are capable of providing significant long-term competition either by establishing

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in-house research groups or by forming collaborative ventures with other entities. In addition, smaller companies and non-profit institutions are active in research relating to cancer and infectious diseases.

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

Certain aspects of CEL-SCI's technologies are covered by U.S. and foreign patents. In addition, CEL-SCI has a number of new patent applications pending.

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There is no assurance that the applications still pending or which may be filed in the future will result in the issuance of any patents. Furthermore, there is no assurance as to the breadth and degree of protection any issued patents might afford CEL-SCI. Disputes may arise between CEL-SCI and others as to the scope and validity of these or other patents. Any defense of the patents could prove costly and time consuming and there can be no assurance that CEL-SCI will be in a position, or will deem it advisable, to carry on such a defense. Other private and public concerns, including universities, may have filed applications for, or may have been issued, patents and are expected to obtain additional patents and other proprietary rights to technology potentially useful or necessary to CEL-SCI. The scope and validity of such patents, if any, the extent to which CEL-SCI may wish or need to acquire the rights to such patents, and the cost and availability of such rights are presently unknown. Also, as far as CEL-SCI relies upon unpatented proprietary technology, there is no assurance that others may not acquire or independently develop the same or similar technology.

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

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

The market price of CEL-SCI's common stock, as well as the securities of other biopharmaceutical and biotechnology companies, have historically been highly volatile, and the market has from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. During the twelve months ended September 30, 2010, CEL-SCI's stock price has ranged from a low of \$0.43 per share to a high of \$1.79 per share. Factors such as fluctuations in CEL-SCI's operating results, announcements of technological innovations or new therapeutic products by CEL-SCI or its competitors, governmental regulation, developments in patent or other proprietary rights, public concern as to the safety of products developed by CEL-SCI or other biotechnology and pharmaceutical companies, and general market conditions may have a significant effect on the future market price of CEL-SCI's common stock.

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

CEL-SCI had outstanding convertible notes, options and warrants which as of November 30, 2010 could potentially allow the holders to acquire approximately 83,340,300 additional shares of its common stock. Until the options and warrants

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expire, and the convertible note is repaid, the holders will have an opportunity to profit from any increase in the market price of CEL-SCI's common stock without assuming the risks of ownership. Holders of options and warrants exercise these securities at a time when CEL-SCI could obtain additional capital on terms more favorable than those provided by the options or warrants. The conversion of the notes or the exercise of the options and warrants will dilute the voting interest of the owners of presently outstanding shares by adding a substantial number of additional shares of CEL-SCI's common stock.

CEL-SCI has filed, or plans to file, registration statements with the Securities and Exchange Commission so that substantially all of the shares of common stock which are issuable upon the exercise of outstanding options and warrants may be sold in the public market. The sale of common stock issued or issuable upon the exercise of these options or warrants, or the perception that such sales could occur, may adversely affect the market price of CEL-SCI's common stock.

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Claims by the former holders of CEL-SCI's Series K notes may potentially result in the issuance of additional shares of CEL-SCI's common stock and the payment of damages.

In August 2006, CEL-SCI sold Series K notes, plus Series K warrants, to a group of private investors. The notes were convertible into shares of CEL-SCI's common stock. One of the Series K note holders, Iroquois Master Fund Ltd., has indicated that it believes the conversion price of the Series K notes, as well as the exercise price of the Series K warrants, should be \$0.20 as opposed to \$0.40. It is CEL-SCI's position that the correct conversion price was \$0.40 and the correct exercise price of the warrants is \$0.40.

On October 21, 2009, Iroquois filed suit against CEL-SCI. In its complaint, alleging breach of contract, breach of fiduciary duty, conversion, and negligence, Iroquois seeks actual and punitive damages, the issuance by CEL-SCI of additional shares and warrants, and a ruling by the court that the conversion price of the notes and the exercise price of the warrants are both \$0.20. See Item 3 of this report for more information.

### ITEM 1B. UNRESOLVED SEC COMMENTS

None

### ITEM 2. PROPERTIES

CEL-SCI leases office space at 8229 Boone Blvd., Suite 802, Vienna, Virginia at a monthly rental of approximately \$9,100. The lease on the office space expires in June 2012. CEL-SCI believes this arrangement is adequate for the conduct of its present business.

CEL-SCI has a 17,900 square foot laboratory located at 4820 A-E Seton Drive, Baltimore, Maryland. The laboratory is leased by CEL-SCI at a cost of approximately \$10,800 per month. The laboratory lease expires in February 2014.

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In August 2007, CEL-SCI leased a building near Baltimore, Maryland. The building, which consists of approximately 73,000 square feet, has been remodeled in accordance with CEL-SCI's specifications so that it can be used by CEL-SCI to manufacture Multikine for CEL-SCI's Phase III clinical trial and sales of the drug if approved by the FDA. The lease expires on October 31, 2028 and requires annual base rent payments of approximately \$1,667,000 during the twelve months ending October 31, 2011, in accordance with the lease agreement. The annual base rent escalates each year thereafter at 3%. CEL-SCI is also required to pay all real and personal property taxes, insurance premiums, maintenance expenses, repair costs and utilities. The lease allows CEL-SCI, at its election, to extend the lease for two ten-year periods or to purchase the building at the end of the 20-year lease. The lease required CEL-SCI to pay \$3,150,000 towards the remodeling costs, which will be recouped by reductions in the annual base rent of \$303,228 beginning in 2014. In July 2008, CEL-SCI was required to deposit \$1,575,000 since the amount of CEL-SCI's cash fell below the amount stipulated in the lease. This amount was refunded by the landlord in February 2010. The landlord has the right to declare CEL-SCI in default if CEL-SCI fails to pay any installment of the Base Annual Rent when such failure continues for five business days after CEL-SCI's receipt of written notice from the Landlord, provided that if CEL-SCI fails to pay any installment of the Base Annual Rent within five business days more than twice in any twelve month period, the Landlord will not be required to provide CEL-SCI with any further notice and CEL-SCI will be deemed to be in default. As of the date of this filing, CEL-SCI was not in default on the lease.

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### ITEM 3. LEGAL PROCEEDINGS

Pursuant to a Securities Purchase Agreement dated August 4, 2006, CEL-SCI sold Series K convertible notes, plus Series K warrants, to a group of private investors for \$8,300,000. The notes were convertible into shares of CEL-SCI's common stock. On August 31, 2009, all of the Series K notes had either been repaid or had been converted into shares of CEL-SCI's common stock. At the holder's option, the Series K notes were convertible into shares of CEL-SCI's common stock equal in number to the amount determined by dividing each \$1,000 of note principal to be converted by the conversion price. Initially, the conversion price was \$0.86.

The Series K warrants allow the note holders to purchase shares of CEL-SCI's common stock, initially at a price of \$0.95 per share, at any time on or prior to February 4, 2012.

If CEL-SCI sold any additional shares of common stock, or any securities convertible into common stock, at a price below the then applicable conversion price of the notes or the exercise price of the warrants, the conversion price of the notes and the exercise price of the warrants would be reduced to the price at which the shares were sold or the lowest price at which the securities were convertible, as the case may have been.

If the warrant exercise price was decreased, the number of shares of common stock issuable upon the exercise of the warrant would be increased proportionately.

However, the conversion price of the Series K notes, the exercise price of the Series K warrants, and the shares issuable upon the exercise of the warrants would not be adjusted as the result of shares issued in connection with a

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Permitted Financing, as that term was defined in the Securities Purchase Agreement. A Permitted Financing included shares of common stock issued or sold in connection with a bona fide licensing agreement, the primary purpose of which was not to raise cash.

In April 2007, the conversion price of the Series K notes and the exercise price of the Series K warrants were reduced to \$0.75 per share as a result of shares sold by CEL-SCI below the original conversion price of the notes and the exercise price of the warrants.

On March 6, 2009, CEL-SCI entered into a licensing agreement with an unrelated third party. In connection with the licensing agreement, CEL-SCI sold shares of its common stock to the third party for \$0.20 per share, a premium to CEL-SCI's share price at the time.

In June 2009, the conversion price of the Series K notes and the exercise price of the Series K warrants were reduced to \$0.40 per share as a result of shares sold by CEL-SCI below the conversion price of the notes and the exercise price of the warrants.

As previously disclosed by CEL-SCI in its public filings, one of the Series K note holders, Iroquois Master Fund, Ltd. ("Iroquois") advised CEL-SCI that the conversion price of the Series K notes, as well as the exercise price of the Series K warrants, should be \$0.20 since it did not believe that the sale of CEL-SCI's shares of its common stock on March 6, 2009 was a Permitted Financing.

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It is CEL-SCI's position that the shares sold on March 6, 2009 were sold in connection with a Permitted Financing and did not cause a reduction in the conversion price of the Series K notes or the exercise price of the Series K warrants.

On October 21, 2009, Iroquois filed suit against CEL-SCI in the United States District Court for the Southern District of New York. In its complaint Iroquois alleges that CEL-SCI is liable for breach of contract, breach of fiduciary duty, conversion, and negligence.

Through its lawsuit Iroquois is seeking \$30 million in actual damages, \$90 million in punitive damages, the issuance of an additional 4,264,681 shares of CEL-SCI's common stock, the issuance of warrants to purchase an additional 6,460,757 shares of CEL-SCI's common stock, and a ruling by the court that the conversion price of the notes and the exercise price of the warrants are both \$0.20.

CEL-SCI believes that Iroquois's claims are without merit and has filed a motion with the District Court seeking the dismissal of Iroquois's lawsuit.

If Iroquois prevails in its suit, CEL-SCI may be required to issue approximately 1,166,000 additional shares of common stock and issue approximately 9,616,000 warrants exercisable at \$0.20 per share to the other holders of the Series K notes and warrants, assuming all of the warrants are exercised.

ITEM 4. (REMOVED AND RESERVED)

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

As of November 30, 2010, there were approximately 1,100 record holders of CEL-SCI's common stock. CEL-SCI's common stock is traded on the NYSE Amex (formerly the American Stock Exchange) under the symbol "CVM". Set forth below are the range of high and low quotations for CEL-SCI's common stock for the periods indicated as reported on the NYSE Amex. The market quotations reflect inter-dealer prices, without retail mark-up, mark-down or commissions and may not necessarily represent actual transactions.

Quarter Ended	High	Low
12/31/08	\$0.50	\$0.18
3/31/09	\$0.40	\$0.14
6/30/09	\$0.80	\$0.20
9/30/09	\$2.10	\$0.38
12/31/09	\$1.79	\$0.85
3/31/10	\$1.12	\$0.50
6/30/10	\$0.76	\$0.45
9/30/10	\$0.84	\$0.43

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

The provisions in CEL-SCI's Articles of Incorporation relating to

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

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

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The graph below matches the cumulative 5-year total return of holders of CEL-SCI Corporation's common stock with the cumulative total returns of the NYSE Amex Composite index and the RDG MicroCap Biotechnology index. The graph assumes that the value of the investment in the CEL-SCI's common stock and in each of the indexes (including reinvestment of dividends) was \$100 on 9/30/2005 and tracks it through 9/30/2010. [GRAPHIC OMITTED]

	9/05	9/06	9/07	9/08	9/09	9/10
CEL-SCI Corporation	100.00	131.91	133.02	85.11	365.96	137.02
NYSE Amex Composite	100.00	110.90	139.96	108.28	113.40	134.71
RDG MicroCap Biotechnology	100.00	70.80	60.46	32.97	32.69	21.73

The stock price performance included in this graph is not necessarily indicative of future stock price performance.

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### ITEM 6. SELECTED FINANCIAL DATA

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

Statements of Operations	2010	2009	2008	2007	2006
-----	----	----	----	----	----
Rent and grant revenue					

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and other	\$ 153,300	80,093	\$ 5,065	\$ 57,043	\$125,457
Operating expenses:					
Research and development	11,911,626	6,011,750	4,101,563	2,528,528	1,896,976
Depreciation and amortization	516,117	417,205	215,060	176,186	170,903
General and administrative	6,285,810	5,671,595	5,200,735	6,704,538	3,406,774
Gain (loss) on derivative instruments	28,843,772	(28,491,650)	1,799,393	868,182	2,325,784
Other costs of financing	-	-	-	-	(4,791,548)
Interest income	362,236	-	483,252	562,973	92,487
Interest expense	(162,326)	(397,923)	(473,767)	(1,708,603)	(216,737)
Net income (loss)	10,483,429	(40,910,030)	(7,703,415)	(9,629,657)	(7,939,210)
Modification of warrants	(1,532,456)	(490,728)	(424,815)	-	-
Net income (loss) available to common shareholders	\$ 8,950,973	(41,400,758)	(8,128,230)	(9,629,657)	(7,939,210)

Statements of Operations

Net income (loss) per common share					
Basic	\$ 0.04	\$ (0.31)	\$ \$0.07)	\$ \$0.10)	\$ (\$0.10)
Diluted	\$ 0.05	\$ (0.31)	\$ \$0.07)	\$ \$0.10)	\$ (\$0.11)
Weighted average common shares outstanding					
Basic	202,102,859	133,535,050	117,060,866	97,310,488	78,971,290
Diluted (1)	226,277,913	133,535,050	117,060,866	97,310,488	93,834,078
Balance Sheets					

Statements of Operations	2010	2009	2008	2007	2006
Working capital	25,799,304	\$34,339,772	\$ (2,492,555)	10,257,568	\$7,109,879
Total assets	37,804,985	46,027,598	14,683,672	20,730,802	9,653,277
Derivative instruments - current (2)	424,286	-	3,018,697	782,732	1,670,234
Derivative instruments - noncurrent (2)	6,521,765	35,113,970	-	4,831,252	8,645,796
Total liabilities	9,950,220	37,186,954	3,847,637	6,060,703	10,583,878
Stockholders' equity (deficit)	27,854,765	8,840,644	10,836,035	14,670,099	(930,601)

(1) The calculation of diluted earnings per share for the years ended September 30, 2009, 2008 and 2007 excluded the potentially dilutive shares because their effect would have been anti-dilutive.

(2) Included in total liabilities.



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No dividends have been declared on CEL-SCI's common stock. However, in December 2007, warrants held by third parties were extended, resulting in a \$424,815 charge, which was treated as a deemed dividend and is shown as such in the consolidated financial statements. In the third and fourth quarters of the fiscal year ended September 30, 2009, additional shares were issued and others extended in accordance with previous financings, resulting in a \$490,728 charge, which was treated as a deemed dividend and is shown as such in the consolidated financial statements. In March 2010, CEL-SCI temporarily reduced the exercise price of the Series M Warrants, increasing the value of the warrants by \$1,432,456. In August 2010, CEL-SCI amended the Series M warrants held by an investor, increasing the value of those warrants by \$100,000. For further discussion, see Note 10. No actual dividends were paid to shareholders.

CEL-SCI's net income (losses) available to common shareholders for each fiscal quarter during the two years ended September 30, 2010 were:

Quarter -----	Net income (loss) -----	Net income (loss) per share	
		Basic -----	Diluted -----
12/31/2008	\$ (2,173,513)	\$ (0.02)	\$ (0.02)
3/31/2009	\$ (2,117,280)	\$ (0.02)	\$ (0.02)
6/30/2009	\$ (6,705,731)	\$ (0.05)	\$ (0.05)
9/30/2009	\$ (30,404,234)	\$ (0.19)	\$ (0.19)
12/31/2009	\$ 19,159,517	\$ 0.10	\$ 0.02
3/31/2010	\$ (2,176,975)	\$ (0.01)	\$ (0.03)
6/30/2010	\$ (601,124)	\$ (0.00)	\$ (0.01)
9/30/2010	\$ (7,330,445)	\$ (0.04)	\$ (0.04)

First three quarters of fiscal year 2009 as adjusted.

CEL-SCI has experienced large swings in its quarterly gains and losses in 2010 and 2009. These swings are caused by the changes in the fair value of the convertible debt and warrants each quarter. These changes in the fair value of the convertible debt and warrants are recorded on the consolidated statements of operations. In addition, the cost of options granted to consultants, as discussed in the results of operations in this report, has affected the quarterly losses recorded by CEL-SCI.

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

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

CEL-SCI's most advanced product, Multikine, which is cleared for a Phase III clinical trial in the U.S. and in Canada, is being developed for the treatment of cancer.

CEL-SCI also owns a pre-clinical technology called L.E.A.P.S. (Ligand Epitope Antigen Presentation System).

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

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

### Results of Operations

#### Fiscal 2010

During the year ended September 30, 2010, research and development expenses increased by \$5,899,876 compared to the year ended September 30, 2009. This increase was due to continuing expenses relating to the preparation for the Phase III clinical trial on Multikine.

During the year ended September 30, 2010, general and administrative expenses increased by \$614,215 compared to the year ended September 30, 2009, primarily due to legal fees caused by the Iroquois lawsuit.

Interest income during the year ended September 30, 2010 increased by \$362,236 compared to the year ended September 30, 2009. The increase was due to the greater amount of capital CEL-SCI had for investment in money market funds.

The gain on derivative instruments of \$28,843,772 for the year ended September 30, 2010, was the result of the change in the fair value of the derivative liabilities on the balance sheet. The Series A-E warrants issued in conjunction with several financings during the fiscal year ended September 30, 2009, as well as others are considered derivative liabilities and must be valued at the end of each period. The fluctuation of the price of CEL-SCI's common stock is a major cause of derivative gains or losses.

The interest expense of \$162,326 for the year ended September 30, 2010 was interest on the related party loan. Previous years included amortization of the Series K discount and the premium on the related party loan.

#### Fiscal 2009

During the year ended September 30, 2009, research and development expenses increased by \$1,910,187 compared to the year ended September 30, 2008. This increase was due to continuing expenses relating to the preparation for the Phase III clinical trial on Multikine.

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During the year ended September 30, 2009, general and administrative expenses increased by \$470,860 compared to the year ended September 30, 2008, primarily because of an increase in the Codification 718-10-30-3 "Share Based Payment" costs of approximately \$1,138,062. The Codification 718-10-30-3 "Share Based Payment" cost is a non-cash charge. This increase was primarily offset by a reduction in travel costs (\$51,349), shareholder costs (\$82,983) and presentation costs (\$242,497).

Interest income during the year ended September 30, 2009 decreased by \$483,252 compared to the year ended September 30, 2008. The decrease was due to lower interest rates and a decline in the funds available to invest, until the later part of the year.

The loss on derivative instruments of \$28,491,650 for the year ended September 30, 2009, was the result of the change in fair value of the Series A-E

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Warrants as well as the Series K Notes and Series K Warrants during the period. The Series A-E warrants issued in conjunction with several financings are considered derivative liabilities and must be valued at the end of each period. The fair value of these warrants was calculated to be \$29,741,372 at September 30, 2009. In addition, the remaining Series K warrants were valued at \$5,372,598 at September 30, 2009. This loss was due to three factors: 1) an increase in the Company's share price, and 2) the repricing of the Series K notes to \$0.40 as a result of the June 2009 financing, and 3) the resulting increase in the number of shares and warrants owned by the Series K investors.

The interest expense of \$397,923 for the year ended September 30, 2009 was composed of five elements: 1) amortization of the Series K discount and short term loan discount (\$438,980), 2) interest paid and accrued on the Series K debt (\$115,559), 3) other interest (\$81,602), 4) interest on the short term loan (\$279,158), and net of 5) amortization of loan premium \$517,376. This represents a decrease of \$75,844 from the year ended September 30, 2008 due to the cost of the warrants issued to the short term note holder, a noncash cost. The corresponding amounts for the year ended September 30, 2008 are: 1) \$249,106, 2) \$217,140, 3) \$7,521, 4) \$0, and 5) \$0.

### Research and Development Expenses

During the five years ended September 30, 2010 CEL-SCI's research and development efforts involved Multikine and LEAPS. The table below shows the research and development expenses associated with each project during this five-year period.

	2010 ----	2009 ----	2008 ----	2007 ----	2006 ----
MULTIKINE	\$10,868,046	\$5,281,999	\$3,765,258	\$2,217,108	\$1,656,362
LEAPS	1,043,580	729,751	336,305	311,420	240,614
	-----	-----	-----	-----	-----
TOTAL	\$11,911,626	\$6,011,750	\$4,101,563	\$2,528,528	\$1,896,976
	=====	=====	=====	=====	=====

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In January 2007, FDA gave the go-ahead for the Phase III clinical trial which had earlier been cleared by the Canadian regulatory agency, the Biologics and Genetic Therapies Directorate.

As explained in Item 1 of this report, as of September 30, 2010, CEL-SCI was involved in a number of pre-clinical studies with respect to its LEAPS technology. As with Multikine, CEL-SCI does not know what obstacles it will encounter in future pre-clinical and clinical studies involving its LEAPS technology. Consequently, CEL-SCI cannot predict with any certainty the funds required for future research and clinical trials and the timing of future research and development projects.

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

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of its products.

### Liquidity and Capital Resources

CEL-SCI has had only limited revenues from operations since its inception in March 1983. CEL-SCI has relied primarily upon proceeds realized from the public and private sale of its common and preferred stock and convertible notes to meet its funding requirements. Funds raised by CEL-SCI have been expended primarily in connection with the acquisition of an exclusive worldwide license to, and later purchase of, certain patented and unpatented proprietary technology and know-how relating to the human immunological defense system, patent applications, the repayment of debt, the continuation of research and development sponsored by CEL-SCI, administrative costs and construction of laboratory facilities. Inasmuch as CEL-SCI does not anticipate realizing revenues until such time as it enters into licensing arrangements regarding the technology and know-how licensed to it (which could take a number of years), CEL-SCI is mostly dependent upon the proceeds from the sale of its securities to meet all of its liquidity and capital resource requirements.

In August 2007, CEL-SCI leased a building near Baltimore, Maryland. The building, which consists of approximately 73,000 square feet, has been remodeled in accordance with CEL-SCI's specifications so that it can be used by CEL-SCI to manufacture Multikine for CEL-SCI's Phase III clinical trials and sales of the drug if approved by the FDA. The lease expires on October 31, 2028, and requires annual base rent payments of approximately \$1,667,000 during the twelve months ending October 31, 2011. See Item 2 of this report for more information concerning the terms of this lease.

In August 2006, CEL-SCI sold Series K convertible notes, plus Series K warrants, to independent private investors for \$8,300,000. The notes were

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convertible into shares of CEL-SCI's common stock. On August 31, 2009, all of the Series K notes had either been repaid or had been converted into shares of CEL-SCI's common stock.

As of November 30, 2010, 9,208,642 Series K warrants had been exercised. The remaining Series K warrants allow the holders to purchase up to 2,638,163 shares of CEL-SCI's common stock at a price of \$0.40 per share at any time prior to February 4, 2012. If CEL-SCI sells any additional shares of common stock, or any securities convertible into common stock at a price below the \$0.40, the warrant exercise price will be lowered to the price at which the shares were sold or the lowest price at which the securities are convertible, as the case may be.

One of the Series K note holders, Iroquois Master Fund Ltd., has indicated that it believes the conversion price of the Series K notes, as well as the exercise price of the Series K warrants, should be \$0.20 as opposed to \$0.40. It is CEL-SCI's position that the correct conversion price was \$0.40 and the correct exercise price of the warrants is \$0.40.

On October 21, 2009, Iroquois filed suit against CEL-SCI. In its complaint, alleging breach of contract, breach of fiduciary duty, conversion, and negligence, Iroquois seeks actual and punitive damages, the issuance by CEL-SCI of additional shares and warrants, and a ruling by the court that the conversion price of the notes and the exercise price of the warrants are both \$0.20. See Item 3 of this report for further information.

On August 18, 2008, CEL-SCI sold 1,383,389 shares of common stock and 2,075,084 warrants in a private financing for \$1,037,500. The shares were sold

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at \$0.75, a significant premium over the closing price of CEL-SCI's common stock. In June 2009, an additional 1,166,667 shares and 1,815,698 warrants were issued to the investors. Each warrant entitles the holder to purchase one share of CEL-SCI's common stock at a price of \$0.40 per share at any time prior to August 18, 2014.

On March 6, 2009, CEL-SCI sold 3,750,000 Units as further consideration under a licensing agreement to Byron Biopharma at a price of \$0.20 per Unit totaling \$750,000. Each Unit consisted of one share of CEL-SCI's common stock and two warrants. Each warrant entitles the holder to purchase one share of CEL-SCI's common stock at a price of \$0.25 per share. The warrants are exercisable at any time prior to March 6, 2016.

Between June 23 and July 8, 2009, CEL-SCI sold 15,349,346 shares of its common stock at a price of \$0.40 per share totaling \$6,139,739. The investors in this offering also received 10,284,060 Series A warrants. Each Series A warrant entitles the holder to purchase one share of CEL-SCI's common stock. The Series A warrants may be exercised at any time on or after December 24, 2009 and on or prior to December 24, 2014 at a price of \$0.50 per share. As of November 30, 2010, 8,813,088 Series A warrants had been exercised. The remaining Series A warrants allow the holders to purchase up to 1,470,972 shares of CEL-SCI's common stock. As of September 30, 2010, the fair value of the warrants was determined to be \$676,647.

On July 31, 2009, CEL-SCI borrowed \$2,000,000 from two institutional investors. The loans were repaid on September 29, 2009. The Series B note holders also received Series B warrants which allow the holders to purchase up

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to 500,000 shares of CEL-SCI's common stock at a price of \$0.68 per share. The Series B warrants may be exercised at any time on or after March 3, 2010 and on or prior to March 3, 2015. The fair value of these warrants was determined to be \$245,000 at the time of issuance. This cost was expensed at the time the loan was repaid. As of September 30, 2010, the fair value of the warrants was determined to be \$220,000.

On August 20, 2009, CEL-SCI sold 10,784,435 shares of its common stock to a group of private investors for \$4,852,995 or \$0.45 per share. The investors also received Series C warrants which entitle the investors to purchase 5,392,217 shares of CEL-SCI's common stock. The Series C warrants may be exercised at any time on or after February 20, 2010 and on or prior to February 20, 2015 at a price of \$0.55 per share. As of September 30, 2010, the fair value of the warrants was determined to be \$2,480,420.

On September 21, 2009, CEL-SCI Corporation sold 14,285,715 shares of its common stock to a group of private investors for \$20,000,000 or \$1.40 per share. The investors also received Series D warrants which entitle the investors to purchase up to 4,714,284 shares of CEL-SCI's common stock. The Series D warrants may be exercised at any time prior to September 21, 2011, at a price of \$1.50 per share. As of September 30, 2010, the fair value of the Series D warrants was determined to be \$424,286. In addition, the broker for the placement agent received 714,286 Series E warrants. The Series E warrants may be exercised at any time prior to August 12, 2014, at a price of \$1.75. As of September 30, 2010, the fair value of the Series E warrants was determined to be \$235,714.

On December 10, 2010 CEL-SCI entered into a sales agreement with McNicoll Lewis & Vlak LLC relating to the sale of shares of its common stock which have been registered by means of a shelf registration statement CEL-SCI filed with the Securities and Exchange Commission in July 2009. In accordance with the terms of the sales agreement, CEL-SCI may offer and sell shares of its common

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stock through McNicoll Lewis & Vlak acting as CEL-SCI's agent.

Under the terms of the sales agreement, CEL-SCI may also sell its common stock to McNicoll Lewis & Vlak, as principal for its own account, at a price negotiated at the time of sale.

Sales of CEL-SCI's common stock, if any, may be made in sales deemed to be "at-the-market" equity offerings as defined in Rule 415 of the Securities and Exchange Commission, including sales made directly on or through the NYSE Amex, the existing trading market for CEL-SCI's common stock, sales made to or through a market maker other than on an exchange or otherwise, in negotiated transactions at market prices prevailing at the time of sale or at prices related to such prevailing market prices, and/or any other method permitted by law. CEL-SCI is not required to sell any shares to McNicoll Lewis & Vlak and McNicoll Lewis & Vlak is not required to sell any shares on CEL-SCI's behalf or purchase any of CEL-SCI's shares for its own account.

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McNicoll Lewis & Vlak will be entitled to a commission in an amount equal to the greater of 3% of the gross proceeds from each sale of the shares, or \$0.025 for each share sold, provided, that, in no event will McNicoll Lewis & Vlak receive a commission greater than 8.0% of the gross proceeds from the sale of the shares. In connection with the sale of the common stock on CEL-SCI's behalf, McNicoll Lewis & Vlak may be deemed to be an "underwriter" within the meaning of the Securities Act of 1933, as amended, and the compensation of McNicoll Lewis & Vlak may be deemed to be underwriting commissions or discounts.

Between December 2008 and June 2009, Maximilian de Clara, CEL-SCI's President and a director, loaned CEL-SCI \$1,104,057. The loan was initially payable at the end of March 2009, but was extended to the end of June 2009. At the time the loan was due, and in accordance with the loan agreement, CEL-SCI issued Mr. de Clara a warrant which entitles Mr. de Clara to purchase 1,648,244 shares of CEL-SCI's common stock at a price of \$0.40 per share. The warrant is exercisable at any time prior to December 24, 2014. Although the loan was to be repaid from the proceeds of CEL-SCI's recent financing, CEL-SCI's Directors deemed it beneficial not to repay the loan and negotiated a second extension of the loan with Mr. de Clara on terms similar to the June 2009 financing. Pursuant to the terms of the second extension the note is now due on July 6, 2014, but, at Mr. de Clara's option, the loan can be converted into shares of CEL-SCI's common stock. The number of shares which will be issued upon any conversion will be determined by dividing the amount to be converted by \$0.40. As further consideration for the second extension, Mr. de Clara received warrants which allow Mr. de Clara to purchase 1,849,295 shares of CEL-SCI's common stock at a price of \$0.50 per share at any time prior to January 6, 2015. The loan from Mr. de Clara bears interest at 15% per year and is secured by a lien on substantially all of CEL-SCI's assets. CEL-SCI does not have the right to prepay the loan without Mr. de Clara's consent.

Between July 29, 2009 and March 18, 2010, CEL-SCI received approximately \$14,900,000 from the exercise of stock options and other warrants (including a number of CEL-SCI's Series A, J, K and L warrants) previously issued to private investors.

Inventory has increased significantly in the fiscal year ended September 30, 2010. CEL-SCI has been purchasing supplies for the manufacturing of Multikine in order to begin the Phase III trial. In addition, prepaids have increased with the purchase of insurance for the Phase III trials.

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### Future Capital Requirements

Other than funding operating losses, funding its research and development program, and paying its liabilities, CEL-SCI does not have any material capital commitments. Material future liabilities as of September 30, 2010 are as follows:

#### Contractual Obligations:

	Years Ending September 30,					
Total	2011	2012	2013	2014	2015	2016
Operating Leases	\$35,250,284	\$1,903,471	\$1,896,205	\$1,855,889	\$1,579,931	1,572,839
Employment Contracts	\$2,730,152	1,202,250	797,166	730,736	--	--

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

In addition, CEL-SCI has an additional contract with a consultant for a nine-month period ending in fiscal year 2011. This contract totals approximately \$45,000.

Further, CEL-SCI has contingent obligations with vendors for work that will be completed in relation to the Phase III trial. The timing of these obligations cannot be determined at this time. The amount of these obligations for the Phase III trial is approximately \$27 million with the net cost to CEL-SCI being between \$25 - \$26 million.

CEL-SCI believes that its capital will allow it to enroll the patients in the Phase III clinical trial. CEL-SCI will need to raise additional funds, either through its existing warrants/options, through a debt or equity financing or a partnering arrangement, to complete the Phase III trial and bring Multikine to market. CEL-SCI management believes that all of the above will be much easier than it used to be in the past since CEL-SCI will be involved in a very large Phase III clinical trial for an unmet medical need and should therefore be more attractive as an investment.

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

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

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

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

### Critical Accounting Policies

CEL-SCI's significant accounting policies are more fully described in Note 1 to the consolidated financial statements included as part of this report. However, certain accounting policies are particularly important to the portrayal of financial position and results of operations and require the application of

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significant judgments by management. As a result, the consolidated financial statements are subject to an inherent degree of uncertainty. In applying those policies, management uses its judgment to determine the appropriate assumptions to be used in the determination of certain estimates. These estimates are based on CEL-SCI's historical experience, terms of existing contracts, observance of trends in the industry and information available from outside sources, as appropriate. CEL-SCI's significant accounting policies include:

**Patents** - Patent expenditures are capitalized and amortized using the straight-line method over 17 years. In the event changes in technology or other circumstances impair the value or life of the patent, appropriate adjustment in the asset value and period of amortization is made. An impairment loss is recognized when estimated future undiscounted cash flows expected to result from the use of the asset, and from disposition, is less than the carrying value of the asset. The amount of the impairment loss is the difference between the estimated fair value of the asset and its carrying value.

**Stock Options and Warrants** - Codification 718-10-30-3 requires companies to recognize expense associated with share based compensation arrangements, including employee stock options, using a fair value-based option pricing model. Codification 718-10-30-3 applies to all transactions involving issuance of equity by a company in exchange for goods and services, including employees. Using the modified prospective transition method of adoption, CEL-SCI reflected compensation expense in its financial statements beginning October 1, 2005. The modified prospective transition method does not require restatement of prior periods to reflect the impact of Codification 718-10-30-3. As such, compensation expense is recognized for awards that were granted, modified, repurchased or cancelled on or after October 1, 2005.

**Options to non-employees** are accounted for in accordance with Codification 505-50-S99-1 Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services. Accordingly, compensation is recognized when goods or services are received and is measured using the Black-Scholes valuation model. The Black-Scholes model requires CEL-SCI's management to make assumptions regarding the fair value of the options at the date of grant and the expected life of the options.

**Asset Valuations and Review for Potential Impairments** - CEL-SCI reviews its fixed assets, intangibles and deferred rent every fiscal quarter. This review requires that CEL-SCI make assumptions regarding the value of these assets and the changes in circumstances that would affect the carrying value of these



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assets. If such analysis indicates that a possible impairment may exist, CEL-SCI is then required to estimate the fair value of the asset and, as deemed appropriate, expense all or a portion of the asset. The determination of fair value includes numerous uncertainties, such as the impact of competition on future value. CEL-SCI believes that it has made reasonable estimates and judgments in determining whether its long-lived assets have been impaired; however, if there is a material change in the assumptions used in its determination of fair values or if there is a material change in economic

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conditions or circumstances influencing fair value, CEL-SCI could be required to recognize certain impairment charges in the future. As a result of the reviews, no changes in asset values were required.

Prepaid Expenses and Inventory--Inventory consists of bulk purchases of laboratory supplies used on a daily basis in the lab and items that will be used for future production. The items in inventory are expensed when used in production or daily activity as Research and Development expenses. These items are disposables and consumables and can be used for both the manufacturing of Multikine for clinical studies and in the laboratory for quality control and bioassay use. They can be used in training, testing and daily laboratory activities. Prepaid expenses are payments for services over a long period and are expensed over the time period for which the service is rendered.

Derivative Instruments--CEL-SCI enters into financing arrangements that consist of freestanding derivative instruments or hybrid instruments that contain embedded derivative features. CEL-SCI accounts for these arrangement in accordance with Codification 815-10-50, "Accounting for Derivative Instruments and Hedging Activities", "Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock", as well as related interpretations of these standards. In accordance with accounting principles generally accepted in the United States ("GAAP"), derivative instruments and hybrid instruments are recognized as either assets or liabilities in the statement of financial position and are measured at fair value with gains or losses recognized in earnings or other comprehensive income depending on the nature of the derivative or hybrid instruments. Embedded derivatives that are not clearly and closely related to the host contract are bifurcated and recognized at fair value with changes in fair value recognized as either a gain or loss in earnings if they can be reliably measured. When the fair value of embedded derivative features cannot be reliably measured, CEL-SCI measures and reports the entire hybrid instrument at fair value with changes in fair value recognized as either a gain or loss in earnings. CEL-SCI determines the fair value of derivative instruments and hybrid instruments based on available market data using appropriate valuation models, giving consideration to all of the rights and obligations of each instrument and precluding the use of "blockage" discounts or premiums in determining the fair value of a large block of financial instruments. Fair value under these conditions does not necessarily represent fair value determined using valuation standards that give consideration to blockage discounts and other factors that may be considered by market participants in establishing fair value.

### Accounting Pronouncements

In March 2008, the FASB issued Codification 815-20-50-1, "Disclosures about Derivative Instruments and Hedging Activities - an amendment of FASB Statement No. 133", which changes disclosure requirements for derivative instruments and hedging activities. The statement is effective for periods ending on or after November 15, 2008, with early application encouraged. CEL-SCI has adopted this statement with no effect on its consolidated financial statements.

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In June 2008, the FASB finalized Codification 815-40-15-7, "Determining Whether an Instrument (or Embedded Feature) is Indexed to an Entity's Own Stock". The EITF lays out a procedure to determine if the debt instrument is indexed to its own common stock. The EITF is effective for fiscal years

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beginning after December 15, 2008. CEL-SCI has adopted this codification and reviewed all outstanding options and warrants as of October 1, 2009. See Note 11 in the financial statements included as part of this report for a discussion.

In September 2008, the FASB staff issued Codification 815-10-50-1A, "Disclosures about Credit Derivatives and Certain Guarantees: An Amendment of FASB Statement No. 133 and FASB Interpretation No. 45; and Clarification of the Effective Date of FASB Statement No. 161". The codification applies to credit derivatives within the scope of Statement 133 and hybrid instruments that have embedded credit derivatives. It deals with disclosures related to these derivatives and is effective for reporting periods ending after November 15, 2008. It also clarifies the effective date of Codification 815-20-50-1 as any reporting period beginning after November 15, 2008. CEL-SCI has adopted this codification and it had no impact on its consolidated financial statements.

In April 2009, the FASB issued Codification 825-10-65-1, "Interim Disclosures about Fair Value of Financial Instruments". The codification amends FASB Statement No. 107, "Disclosures about Fair Values of Financial Instruments", to require disclosures about fair values of financial instruments for interim reporting periods of publicly traded companies as well as in annual financial statements. The codification also amends APB Opinion No. 28, "Interim Financial Reporting", to require those disclosures in summarized financial information at interim reporting periods. This Codification topic became effective for interim and annual reporting periods ending after June 15, 2009. CEL-SCI adopted this codification in the quarter ended June 30, 2009. There was no significant impact from this adoption on CEL-SCI's consolidated financial statements.

In May 2009, the FASB issued Codification 855-10-50, "Subsequent Events", which establishes general standards of accounting for and disclosure of events that occur after the balance sheet date but before the financial statements are issued or are available to be issued. It requires the disclosure of the date through which an entity has evaluated subsequent events and the basis for that date. The codification establishes the period after the balance sheet date during which management of a reporting entity should evaluate events or transactions that may occur for potential recognition or disclosure in the financial statements, the circumstances under which an entity should recognize events or transactions occurring after the balance sheet date in its financial statements and the disclosures that an entity should make about events or transactions that occurred after the balance sheet date. The codification became effective for CEL-SCI for the period ended June 30, 2009 and is to be applied prospectively. The impact of the adoption was not significant.

In January 2010, the FASB amended Codification 820-10, "Improving Disclosures about Fair Value Measurement", effective for interim periods beginning after December 15, 2009. This amendment changes disclosures required for interim and annual periods with respect to fair value measurements. CEL-SCI has adopted the change in the disclosure requirements and the effect was immaterial.

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### ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISKS

Market risk is the potential change in an instrument's value caused by, for example, fluctuations in interest and currency exchange rates. CEL-SCI enters into financing arrangements that are or include freestanding derivative instruments or that are, or include, hybrid instruments that contain embedded derivative features. CEL-SCI does not enter into derivative instruments for trading purposes. Additional information is presented in the notes to consolidated financial statements. The fair value of these instruments is affected primarily by volatility of the trading prices of the CEL-SCI's common stock. For three years ended September 30, 2010, CEL-SCI recognized a gain or (loss) of \$28,843,772, \$(28,491,650) and \$1,799,393, respectively, resulting from changes in fair value of derivative instruments. CEL-SCI has no exposure to risks associated with foreign exchange rate changes because none of the operations of CEL-SCI are transacted in a foreign currency. The interest risk on investments on September 30, 2010 was considered immaterial due to the fact that the interest rates at that time were nominal at best and CEL-SCI keeps its cash and cash equivalents in short term maturities.

### ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

See the consolidated financial statements included with this Report.

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

Not applicable

### ITEM 9A. CONTROLS AND PROCEDURES

Under the direction and with the participation of CEL-SCI's management, including CEL-SCI's Chief Executive Officer and Chief Financial Officer, CEL-SCI carried out an evaluation of the effectiveness of the design and operation of its disclosure controls and procedures as of September 30, 2010. CEL-SCI maintains disclosure controls and procedures that are designed to ensure that information required to be disclosed in its periodic reports with the Securities and Exchange Commission is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and regulations, and that such information is accumulated and communicated to CEL-SCI's management, including its principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure. CEL-SCI's disclosure controls and procedures are designed to provide a reasonable level of assurance of reaching its desired disclosure control objectives. Based on the evaluation, the Chief Executive and Principal Financial Officer has concluded that CEL-SCI's disclosure controls were effective as of September 30, 2010.

#### Management's Report on Internal Control Over Financial Reporting

CEL-SCI's management is responsible for establishing and maintaining adequate internal control over financial reporting and for the assessment of the

effectiveness of internal control over financial reporting. As defined by the Securities and Exchange Commission, internal control over financial reporting is a process designed by, or under the supervision of CEL-SCI's principal executive officer and principal financial officer and implemented by CEL-SCI's Board of Directors, management and other personnel, to provide reasonable assurance

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regarding the reliability of financial reporting and the preparation of CEL-SCI's financial statements in accordance with U.S. generally accepted accounting principles.

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

Geert Kersten, CEL-SCI's Chief Executive and Principal Financial Officer, evaluated the effectiveness of CEL-SCI's internal control over financial reporting as of September 30, 2010 based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission, or the COSO Framework. Management's assessment included an evaluation of the design of CEL-SCI's internal control over financial reporting and testing of the operational effectiveness of those controls.

Based on this evaluation, Mr. Kersten concluded that CEL-SCI's internal control over financial reporting was effective as of September 30, 2010.

There was no change in CEL-SCI's internal control over financial reporting that occurred during the quarter ended September 30, 2010 that has materially affected, or is reasonably likely to materially affect, CEL-SCI's internal control over financial reporting.

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

### ITEM 9B. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

The annual meeting of CEL-SCI's shareholders was held on July 16, 2010. At the meeting the following persons were elected as directors for the upcoming year:

Name	Votes For	Votes Withheld
Maximilian de Clara	32,097,084	11,280,445
Geert Kersten	34,808,573	8,568,956
Alexander Esterhazy	34,664,725	8,712,804
C. Richard Kinsolving	35,236,897	8,140,632
Peter R. Young	35,223,756	8,153,773

At the meeting the following proposals were ratified by the shareholders.

(1) to approve the adoption of CEL-SCI's 2010 Incentive Stock Option Plan which provides that up to 2,000,000 shares of common stock may be issued upon the exercise of options granted pursuant to the Incentive Stock Option Plan;

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(2) to approve the adoption of CEL-SCI's 2010 Non-Qualified Stock Option Plan which provides that up to 5,000,000 shares of common stock may be issued upon the exercise of options granted pursuant to the Non-Qualified Stock Option Plan;

(3) to approve the adoption of CEL-SCI's 2010 Stock Bonus Plan which provides that up to 2,000,000 shares of common stock may be issued to persons

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granted stock bonuses pursuant to the Stock Bonus Plan;

(4) to approve an amendment to CEL-SCI's Stock Compensation Plan to provide for the issuance of up to 2,000,000 additional restricted shares of common stock to CEL-SCI's directors, officers, employees and consultants for services provided to the Company;

(5) to ratify the appointment of BDO USA, LLP as CEL-SCI's independent registered public accounting firm for the fiscal year ending September 30, 2010.

The following is a tabulation of votes cast with respect to these proposals:

Proposal	Votes			Broker Non-Votes
	For	Against	Abstain	
1.	29,741,736	13,177,965	457,828	113,983,024
2.	27,610,822	14,884,483	882,224	113,983,024
3.	28,725,699	13,840,290	811,540	113,983,024
4.	27,898,687	14,166,249	1,312,593	113,983,024
5.	150,860,671	4,347,654	2,152,228	0

### ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

#### Officers and Directors

Name	Age	Position
Maximilian de Clara	80	Director and President
Geert R. Kersten, Esq.	51	Director, Chief Executive Officer and Treasurer
Patricia B. Prichep	59	Senior Vice President of Operations and Secretary
Dr. Eyal Talor	54	Chief Scientific Officer
Dr. Daniel H. Zimmerman	69	Senior Vice President of Research, Cellular Immunology
John Cipriano	68	Senior Vice President of Regulatory Affairs
Alexander G. Esterhazy	68	Director
Dr. C. Richard Kinsolving	73	Director
Dr. Peter R. Young	65	Director

The directors of CEL-SCI serve in such capacity until the next annual meeting of CEL-SCI's shareholders and until their successors have been duly elected and qualified. The officers of CEL-SCI serve at the discretion of CEL-SCI's directors.

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Mr. Maximilian de Clara, by virtue of his position as an officer and director of CEL-SCI, may be deemed to be the "parent" and "founder" of CEL-SCI as those terms are defined under applicable rules and regulations of the SEC.

All of CEL-SCI's directors have served as directors for a significant period of time. Consequently, their long-standing experience with CEL-SCI benefits both CEL-SCI and its shareholders.

The principal occupations of CEL-SCI's officers and directors, during the

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past several years, are as follows:

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. During the summers of 1954 and 1955, he worked as a research assistant at the University of Istanbul in the field of cancer research. 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.

Geert Kersten has served in his current leadership role at CEL-SCI since 1995. Mr. Kersten has been with CEL-SCI since 1987. He has been involved in the pioneering field of cancer immunotherapy for almost two decades and has successfully steered CEL-SCI through many challenging cycles in the biotechnology industry. Mr. Kersten also provides CEL-SCI with significant expertise in the fields of finance and law and has a unique vision of how Multikine will change the way cancer is treated. Prior to his association with 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, and completed his studies in the U.S.

Mr. Kersten completed his Undergraduate Degree in Accounting, received an M.B.A. from George Washington University, and a law degree (J.D.) from American University in Washington, DC.

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 the auditing firm for financial reporting. Between June 1990 and December 1992, Ms. Prichep was the Manager of Quality and Productivity for the NASD's Management, Systems and Support Department where 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. where she was responsible for all operations and compliance for the company and was licensed as a securities broker. Ms. Prichep received her B.A. from the University of Bridgeport in Connecticut.

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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), 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

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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 Institutions; School of Public Health. He holds two US 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. He also has numerous product and process inventions as well as a number of pending US 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.

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 holds 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 in 1969, a Masters in Zoology in 1966 from the University of Florida and a B.S. in Biology from Emory and Henry College in 1963.

John Cipriano, was 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

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companies. In addition, he held positions at the United States Food and Drug Administration (FDA) 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.

Alexander G. Esterhazy has been a Director of CEL-SCI since December 1999 and has been an independent financial advisor since November 1997. Between July 1991 and October 1997, Mr. Esterhazy was a senior partner of Corpofina S.A. Geneva, a firm engaged in mergers, acquisitions and portfolio management. Between January 1988 and July 1991, Mr. Esterhazy was a managing director of DG Bank in Switzerland. During this period Mr. Esterhazy was in charge of the Geneva, Switzerland branch of the DG Bank, founded and served as vice president of DG Finance (Paris) and was the President and Chief Executive officer of DG-Bourse, a securities brokerage firm.

C. Richard Kinsolving, Ph.D. has been a Director of CEL-SCI since April 2001. Since February 1999, Dr. Kinsolving has been the Chief Executive Officer of BioPharmacon, a pharmaceutical development company. Between December 1992 and February 1999, Dr. Kinsolving was the President of Immuno-Rx, Inc., a company

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engaged in immuno-pharmaceutical development. Between December 1991 and September 1995, Dr. Kinsolving was President of Bestechnology, Inc. a nonmedical research and development company producing bacterial preparations for industrial use. Dr. Kinsolving received his Ph.D. in Pharmacology from Emory University (1970), his Masters degree in Physiology/Chemistry from Vanderbilt University (1962), and his Bachelor's degree in Chemistry from Tennessee Tech. University (1957).

Peter R. Young, Ph.D. has been a Director of CEL-SCI since August 2002. Dr. Young has been a senior executive within the pharmaceutical industry in the United States and Canada for most of his career. Over the last 20 years he has primarily held positions of Chief Executive Officer or Chief Financial Officer and has extensive experience with acquisitions and equity financings. Since November 2001, Dr. Young has been the President of Agnus Dei, LLC, which acts as a partner in an organization managing immune system clinics which treat patients with diseases such as cancer, multiple sclerosis and hepatitis. Since January 2003, Dr. Young has been the President and Chief Executive Officer of SRL Technology, Inc., a company involved in the development of pharmaceutical (drug) delivery systems. Between 1998 and 2001, Dr. Young was the Chief Financial Officer of Adams Laboratories, Inc. Dr. Young received his Ph.D. in Organic Chemistry from the University of Bristol, England (1969), and his Bachelor's degree in Honors Chemistry, Mathematics and Economics also from the University of Bristol, England (1966).

All of CEL-SCI's officers devote substantially all of their time to CEL-SCI's business.

Alexander G. Esterhazy, Dr. C. Richard Kinsolving and Dr. Peter R. Young are independent directors as that term is defined in section 803 of the listing standards of the NYSE Amex.

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CEL-SCI has an audit committee and compensation committee. The members of the audit committee are Alexander G. Esterhazy, Dr. C. Richard Kinsolving and Dr. Peter Young. Dr. Peter Young serves as the audit committee's financial expert. The members of the compensation committee are Alexander Esterhazy, Dr. C. Richard Kinsolving and Dr. Peter Young.

CEL-SCI's Board of Directors does not have a "leadership structure", as such, since each director is entitled to introduce resolutions to be considered by the Board and each director is entitled to one vote on any resolution considered by the Board. CEL-SCI's Chief Executive Officer is not the Chairman of CEL-SCI's Board of Directors.

CEL-SCI's Board of Directors has the ultimate responsibility to evaluate and respond to risks facing CEL-SCI. CEL-SCI's Board of Directors fulfills its obligations in this regard by meeting on a regular basis and communicating, when necessary, with CEL-SCI's officers.

CEL-SCI has adopted a Code of Ethics which is applicable to CEL-SCI'S principal executive, financial, and accounting officers and persons performing similar functions. The Code of Ethics is available on CEL-SCI's website, located at [www.cel-sci.com](http://www.cel-sci.com).

If a violation of this code of ethics act is discovered or suspected, the Senior Officer must (anonymously, if desired) send a detailed note, with relevant documents, to CEL-SCI's Audit Committee, c/o Dr. Peter Young, 5458 Beacon Hill Drive, Frisco, TX 75034.

For purposes of electing directors at its annual meeting CEL-SCI does not



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have a nominating committee or a committee performing similar functions. CEL-SCI's Board of Directors does not believe a nominating committee is necessary since CEL-SCI's Board of Directors is small and the Board of Directors as a whole performs this function. CEL-SCI's Directors have adopted a policy which provides that nominees to the Board of Directors are selected by a majority vote of CEL-SCI's independent directors.

CEL-SCI does not have any policy regarding the consideration of director candidates recommended by shareholders since a shareholder has never recommended a nominee to the Board of Directors. However, CEL-SCI's Board of Directors will consider candidates recommended by shareholders. To submit a candidate for the Board of Directors the shareholder should send the name, address and telephone number of the candidate, together with any relevant background or biographical information, to CEL-SCI's Chief Executive Officer, at the address shown on the cover page of this report. The Board has not established any specific qualifications or skills a nominee must meet to serve as a director. Although the Board does not have any process for identifying and evaluating director nominees, the Board does not believe there would be any differences in the manner in which the Board evaluates nominees submitted by shareholders as opposed to nominees submitted by any other person.

CEL-SCI does not have a policy with regard to Board member's attendance at annual meetings. All Board members, with the exception of Mr. de Clara and Mr. Esterhazy, attended the last annual shareholder's meeting held on July 16, 2010.

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Holders of CEL-SCI's common stock can send written communications to CEL-SCI's entire Board of Directors, or to one or more Board members, by addressing the communication to "the Board of Directors" or to one or more directors, specifying the director or directors by name, and sending the communication to CEL-SCI's offices in Vienna, Virginia. Communications addressed to the Board of Directors as whole will be delivered to each Board member. Communications addressed to a specific director (or directors) will be delivered to the director (or directors) specified.

Security holder communications not sent to the Board of Directors as a whole or to specified Board members are not relayed to Board members.

### ITEM 11. EXECUTIVE COMPENSATION

#### Compensation Discussion and Analysis

This Compensation Discussion and Analysis (CD&A) outlines CEL-SCI's compensation philosophy, objectives and process for its executive officers. This CD&A includes information on how compensation decisions are made, the overall objectives of CEL-SCI's compensation program, a description of the various components of compensation that are provided, and additional information pertinent to understanding CEL-SCI's executive officer compensation program.

The Compensation Committee determines the compensation of CEL-SCI's Chief Executive Officer and President and delegates to the Chief Executive Officer the responsibility to determine the base salaries of all officers other than himself under the constraints of an overall limitation on the total amount of compensation to be paid to them.

#### Compensation Philosophy

CEL-SCI's compensation philosophy extends to all employees, including executive officers, and is designed to align employee and shareholder interests. The philosophy's objective is to pay fairly based upon the employee's position,

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experience and individual performance. Employees may be rewarded through additional compensation when CEL-SCI meets or exceeds targeted business objectives. Generally, under CEL-SCI's compensation philosophy, as an employee's level of responsibility increases, a greater portion of his or her total potential compensation becomes contingent upon annual performance.

A substantial portion of an executive's compensation incorporates performance criteria that support and reward achievement of CEL-SCI's long term business goals.

The fundamental principles of CEL-SCI's compensation philosophy are described below:

- o Market-driven. Compensation programs are structured to be competitive both in their design and in the total compensation that they offer.
- o Performance-based. Certain officers have some portion of their incentive compensation linked to CEL-SCI's performance. The

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application of performance measures as well as the form of the reward may vary depending on the employee's position and responsibilities.

Based on a review of its compensation programs, CEL-SCI does not believe that such programs encourage any of its employees to take risks that would be likely to have a material adverse effect on CEL-SCI. CEL-SCI reached this conclusion based on the following:

- o The salaries paid to employees are consistent with the employees' duties and responsibilities.
- o Employees who have high impact relative to the expectations of their job duties and functions are rewarded.
- o CEL-SCI retains employees who have skills critical to its long term success.

### Review of Executive Officer Compensation

CEL-SCI's current policy is that the various elements of the compensation package are not interrelated in that gains or losses from past equity incentives are not factored into the determination of other compensation. For instance, if options that are granted in a previous year become underwater the next year, the Committee does not take that into consideration in determining the amount of the options or restricted stock to be granted the next year. Similarly, if the options or restricted shares granted in a previous year become extremely valuable, the Committee does not take that into consideration in determining the options or restricted stock to be awarded for the next year.

CEL-SCI does not have a policy with regard to the adjustment or recovery of awards or payments if our relevant performance measures upon which they are based are restated or otherwise adjusted in a manner that would reduce the size of an award or payment.

### Components of Compensation--Executive Officers

CEL-SCI's executive officers are compensated through the following three components:

- o Base Salary

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- o Long-Term Incentives (stock options and/or grants of stock)
- o Benefits

These components provide a balanced mix of base compensation and compensation that is contingent upon each executive officer's individual performance. A goal of the compensation program is to provide executive officers with a reasonable level of security through base salary and benefits. CEL-SCI wants to ensure that the compensation programs are appropriately designed to encourage executive officer retention and motivation to create shareholder value. The Compensation Committee believes that CEL-SCI's stockholders are best served when CEL-SCI can attract and retain talented executives by providing compensation packages that are competitive but fair.

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In past years, base salaries, benefits and incentive compensation opportunities were generally targeted near the median of general survey market data derived from indices covering similar biotech/pharmaceutical companies. The companies included Achillion Pharmaceuticals, Inc., Acura Pharmaceutical, Inc., Alimera Sciences, Inc., Amorfix Life Sciences Ltd., Antigenics, Inc., ARCA biopharma (ARCA Discovery), ARYx Therapeutics, Inc., Avanir Pharmaceuticals, Bellus Health, Inc., Cadence Pharmaceuticals, Inc., Capstone Therapeutics, Chelsea Therapeutics, Inc., Cortex Pharmaceuticals, Inc., EpiCept Corp., EXACT Sciences Corp., Helix BioPharma, IGI Laboratories Inc., Inhibitex, Inc., Isotechnika Pharma Inc., Medicis Technologies Corp., NeurogesX, Inc., Novavax, Inc., Orbus Pharma Inc., Orexigen Therapeutics Inc., OXiGENE, Inc., Pharmacyclics, Inc., Quest PharmaTech Inc., Reata Pharmaceuticals, Inc., Resverlogix Corp., SCOLR Pharma, Inc., StemCells, Inc. and Threshold Pharmaceuticals, Inc. CEL-SCI has not used third party consultants to provide it with recommendations or reports.

### Base Salaries

Base salaries generally have been targeted to be competitive when compared to the salary levels of persons holding similar positions in other pharmaceutical companies and other publicly traded companies of comparable size. Each executive officer's respective responsibilities, experience, expertise and individual performance are considered.

A further consideration in establishing compensation for the senior employees is their long term history with CEL-SCI. Taken into consideration are factors that have helped CEL-SCI survive in times when it was financially extremely weak, such as: willingness to accept salary cuts, willingness not to be paid at all for extended time periods, and in general an attitude that helped CEL-SCI survive during financially difficult times. For example, Geert Kersten, Maximilian de Clara and Patricia Prichep were without any salary between September 2008 and June 2009. Other senior members took substantial salary cuts, all geared towards helping CEL-SCI survive. In all of these cases the officers continued to work without any guarantee of payment.

### Long-Term Incentives

Stock grants and option grants help to align the interests of CEL-SCI's employees with those of its shareholders. Options and stock grants are made under CEL-SCI's Stock Option, Stock Bonus and Stock Compensation Plans. Options are granted with exercise prices equal to the closing price of CEL-SCI's common stock on the day immediately preceding the date of grant, with pro rata vesting at the end of each of the following three years.

CEL-SCI believes that grants of equity-based compensation:

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- o Enhance the link between the creation of shareholder value and long-term executive incentive compensation;
- o Provide focus, motivation and retention incentive; and
- o Provide competitive levels of total compensation.

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CEL-SCI's management believes that the pricing for biotechnology stocks is highly inefficient until the time of product sales. As such any long term compensation tied to progress as measured by share price is not as efficient as it should be. However, CEL-SCI's Compensation Committee has not been able to substitute a better measurement and therefore continues to believe that stock grants and option grants best align the needs of the corporation and the employee with those of the shareholders.

### Benefits

In addition to cash and equity compensation programs, executive officers participate in the health and welfare benefit programs available to other employees. In a few limited circumstances, CEL-SCI provides other benefits to certain executive officers, such as car allowances.

All executive officers are eligible to participate in CEL-SCI's 401(k) plan on the same basis as its other employees. CEL-SCI matches 100% of each employee's contribution up to the first 6% of his or her salary.

The following table sets forth in summary form the compensation received by (i) the Chief Executive Officer of CEL-SCI and (ii) by each other executive officer of CEL-SCI who received in excess of \$100,000 during the three fiscal years ended September 30, 2010.

Name and Principal Position	Fiscal Year	Salary (1)	Bonus (2)	Restrict- ed Stock Awards (3)	Option Awards (4)	All Other Annual Compen- sation (5)	Total
Maximilian de Clara, President	2010	\$363,000	--	\$26,499	136,197	\$102,219	\$ 627,8
	2009	334,720	--	267,000	380,121	83,274	1,065,1
	2008	363,000	--	543,174	103,320	89,268	1,098,7
Geert R. Kersten, Chief Executive Officer and Treasurer	2010	454,009	220,995	37,524	359,089	55,309	1,126,5
	2009	408,691	--	81,700	526,366	34,892	1,051,6
	2008	404,900	--	156,674	103,320	39,901	704,7
Patricia B. Prichep Senior Vice President of Operations and Secretary	2010	199,898	--	25,039	237,090	6,027	468,0
	2009	174,913	--	41,603	235,467	4,225	456,2
	2008	185,780	--	82,558	51,660	4,225	324,2
Eyal Talor, Ph.D. Chief Scientific Officer	2010	239,868	--	28,872	237,090	6,027	511,8
	2009	212,265	--	36,627	137,878	4,225	390,9
	2008	229,353	--	81,187	51,660	4,225	366,4

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Daniel Zimmerman, Ph.D.	2010	165,800	--	15,857	64,455	5,027	251,1
Senior Vice President	2009	47,124	--	16,892	--	875	64,8
of Research. Cellular Immunology (6)	2008	175,988	--	46,186	38,745	4,225	265,1
John Cipriano	2010	175,952	--	6,625	240,711	27	423,3
Senior Vice President	2009	48,594	--	15,840	--	25	64,4
of Regulatory Affairs(7)	2008	171,028	--	45,893	38,745	25	55,6

- (1) The dollar value of base salary (cash and non-cash) earned. During three years ended September 30, 2010, \$0.00, \$0.00 and \$18,730, respectively, of the total salaries paid to the persons shown in the table were paid in restricted shares of CEL-SCI's common stock.

Information concerning the issuance of these restricted shares is shown in the following table:

Date Issued	Shares	Number of Shares Issued	Price Per Share
01/15/2008		36,020	\$0.52

On January 15, 2008 the amount of compensation satisfied through the issuance of shares was determined by multiplying the number of shares issued by the price per share. The price per share was equal to the closing price of CEL-SCI's common stock on the date prior to the date the shares were issued.

- (2) The dollar value of bonus (cash and non-cash) earned.
- (3) During the periods covered by the table, the value of the shares of restricted stock issued as compensation for services to the persons listed in the table. In the case of Mr. de Clara, during the three years ended September 30, 2010, \$0.00, \$200,000 and \$400,000, respectively, were paid in restricted shares of CEL-SCI's common stock which cannot be sold in the public market for a period of three years after the date of issuance. In the case of all other persons listed in the table, the shares were issued as CEL-SCI's contribution on behalf of the named officer to CEL-SCI's 401(k) retirement plan and restricted shares issued at the market price from the Stock Compensation Plan. The value of all stock awarded during the periods covered by the table are calculated in accordance with Codification 718-10-30-3 requirements.
- (4) The greatest part of the value in FY 2009 was derived from options awarded to employees who did not collect a salary, or reduced or deferred their salary between September 15, 2008 and June 30, 2009. For example, Mr. de Clara, Mr. Kersten and Ms. Prichep did not collect any salary between September 30, 2008 and June 30, 2009. The fair value of all stock options granted during the periods covered by the table are calculated on the grant date in accordance with Codification 718-10-30-3 requirements.

- (5) All other compensation received that CEL-SCI could not properly report in any other column of the table including annual contributions or other allocations to vested and unvested defined contribution plans, and the dollar value of any insurance premiums paid by, or on behalf of, CEL-SCI with respect to term life insurance for the benefit of the named executive officer, and the full dollar value of the remainder of the premiums paid by,

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or on behalf of, CEL-SCI. Includes board of directors fees for Mr. de Clara and Mr. Kersten.

- (6) Dr. Zimmerman was CEL-SCI's Senior Vice President of Research, Cellular Immunology between January 1996 and December 2008 and since November 2009.
- (7) Mr. Cipriano was CEL-SCI's Senior Vice President of Regulatory Affairs between March 2004 and December 2008 and since October 2009.

### Long Term Incentive Plans - Awards in Last Fiscal Year

See footnote 6 to the financial statements included as part of this report.

### Employee Pension, Profit Sharing or Other Retirement Plans

CEL-SCI has a defined contribution retirement plan, qualifying under Section 401(k) of the Internal Revenue Code and covering substantially all CEL-SCI's employees. CEL-SCI's contribution to the plan is made in shares of CEL-SCI's common stock. Each participant's contribution is matched by CEL-SCI with shares of common stock which have a value equal to 100% of the participant's contribution, not to exceed the lesser of \$1,000 or 6% of the participant's total compensation. CEL-SCI's contribution of common stock is valued each quarter based upon the closing price of its common stock. The fiscal 2010 expenses for this plan were \$123,500. Other than the 401(k) Plan, CEL-SCI does not have a defined benefit, pension plan, profit sharing or other retirement plan.

### Compensation of Directors During Year Ended September 30, 2010

Name	Paid in Cash	Stock Awards (1)	Option Awards (2)	Total
----	-----	-----	-----	-----
Maximilian de Clara	\$ 40,000	-	\$ 136,197	\$ 176,197
Geert Kersten	\$ 40,000	-	\$ 359,089	\$ 399,089
Alexander Esterhazy	\$ 41,000	-	\$ 64,455	\$ 105,455
C. Richard Kinsolving	\$ 41,000	-	\$ 64,455	\$ 105,455
Peter R. Young	\$ 41,000	-	\$ 64,455	\$ 105,455

- (1) The fair value of stock issued for services.
- (2) The fair value of options granted computed in accordance with Codification 718-10-30-3 on the date of grant. Also includes the fair value of the milestone options expensed during fiscal year 2010 that were issued to Mr. de Clara and Mr. Kersten in 2009.

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Directors' fees paid to Maximilian de Clara and Geert Kersten are included in the Executive Compensation table.

### Employment Contracts.

#### Maximilian de Clara

In April 2005, CEL-SCI entered into a three-year employment agreement with Maximilian de Clara, CEL-SCI's President. The employment agreement provided that CEL-SCI would pay Mr. de Clara an annual salary of \$363,000 during the term of the agreement. On September 8, 2006 Mr. de Clara's Employment Agreement was amended and extended to April 30, 2010. The terms of the amendment to Mr. de

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Clara's employment agreement are referenced in a report on Form 8-K filed with the Securities and Exchange Commission on September 8, 2006. On August 30, 2010, Mr. de Clara's employment agreement, as amended on September 8, 2006, was extended to August 30, 2013.

In the event that there is a material reduction in Mr. de Clara's authority, duties or activities, or in the event there is a change in the control of CEL-SCI, the agreement allows Mr. de Clara to resign from his position at CEL-SCI and receive a lump-sum payment from CEL-SCI equal to 18 months salary (\$544,500) and the unvested portion of any stock options would vest immediately (\$284,794). For purposes of the employment agreement, a change in the control of CEL-SCI means the sale of more than 50% of the outstanding shares of CEL-SCI's common stock, or a change in a majority of CEL-SCI's directors.

The employment agreement will also terminate upon the death of Mr. de Clara, Mr. de Clara's physical or mental disability, the conviction of Mr. de Clara for any crime involving fraud, moral turpitude, or CEL-SCI's property, or a breach of the employment agreement by Mr. de Clara. If the employment agreement is terminated for any of these reasons, Mr. de Clara, or his legal representatives, as the case may be, will be paid the salary provided by the employment agreement through the date of termination.

Geert Kersten

Effective September 1, 2003, CEL-SCI entered into a three-year employment agreement with Mr. Kersten. The employment agreement provides that during the term of the employment agreement CEL-SCI will pay Mr. Kersten an annual salary of \$370,585 plus any increases approved by the Board of Directors during the period of the employment agreement. In the event there is a change in the control of CEL-SCI, the agreement allows Mr. Kersten to resign from his position at CEL-SCI and receive a lump-sum payment from CEL-SCI equal to 24 months salary (\$883,818) and the unvested portion of any stock options would vest immediately (\$1,172,265). For purposes of the employment agreement a change in the control of CEL-SCI means: (1) the merger of CEL-SCI with another entity if after such merger the shareholders of CEL-SCI do not own at least 50% of voting capital stock of the surviving corporation; (2) the sale of substantially all of the assets of CEL-SCI; (3) the acquisition by any person of more than 50% of CEL-SCI's common stock; or (4) a change in a majority of CEL-SCI's directors which has not been approved by the incumbent directors. Effective September 1, 2006, Mr. Kersten's employment agreement was extended to September 1, 2011.

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The Employment Agreement will also terminate upon the death of Mr. Kersten, Mr. Kersten's physical or mental disability, willful misconduct, an act of fraud against CEL-SCI, or a breach of the Employment Agreement by Mr. Kersten. If the Employment Agreement is terminated for any of these reasons Mr. Kersten, or his legal representatives, as the case may be, will be paid the salary provided by the Employment Agreement through the date of termination.

Patricia B. Prichep / Eyal Talor, Ph.D.

On August 30, 2010, CEL-SCI entered into a three-year employment agreement with Patricia B. Prichep, CEL-SCI's Senior Vice President of Operations. The employment agreement with Ms. Prichep provides that during the term of the agreement CEL-SCI will pay Ms. Prichep an annual salary of \$194,298 plus any increases approved by the Board of Directors during the period of the employment agreement.

On August 30, 2010, CEL-SCI also entered into a three-year employment

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agreement with Eyal Talor, Ph.D., CEL-SCI's Chief Scientific Officer. The employment agreement with Dr. Talor provides that during the term of the agreement CEL-SCI will pay Dr. Talor an annual salary of \$239,868 plus any increases approved by the Board of Directors during the period of the employment agreement.

If Ms. Prichep or Dr. Talor resigns within ninety (90) days of the occurrence of any of the following events: (i) a relocation (or demand for relocation) of employee's place of employment to a location more than thirty-five (35) miles from the employee's current place of employment, (ii) a significant and material reduction in the employee's authority, job duties or level of responsibility or (iii) the imposition of significant and material limitations on the employee's autonomy in her or his position, the employment agreement will be terminated and the employee will be paid the salary provided by the employment agreement through the date of termination and the unvested portion of any stock options held by the employee will vest immediately.

In the event there is a change in the control of CEL-SCI, the employment agreements with Ms. Prichep and Dr. Talor allow Ms. Prichep and/or Dr. Talor (as the case may be) to resign from her or his position at CEL-SCI and receive a lump-sum payment from CEL-SCI equal to 18 months salary (\$291,447 and \$359,802 respectively). In addition, the unvested portion of any stock options held by the employee will vest immediately (\$830,817 and \$830,062 respectively). For purposes of the employment agreements, a change in the control of CEL-SCI means: (1) the merger of CEL-SCI with another entity if after such merger the shareholders of CEL-SCI do not own at least 50% of voting capital stock of the surviving corporation; (2) the sale of substantially all of the assets of CEL-SCI; (3) the acquisition by any person of more than 50% of CEL-SCI's common stock; or (4) a change in a majority of CEL-SCI's directors which has not been approved by the incumbent directors.

The employment agreements with Ms. Prichep and Dr. Talor will also terminate upon the death of the employee, the employee's physical or mental

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disability, willful misconduct, an act of fraud against CEL-SCI, or a breach of the employment agreement by the employee. If the employment agreement is terminated for any of these reasons the employee, or her or his legal representatives, as the case may be, will be paid the salary provided by the employment agreement through the date of termination.

### Compensation Committee Interlocks and Insider Participation

CEL-SCI has a compensation committee comprised of Alexander Esterhazy, Dr. C. Richard Kinsolving and Dr. Peter Young, all of whom are outside directors.

During the year ended September 30, 2010, no director of CEL-SCI was also an executive officer of another entity, which had an executive officer of CEL-SCI serving as a director of such entity or as a member of the compensation committee of such entity.

### Stock Options

The following tables show information concerning the options granted during the fiscal year ended September 30, 2010, to the persons named below.

Options Granted

Exercise



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Name	Grant Date	Options Granted (#)	Price Per Share	Expiration Date
Maximilian de Clara	7/21/10	250,000	\$ 0.48	7/20/20
Geert Kersten	7/21/10	300,000	\$ 0.48	7/20/20
Patricia B. Prichep	7/21/10	150,000	\$ 0.48	7/20/20
Eyal Talor, Ph.D.	7/21/10	150,000	\$ 0.48	7/20/20
Daniel Zimmerman, Ph.D.	7/21/10	150,000	\$ 0.48	7/20/20
John Cipriano	7/21/10	150,000	\$ 0.48	7/20/20

Options Exercised

Date of Exercise	Shares Acquired On Exercise	Value Realized
-	-	-

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The following lists the outstanding options held by the persons named below:

Name	Shares Underlying Unexercised Options Which are:		Exercise Price	Expiration Date
	Exercisable	Unexercisable		
Maximilian de Clara	23,333		2.87	07/31/13
	95,000 (1)		1.94	08/31/13
	70,000		1.05	09/25/12
	56,666		1.05	05/01/13
	50,000		1.05	05/01/13
	50,000		1.05	04/12/12
	60,000		1.05	04/19/13
	60,000		1.38	03/22/11
	75,000		0.54	03/14/12
	50,000		0.61	09/02/14
	50,000		0.48	09/21/15
	100,000		0.58	09/12/16
	200,000		0.63	09/13/17
	133,334		0.62	03/04/18
1,436,250 (2)		0.25	04/23/19	
83,334		0.38	07/20/19	
-----				
2,592,917				
	66,666	0.62	03/04/18	
	500,000 (3)	0.38	07/06/19	
	166,666	0.38	07/20/19	
	250,000	0.48	07/20/20	
	-----			
	983,332			

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Geert R. Kersten	50,000	1.05	11/01/13
	14,000	1.05	10/31/13
	50,000	1.05	07/31/13
	224,000 (1)	1.05	06/10/13
	50,000	1.05	09/25/12
	150,000	1.05	05/01/13
	50,000	1.05	05/01/13
	50,000	1.05	04/12/12
	95,000 (1)	1.94	08/31/13
	60,000	1.05	04/19/13
	60,000	1.38	03/22/11
	560,000 (1)	1.05	10/16/13
	105,000	0.54	03/14/12
	1,890,000	0.22	04/01/13
	50,000	0.61	09/02/14
	50,000	0.48	09/21/15
	200,000	0.58	09/12/16
	200,000	0.63	09/13/17
	133,334	0.62	03/04/18
	1,838,609 (2)	0.25	04/23/19

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Name	Shares Underlying Unexercised Options Which are:		Exercise Price	Expiration Date
	Exercisable	Unexercisable		
Geert R. Kersten (cont'd)	100,000		0.38	07/20/19
	-----			
	5,979,943			
		66,666	0.62	03/04/18
		4,000,000 (3)	0.38	07/06/19
		200,000	0.38	07/20/19
		300,000	0.48	07/20/20
		-----		
		4,566,666		
-----				
Patricia B. Prichep		6,000	1.05	12/01/13
	10,000		1.05	11/30/13
	9,500		1.05	07/31/13
	3,000		1.05	12/31/12
	35,000		1.05	03/01/13
	17,000		1.05	12/01/13
	15,000		1.05	04/12/12
	47,500 (1)		1.94	08/31/13
	23,000		1.05	02/02/13
	25,000		1.18	12/08/13
	30,000		1.00	12/03/11
	200,000 (1)		1.05	10/16/13
	10,500		0.54	03/14/12
	50,000		0.33	04/26/12
	243,000		0.22	04/01/13
	337,000		0.22	04/01/13
	50,000		0.61	09/02/14
	30,000		0.48	09/21/15
	90,000		0.58	09/12/16

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100,000		0.63	09/13/17
66,667		0.62	03/04/18
717,096 (2)		0.25	04/23/19
50,000		0.38	07/20/19
-----			
2,165,263			
	33,333	0.62	03/04/18
	3,000,000 (3)	0.38	07/06/19
	100,000	0.38	07/20/19
	150,000	0.48	07/20/20
	-----		
	3,283,333		

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Eyal Talor, Ph.D.	15,500	1.05	07/31/13
	16,666	1.05	03/16/13
	15,000	1.05	08/03/13
	10,000 (1)	1.94	08/31/13
	20,000	1.05	08/02/12

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Name	Shares Underlying Unexercised Options Which are:		Exercise Price	Expiration Date
	Exercisable	Unexercisable		
Eyal Talor, Ph.D. (cont'd)	25,000		1.76	11/10/13
	35,000		1.00	12/03/11
	160,000 (1)		1.05	10/16/13
	50,000		0.33	04/26/12
	374,166		0.22	04/01/13
	50,000		0.61	09/02/14
	30,000		0.48	09/21/15
	80,000		0.58	09/12/16
	100,000		0.63	09/13/17
	66,667		0.62	03/04/18
	240,820 (2)		0.25	04/23/19
	50,000		0.38	07/20/19
	-----			
	1,338,819			
		33,333	0.62	03/04/18
		3,000,000 (3)	0.38	07/06/19
		100,000	0.38	07/20/19
		150,000	0.48	07/20/20
		-----		
		3,283,333		

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Daniel Zimmerman, Ph.D.	12,000	1.05	12/31/13
	7,000	1.05	06/19/13
	15,000	1.05	02/19/13
	30,000 (1)	1.94	08/31/13
	20,000	1.05	02/02/13
	20,000	1.85	01/26/11

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120,000 (1)		1.05	10/16/13
41,000		0.54	03/14/12
50,000		0.33	04/16/12
392,000		0.22	04/01/13
50,000		0.61	09/02/14
30,000		0.48	09/21/15
60,000		0.58	09/12/16
75,000		0.63	09/13/17
75,000		0.62	03/04/18
200,000 (4)		0.38	07/15/14
-----			
1,197,000			
	150,000	0.48	07/20/20
	-----		
	150,000		

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John Cipriano			
	20,000	0.61	09/02/14
	30,000	0.48	09/21/15
	60,000	0.58	09/12/16

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Name	Shares Underlying Unexercised Options Which are:		Exercise Price	Expiration Date
	Exercisable	Unexercisable		
John Cipriano (cont'd)		75,000	0.63	09/13/17
	75,000		0.62	03/04/18
	33,334		1.93	09/30/19
	-----			
	293,334			
		66,666	1.93	09/30/19
		150,000	0.48	07/20/20
		-----		
		216,666		

- (1) Options purchased by Employee through the Salary Reduction Plan.
- (2) Options awarded to employees who did not collect a salary, or reduced or deferred their salary between September 15, 2008 and June 30, 2009. For example, Mr. de Clara, Mr. Kersten and Ms. Prichep did not collect any salary between September 30, 2008 and June 30, 2009.
- (3) Long-term performance options: The Board of Directors has identified the successful Phase III clinical trial for Multikine to be the most important corporate event to create shareholder value. Therefore, one third of the options can be exercised when the first 400 patients are enrolled in CEL-SCI's Phase III head and neck cancer clinical trial. One third of the options can be exercised when all of the patients have been enrolled in the Phase III clinical trial. One third of the options can be exercised when the Phase III trial is completed.
- (4) Options awarded to employee during the period that he was a consultant to CEL-SCI.

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### Stock Option, Bonus and Compensation Plans

CEL-SCI has Incentive Stock Option Plans, Non-Qualified Stock Option Plans, Stock Bonus Plans and a Stock Compensation Plan, all of which have been approved by CEL-SCI's stockholders. A summary description of these Plans follows. In some cases these Plans are collectively referred to as the "Plans".

**Incentive Stock Option Plans.** The Incentive Stock Option Plans authorize the issuance of shares of CEL-SCI's common stock to persons who exercise options granted pursuant to the Plans. Only CEL-SCI's employees may be granted options pursuant to the Incentive Stock Option Plans.

Options may not be exercised until one year following the date of grant. Options granted to an employee then owning more than 10% of the common stock of CEL-SCI may not be exercisable by its terms after five years from the date of grant. Any other option granted pursuant to the Plan may not be exercisable by its terms after ten years from the date of grant.

The purchase price per share of common stock purchasable under an option is determined by the Committee but cannot be less than the fair market value of

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the common stock on the date of the grant of the option (or 110% of the fair market value in the case of a person owning more than 10% of CEL-SCI's outstanding shares).

**Non-Qualified Stock Option Plans.** The Non-Qualified Stock Option Plans authorize the issuance of shares of CEL-SCI's common stock to persons that exercise options granted pursuant to the Plans. CEL-SCI's employees, directors, officers, consultants and advisors are eligible to be granted options pursuant to the Plans, provided however that bona fide services must be rendered by such consultants or advisors and such services must not be in connection with the offer or sale of securities in a capital-raising transaction. The option exercise price is determined by CEL-SCI's Board of Directors.

**Stock Bonus Plans.** Under the Stock Bonus Plans shares of CEL-SCI's common stock may be issued to CEL-SCI's employees, directors, officers, consultants and advisors, provided however that bona fide services must be rendered by consultants or advisors and such services must not be in connection with the offer or sale of securities in a capital-raising transaction.

**Stock Compensation Plan.** Under the Stock Compensation Plan, shares of CEL-SCI's common stock may be issued to CEL-SCI's employees, directors, officers, consultants and advisors in payment of salaries, fees and other compensation owed to these persons. However, bona fide services must be rendered by consultants or advisors and such services must not be in connection with the offer or sale of securities in a capital-raising transaction.

**Other Information Regarding the Plans.** The Plans are administered by CEL-SCI's Compensation Committee ("the Committee"), each member of which is a director of CEL-SCI. The members of the Committee were selected by CEL-SCI's Board of Directors and serve for a one-year tenure and until their successors are elected. A member of the Committee may be removed at any time by action of the Board of Directors. Any vacancies which may occur on the Committee will be filled by the Board of Directors. The Committee is vested with the authority to interpret the provisions of the Plans and supervise the administration of the Plans. In addition, the Committee is empowered to select those persons to whom shares or options are to be granted, to determine the number of shares subject to each grant of a stock bonus or an option and to determine when, and upon what conditions, shares or options granted under the Plans will vest or otherwise be

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subject to forfeiture and cancellation.

In the discretion of the Committee, any option granted pursuant to the Plans may include installment exercise terms such that the option becomes fully exercisable in a series of cumulating portions. The Committee may also accelerate the date upon which any option (or any part of any options) is first exercisable. Any shares issued pursuant to the Stock Bonus Plans and any options granted pursuant to the Incentive Stock Option Plans or the Non-Qualified Stock Option Plans will be forfeited if the "vesting" schedule established by the Committee administering the Plans at the time of the grant is not met. For this purpose, vesting means the period during which the employee must remain an employee of CEL-SCI or the period of time a non-employee must provide services to CEL-SCI. At the time an employee ceases working for CEL-SCI (or at the time a non-employee ceases to perform services for CEL-SCI), any shares or options not fully vested will be forfeited and cancelled. At the discretion of the Committee

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payment for the shares of common stock underlying options may be paid through the delivery of shares of CEL-SCI's common stock having an aggregate fair market value equal to the option price, provided such shares have been owned by the option holder for at least one year prior to such exercise. A combination of cash and shares of common stock may also be permitted at the discretion of the Committee.

Options are generally non-transferable except upon death of the option holder. Shares issued pursuant to the Stock Bonus Plans will generally not be transferable until the person receiving the shares satisfies the vesting requirements imposed by the Committee when the shares were issued.

The Board of Directors of CEL-SCI may at any time, and from time to time, amend, terminate, or suspend one or more of the Plans in any manner they deem appropriate, provided that such amendment, termination or suspension will not adversely affect rights or obligations with respect to shares or options previously granted. The Board of Directors may not, without shareholder approval: make any amendment which would materially modify the eligibility requirements for the Plans; increase or decrease the total number of shares of common stock which may be issued pursuant to the Plans except in the case of a reclassification of CEL-SCI's capital stock or a consolidation or merger of CEL-SCI; reduce the minimum option price per share; extend the period for granting options; or materially increase in any other way the benefits accruing to employees who are eligible to participate in the Plans.

Summary. The following shows certain information as of November 30, 2010 concerning the stock options and stock bonuses granted by CEL-SCI. Each option represents the right to purchase one share of CEL-SCI's common stock.

Name of Plan	Total Shares Reserved Under Plans	Shares Reserved for Outstanding Options	Shares Issued as Stock Bonus	Remaining Options/Shares Under Plans
Incentive Stock Option Plans	17,100,000	10,593,041	N/A	5,920,225
Non-Qualified Stock Option Plans	33,760,000	21,691,146	N/A	8,468,436
Stock Bonus Plans	11,940,000	N/A	7,400,920	4,537,321
Stock Compensation Plan	9,500,000	N/A	5,386,531	2,113,469

Of the shares issued pursuant to CEL-SCI's Stock Bonus Plans 1,454,543 shares were issued as part of CEL-SCI's contribution to its 401(k) plan.

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The following table shows the weighted average exercise price of the outstanding options granted pursuant to CEL-SCI's Incentive and Non-Qualified Stock Option Plans as of September 30, 2010, CEL-SCI's most recent fiscal year end. CEL-SCI's Incentive and Non-Qualified Stock Option Plans have been approved by CEL-SCI's shareholders.

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Plan category	Number of Securities to be Issued Upon Exercise of Outstanding Options (a)	Weighted-Average Exercise Price of of Outstanding Options	Number of Securities Remaining Available For Future Issuance Under Equity Compensation Plans, Excluding Securities Reflected in Column (a)
Incentive Stock Option Plans	10,593,041	\$ 0.40	5,920,225
Non-Qualified Stock Option Plans	21,720,414	\$ 0.50	8,468,436

### ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The following table shows, as of November 30, 2010, information with respect to the only persons owning beneficially 5% or more of CEL-SCI's outstanding common stock and the number and percentage of outstanding shares owned by each director and officer of CEL-SCI and by the officers and directors as a group. Unless otherwise indicated, each owner has sole voting and investment powers over his shares of common stock.

Name and Address	Number of Shares (1)	Percent of Class (3)
Maximilian de Clara Bergstrasse 79 6078 Lungern, Obwalden, Switzerland	6,441,690	3.1%
Geert R. Kersten 8229 Boone Blvd., Suite 802 Vienna, VA 22182	9,355,855 (2)	4.4%
Patricia B. Prichep 8229 Boone Blvd., Suite 802 Vienna, VA 22182	2,992,116	1.4%
Eyal Talor, Ph.D. 8229 Boone Blvd., Suite 802 Vienna, VA 22182	1,787,122	0.9%

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Daniel H. Zimmerman, Ph.D. 8229 Boone Blvd., Suite 802 Vienna, VA 22182	1,531,522	0.7%
	60	
John Cipriano 8229 Boone Blvd., Suite 802 Vienna, VA 22182	480,027	0.2%
Alexander G. Esterhazy 20 Chemin du Pre-Poiset CH- 1253 Vandoeuvres Geneve, Switzerland	808,156	0.4%
C. Richard Kinsolving, Ph.D. P.O. Box 20193 Bradenton, FL 34204-0193	983,914	0.5%
Peter R. Young, Ph.D. 5458 Beacon Hill Drive Frisco, TX 75034	809,424	0.4%
All Officers and Directors as a Group (9 persons)	25,189,826	11.2%

- (1) Includes shares issuable prior to February 28, 2011 upon the exercise of options or warrants granted to the following persons:

Name -----	Options or Warrants Exercisable Prior to February 28, 2011 -----
Maximilian de Clara	6,090,456
Geert R. Kersten	5,979,943
Patricia B. Prichep	2,165,263
Eyal Talor, Ph.D.	1,338,819
Daniel Zimmerman	1,197,000
John Cipriano	293,334
Alexander G. Esterhazy	574,999
C. Richard Kinsolving, Ph.D.	681,667
Peter R. Young, Ph.D.	561,666

- (2) Amount includes shares held in trust for the benefit of Mr. Kersten's minor children. Geert R. Kersten is the stepson of Maximilian de Clara.
- (3) Amount includes shares referred to in (1) above but excludes shares which may be issued upon the exercise or conversion of other options, warrants and other convertible securities previously issued by CEL-SCI.



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None.

### ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

BDO USA, LLP served as CEL-SCI's independent registered public accountant for the two years ended September 30, 2010. The following table shows the aggregate fees billed to CEL-SCI for these years by BDO USA, LLP:

	Year Ended September 30,	
	2010	2009
	----	----
Audit Fees	\$232,725	\$219,675
Audit-Related Fees	--	--
Tax Fees	--	--
All Other Fees	\$ 44,126	--

Audit fees represent amounts billed for professional services rendered for the audit of the CEL-SCI's annual financial statements and the reviews of the financial statements included in CEL-SCI's 10-Q reports for the fiscal year and all regulatory filings. All other fees were for services in connection with the preparation of the application for the PPACA grant. See Note 15 to the financial statements included with this report for more information.

Before BDO USA, LLP was engaged by CEL-SCI to render audit or non-audit services, the engagement was approved by CEL-SCI's audit committee. CEL-SCI's Board of Directors is of the opinion that the Audit Related Fees charged by BDO USA, LLP are consistent with BDO USA, LLP maintaining its independence from CEL-SCI.

### ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

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

#### Exhibits

3(a) Articles of Incorporation	Incorporated by reference to Exhibit 3(a) of CEL-SCI's combined Registration Statement on Form S-1 and Post-Effective Amendment ("Registration Statement"), Registration Nos. 2-85547-D and 33-7531.
3(b) Amended Articles	Incorporated by reference to Exhibit 3(a) of CEL-SCI's Registration Statement on Form S-1, Registration Nos. 2-85547-D and 33-7531.
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3(c) Amended Articles (Name change only)	Filed as Exhibit 3(c) to CEL-SCI's Registration Statement on Form S-1 Registration Statement (No. 33-34878).
3(d) Bylaws	Incorporated by reference to Exhibit 3(b) of CEL-SCI's Registration Statement on Form S-1, Registration Nos. 2-85547-D and 33-7531.
4 Shareholders Rights Agreement	Incorporated by reference to Exhibit 4

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of CEL-SCI'S report on Form 8-K dated November 7, 2007.

### 5 Opinion of Counsel

- |  |   |
|--|---|
| 10(d) Employment Agreement with Maximilian de Clara  | Incorporated by reference to Exhibit 10(d) of CEL-SCI's report on Form 8-K (dated April 21, 2005) and Exhibit 10(d) to CEL-SCI's report on Form 8-K dated September 8, 2006.                    |
| 10(e) Employment Agreement with Geert Kersten  | Incorporated by reference to Exhibit 10(e) of CEL-SCI's Registration Statement on Form S-3 (Commission File #106879) and Exhibit 10(c) to CEL-SCI's report on Form 8-K dated September 8, 2006. |
| 10(f) Distribution and Royalty Agreement with Eastern Biotech  | Incorporated by reference to Exhibit 10(x) to Amendment No. 2 to CEL-SCI's Registration statement on Form S-3 (Commission File No. 333-106879).   |
| 10(g) Securities Purchase Agreement (together with schedule required by Instruction 2 to Item 601 of Regulation S-K) pertaining to Series K notes and warrants, together with The exhibits to the Securities Purchase Agreement.                           | Incorporated by reference to Exhibit 10 to CEL-SCI's report on Form 8-K dated August 4, 2006.   |
| 10(h) Subscription Agreement (together with Schedule required by Instruction 2 to Item 601 of Regulation S-K) pertaining to April 2007 sale of 20,000,000 shares of CEL-SCI's common stock, 10,000,000 Series L warrants and 10,000,000 Series M Warrants. | Incorporated by reference to Exhibit 10 CEL-SCI's report on Form 8-K dated April 18, 2007.  |
| 10(i) Warrant Adjustment Agreement with Laksys Ventures  | Incorporated by reference to Exhibit 10(i) of CEL-SCI's report on Form 8-K dated August 3, 2010.  |

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- |  |   |
|--|---|
| 10(j) Employment Agreement with Patricia Prichep   | Incorporated by reference to Exhibit 10(j) of CEL-SCI's report on Form 8-K dated August 30, 2010. |
| 10(k) Employment Agreement with Eyal Taylor  | Incorporated by reference to Exhibit 10(k) of CEL-SCI's report on Form 8-K dated August 30, 2010. |
| 10(l) Amendment to Employment Agreement with Maximilian de Clara   | Incorporated by reference to Exhibit 10(l) of CEL-SCI's report on Form 8-K dated August 30, 2010. |
| 10(m) Amendment to Development Supply and Distribution Agreement with Orient Europharma. (part of Exhibit 10(m) has been omitted pursuant to |   |

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- a request for confidential treatment).
- 10(n) Licensing Agreement with Teva Pharmaceutical Industries Ltd. (parts of Exhibit 10(n) have been omitted pursuant to a request for confidential treatment.)
- 10(o) Lease Agreement (parts of Exhibit 10(o) have been omitted pursuant to a request for confidential treatment).
- 10(p) Loan Agreements with Maximilian de Clara
- 10(q) Licensing Agreement with Byron Biopharma                      Incorporated by reference to Exhibit 10(i) of CEL-SCI's report on Form 8-K dated March 27, 2009.
- 10(r) At Market Issuance Sales Agreement with McNicoll, Lewis & Vlak LLC
- 10(z) Development, Supply and Distribution Agreement with Orient Europharma                      Incorporated by reference to Exhibit 10(z) filed with the Company's report on Form 10-K for the year ended September 30, 2003.
- 23.1 Consent of BDO USA, LLP
- 23.2 Consent of Hart & Trinen, LLP
- 31 Rule 13a-14(a) Certifications
- 32 Section 1350 Certifications

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CEL-SCI CORPORATION

Consolidated Financial Statements for the Years  
Ended September 30, 2010, 2009, and 2008, and  
Report of Independent Registered Public Accounting Firm

CEL-SCI CORPORATION

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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Report of Independent Registered Public Accounting Firm

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

We have audited the accompanying consolidated balance sheets of CEL-SCI Corporation as of September 30, 2010 and 2009 and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended September 30, 2010. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of CEL-SCI Corporation at September 30, 2010 and 2009, and the results of its operations and its cash flows for each of the three years in the period ended September 30, 2010, in conformity with accounting principles generally accepted in the United States of America.

As described in Note 10, effective October 1, 2009, the Company adopted ASC 815-40, "Determining Whether an Instrument (or Embedded Feature) Is Indexed to a Company's Own Stock".

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), CEL-SCI Corporation's internal control over financial reporting as of September 30, 2010, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) and our report dated December 10, 2010 expressed an unqualified opinion thereon.

/s/ BDO USA, LLP

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-----  
Bethesda, Maryland

December 10, 2010

Report of Independent Registered Public Accounting Firm

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

We have audited CEL-SCI Corporation's internal control over financial reporting as of September 30, 2010, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). CEL-SCI Corporation's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Item 9A, Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit.

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

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

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

In our opinion, CEL-SCI Corporation maintained, in all material respects, effective internal control over financial reporting as of September 30, 2010, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company

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Accounting Oversight Board (United States), the consolidated balance sheets of CEL-SCI Corporation as of September 30, 2010 and 2009, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended September 30, 2010 and our report dated December 10, 2010 expressed an unqualified opinion thereon.

/s/ BDO USA, LLP  
-----

Bethesda, Maryland

December 10, 2010

### CEL-SCI CORPORATION CONSOLIDATED BALANCE SHEETS SEPTEMBER 30, 2010 AND 2009

ASSETS	2010 -----	2009 -----
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$26,568,243	\$33,567,516
Prepaid expenses	298,719	39,972
Inventory used for R&D and manufacturing	1,476,234	399,474
Deferred rent - current portion	751,338	806,425
Deposits	-	1,585,064
	-----	-----
Total current assets	29,094,534	36,398,451
<b>RESEARCH AND OFFICE EQUIPMENT AND LEASEHOLD IMPROVEMENTS-- less accumulated depreciation of \$2,626,759 and \$2,259,237</b>		
	1,264,831	1,200,611
<b>PATENT COSTS--less accumulated amortization of \$1,205,690 and \$1,132,612</b>		
	356,079	423,104
RESTRICTED CASH	21,357	68,552
DEFERRED RENT - net of current portion	7,068,184	7,936,880
	-----	-----
<b>TOTAL ASSETS</b>	<b>\$37,804,985</b>	<b>\$46,027,598</b>
	=====	=====
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable	\$ 1,497,383	\$ 793,148
Accrued expenses	223,696	98,665
Due to employees	45,808	49,527
Related party loan	1,104,057	1,107,339
Deposits held	-	10,000
Derivative instruments - current portion	424,286	-
	-----	-----
Total current liabilities	3,295,230	2,058,679
Derivative instruments - net of current portion	6,521,765	35,113,970
Deferred revenue	125,000	-
Deferred rent	8,225	14,305
	-----	-----
Total liabilities	9,950,220	37,186,954
	-----	-----

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### COMMITMENTS AND CONTINGENCIES

#### STOCKHOLDERS' EQUITY

Preferred stock, \$.01 par value--authorized 100,000 shares, issued and outstanding, -0-	-	-
Common stock, \$.01 par value--authorized 450,000,000 shares; issued and outstanding, 204,868,853 and 191,972,021 shares at September 30, 2010 and 2009, respectively	2,048,689	1,919,720
Additional paid-in capital	187,606,044	173,017,978
Accumulated deficit	(161,799,968)	(166,097,054)
	-----	-----
Total stockholders' equity	27,854,765	8,840,644
	-----	-----

#### TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY

	\$ 37,804,985	\$46,027,598
	=====	=====

See notes to consolidated financial statements

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### CEL-SCI CORPORATION CONSOLIDATED STATEMENTS OF OPERATIONS YEARS ENDED SEPTEMBER 30, 2010, 2009 AND 2008

	2010 -----	2009 -----	2008 -----
RENT INCOME AND OTHER	\$ 153,300	\$ 80,093	\$ 5,065
OPERATING EXPENSES:			
Research and development (excluding R&D depreciation of \$434,030, \$329,866 and \$91,292 respectively, included below)	11,911,626	6,011,750	4,101,563
Depreciation and amortization	516,117	417,205	215,060
General & administrative	6,285,810	5,671,595	5,200,735
	-----	-----	-----
Total operating expenses	18,713,553	12,100,550	9,517,358
	-----	-----	-----
OPERATING LOSS	(18,560,253)	(12,020,457)	(9,512,293)
GAIN (LOSS) ON DERIVATIVE INSTRUMENTS	28,843,772	(28,491,650)	1,799,393
INTEREST INCOME	362,236	-	483,252
INTEREST EXPENSE	(162,326)	(397,923)	(473,767)
	-----	-----	-----
NET INCOME (LOSS)	10,483,429	(40,910,030)	(7,703,415)
MODIFICATIONS OF WARRANTS	(1,532,456)	(490,728)	(424,815)
	-----	-----	-----
NET INCOME (LOSS) AVAILABLE TO COMMON SHAREHOLDERS	\$ 8,950,973	\$ (41,400,758)	\$ (8,128,230)
	=====	=====	=====
NET INCOME (LOSS) PER COMMON SHARE			
BASIC	\$ 0.04	\$ (0.31)	\$ (0.07)
DILUTED	\$ (0.05)	\$ (0.31)	\$ (0.07)
WEIGHTED AVERAGE COMMON SHARES OUTSTANDING			
BASIC	202,102,859	133,535,050	117,060,866

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DILUTED 226,277,913 133,535,050 117,060,866

See notes to consolidated financial statements.

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CEL-SCI CORPORATION  
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY  
YEARS ENDED SEPTEMBER 30, 2010, 2009 AND 2008

	Common Shares	Stock Amount	Additional Paid-In Capital	Accumulated Deficit	
	-----	-----	-----	-----	-----
BALANCE, SEPTEMBER 30, 2007	115,678,662	\$1,156,787	\$130,081,378	\$(116,568,066)	\$14
Sale of common stock	1,383,389	13,834	1,023,708		1
401(k) contributions paid in common stock	205,125	2,051	106,539		
Issuance of common stock to employees	1,789,451	17,894	1,306,580		1
Exercise of stock options	50,467	505	13,898		
Correction of stock overpayment pricing			1,471		
Stock issued to nonemployees for service	1,689,000	16,890	251,858		
Issuance of stock options to nonemployees			12,342		
Employee option cost			561,387		
Modification of stock options			564,189		
Financing costs			(23,795)		
Dividends			424,815	(424,815)	
Net loss				(7,703,415)	(7)
	-----	-----	-----	-----	-----
BALANCE, SEPTEMBER 30, 2008	120,796,094	\$1,207,961	\$134,324,370	\$(124,696,296)	\$10

(continued)

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CEL-SCI CORPORATION  
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (cont'd)  
YEARS ENDED SEPTEMBER 30, 2010, 2009 AND 2008

Additional

Common Shares	Stock Amount	Additional Paid-In Capital	Accumulated Deficit
------------------	-----------------	----------------------------------	------------------------



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Sale of common stock	45,451,547	\$ 454,515	\$31,788,201		\$32
401(k) contributions paid in common stock	91,766	917	56,912		
Exercise of stock options	15,659,116	156,591	8,524,663		8
Stock issued to nonemployees for service	3,316,438	33,164	1,528,179		1
Stock issued to employees	1,324,385	13,244	672,614		
Stock issued for principal payments on Series K notes	972,753	9,728	275,272		
Stock issued for interest on Series K Notes	177,403	1,774	41,111		
Issuance of stock options and warrants to nonemployees			449,641		
Loss on conversion of convertible debt			2,145,754		2
Issuance of warrants for short term loan			65,796		
Modification of options			6,142		
Employee option cost			1,699,448		1
Premium on loan from shareholder			489,776		
Conversion of convertible debt into common stock	3,015,852	30,159	1,176,182		
Cost of derivative liabilities			(8,632,217)		(8
Financing costs			(2,072,927)		(2
Dividends	1,166,667	11,667	479,061	(490,728)	
Net loss				(40,910,030)	(40
BALANCE, SEPTEMBER 30, 2009	191,972,021	1,919,720	173,017,978	(166,097,054)	8
401(k) contributions paid in common stock	182,233	1,822	110,503		
Exercise of warrants and stock options	12,249,441	122,495	6,186,379		6
Stock issued to employees and nonemployees for service	465,158	4,652	1,236,374		1
Exercise of derivative liabilities			5,510,490		5
Modification of stock options and warrants			227,921		
Employee option cost			1,316,399		1
Adoption of ASC 815-40				(6,186,343)	(6
Net income				10,483,429	10
BALANCE, SEPTEMBER 30, 2010	204,868,853	\$2,048,689	\$187,606,044	\$ (161,799,968)	\$27
	=====	=====	=====	=====	=====

See notes to consolidated financial statements

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CEL-SCI CORPORATION  
CONSOLIDATED STATEMENTS OF CASH FLOWS  
YEARS ENDED SEPTEMBER 30, 2010, 2009 AND 2008

	2010	2009	2008
	-----	-----	-----
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>			
Net income (loss)	\$10,483,429	\$ (40,910,030)	\$ (7,703,415)
Adjustments to reconcile net income (loss) to net cash used for operating activities:			
Depreciation and amortization	516,117	417,205	215,060
Issuance of stock options and warrants to nonemployees for services	-	449,641	12,342
Issuance of common stock for services	1,241,026	1,561,343	268,748
Correction of stock overpayment pricing	-	-	1,471
Premium on loan	-	341,454	-
Loan premium adjustment	-	489,776	-
Amortization of loan premium	(3,282)	(338,172)	-
Modification of stock options and warrants	227,921	6,142	564,189
Issuance of stock to employees	-	685,858	1,324,474
Loss on conversion of convertible notes	-	2,145,754	-
Employee option cost	1,316,399	1,699,448	561,387
Common stock contributed to 401(k) plan	112,325	57,829	108,590
Warrants issued in consideration for loan	-	65,796	-
Impairment loss on abandonment of patents	13,877	138,525	8,114
Loss on retired equipment	2,323	270	595
Deferred rent	(6,080)	7,688	5,151
Amortization of discount on convertible note	-	193,980	249,106
(Gain)/loss on derivative instruments	(28,843,772)	25,514,667	(1,799,393)
Change in assets and liabilities:			
Decrease/(increase) in deposits	1,585,064	4,764	(1,575,000)
Decrease/(increase) in deferred rent	955,842	622,350	(142,117)
(Increase)/decrease in prepaid expenses	(258,747)	(12,763)	7,369
Increase in inventory used in R&D and manufacturing	(1,076,760)	(4,304)	(9,520)
Increase/(decrease) in accounts payable	693,799	343,208	(36,622)
Increase/(decrease) in accrued expenses	125,031	(14,514)	14,576
Decrease in accrued interest on convertible debt	-	(2,674)	(23,237)
Increase in deferred revenue	125,000	-	-

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(Decrease)/increase in due to employees	(3,719)	13,450	9,342
(Decrease)/increase in deposits held	(10,000)	10,000	(3,000)
	-----	-----	-----
Net cash used in operating activities	(12,804,207)	(6,513,309)	(7,941,790)
	-----	-----	-----
CASH FLOWS FROM INVESTING ACTIVITIES:			
Additional investment in manufacturing facility	(32,059)	(505,225)	(2,359,473)
Decrease in restricted cash	47,195	919,100	1,180,977
Investment in available-for-sale securities	-	-	(6,000,000)
Sale of investments in available-for-sale securities	-	200,000	5,800,000
Purchases of equipment	(493,736)	(191,868)	(1,023,011)
Expenditures for patent costs	(25,340)	(53,290)	(121,616)
	-----	-----	-----
Net cash (used in) provided by investing activities	(503,940)	368,717	(2,523,123)
	-----	-----	-----

(continued)

See notes to consolidated financial statements.

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CEL-SCI CORPORATION  
CONSOLIDATED STATEMENTS OF CASH FLOWS (cont'd)  
YEARS ENDED SEPTEMBER 30, 2010, 2009 AND 2008

	2010	2009	2008
	-----	-----	-----
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from issuance of common stock	\$ -	\$ 32,242,716	\$ 1,037,542
Proceeds from exercise of warrants and stock options	6,308,874	8,681,254	14,403
Proceeds from short-term loan	-	3,104,057	1,956,803
Repayment of short-term loan	-	(2,200,000)	(1,756,803)
Principal payments on convertible debt	-	(754,250)	(1,045,000)
Costs for equity related transactions	-	(2,072,927)	(23,795)
	-----	-----	-----
Net cash provided by financing activities	6,308,874	39,000,850	183,150
	-----	-----	-----
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(6,999,273)	32,856,258	(10,281,763)
	-----	-----	-----
CASH AND CASH EQUIVALENTS, BEGINNING OF YEAR	33,567,516	711,258	10,993,021
	-----	-----	-----
CASH AND CASH EQUIVALENTS, END OF YEAR	\$ 26,568,243	\$ 33,567,516	\$ 711,258
	=====	=====	=====

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CONVERSION OF CONVERTIBLE DEBT					
INTO COMMON STOCK:					
Decrease in convertible debt	\$	-	\$ 1,206,341	\$	-
Increase in common stock		-	(30,159)		-
Increase in additional paid-in capital		-	(1,176,182)		-
		-----		-----	
	\$	-	\$ -	\$	-
		=====		=====	
CONVERSION OF INTEREST ON					
CONVERTIBLE DEBT INTO COMMON STOCK:					
Decrease in accrued liabilities	\$	-	\$ 42,885	\$	-
Increase in common stock		-	(1,774)		-
Increase in additional paid-in capital		-	(41,111)		-
		-----		-----	
	\$	-	\$ -	\$	-
		=====		=====	
PAYMENT OF CONVERTIBLE DEBT PRINCIPAL					
WITH					
COMMON STOCK:					
Decrease in convertible debt	\$	-	\$ 285,000	\$	-
Increase in common stock		-	(9,728)		-
Increase in additional paid-in capital		-	(275,272)		-
		-----		-----	
	\$	-	\$ -	\$	-
		=====		=====	
ISSUANCE OF WARRANTS:					
Increase in derivative liabilities	\$	-	\$ (8,877,217)	\$	(891,336)
Increase in discount on notes payable		-	245,000		-
Decrease in additional paid-in capital		-	8,632,217		891,336
		-----		-----	
	\$	-	\$ -	\$	-
		=====		=====	
EXERCISE OF DERIVATIVE LIABILITIES:					
Decrease in derivative liabilities	\$	5,510,490	\$ -	\$	-
Increase in additional paid-in capital		(5,510,490)	-		-
		-----		-----	
	\$	-	\$ -	\$	-
		=====		=====	
MODIFICATION OF WARRANTS:					
Increase in additional paid-in capital	\$	(1,532,456)	\$ (24,061)	\$	(173,187)
Decrease in additional paid-in capital		1,532,456	24,061		173,187
		-----		-----	
	\$	-	\$ -	\$	-
		=====		=====	

See notes to consolidated financial statements.

(continued)

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YEARS ENDED SEPTEMBER 30, 2010, 2009 AND 2008

	2010	2009	2008
<b>ACCOUNTS PAYABLE:</b>			
Increase in patent costs	\$ -	\$ 7,285	\$ 14,013
Increase in accounts payable	-	(7,285)	(14,013)
	\$ -	\$ -	\$ -
<b>EQUIPMENT COSTS INCLUDED IN ACCOUNTS PAYABLE:</b>			
Increase in research and office equipment	\$ 10,436	\$ 15,147	\$ 201,998
Increase in accounts payable	(10,436)	(15,147)	(201,998)
	\$ -	\$ -	\$ -
<b>WARRANTS ISSUED FOR LOAN:</b>			
Increase in debt discount	\$ -	\$ 65,796	\$ -
Increase in additional paid-in capital	-	(65,796)	-
	\$ -	\$ -	\$ -
<b>STOCK MODIFICATION RECORDED AS DIVIDEND</b>			
Increase in common stock	\$ -	\$ (11,667)	\$ -
Increase additional paid-in capital	-	(479,061)	(424,815)
Increase accumulated deficit	-	490,728	424,815
	\$ -	\$ -	\$ -
<b>ADOPTION OF ASC 815-40</b>			
Increase in derivative liabilities	\$ (6,186,343)	\$ -	\$ -
Increase in accumulated deficit	6,186,343	-	-
	\$ -	\$ -	\$ -
<b>SUPPLEMENTAL DISCLOSURE OF CASH FLOWS INFORMATION:</b>			
Cash expenditure for interest expense	\$ 162,326	\$ 115,559	\$ 224,662

See notes to consolidated financial statements.

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### 1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

CEL-SCI Corporation (the "Company") was incorporated on March 22, 1983, in the state of Colorado, to finance research and development in biomedical science and ultimately to engage in marketing and selling products.

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The Company's lead product, Multikine(R), is being developed for the treatment of cancer. Multikine is a patented immunotherapeutic agent consisting of a mixture of naturally occurring cytokines, including interleukins, interferons, chemokines and colony-stimulating factors, currently being developed for the treatment of cancer. Multikine is designed to target the tumor micro-metastases that are mostly responsible for treatment failure. The basic concept is to add Multikine to the current cancer treatments with the goal of making the overall cancer treatment more successful. Phase II data indicated that Multikine treatment resulted in a substantial increase in the survival of patients. The lead indication is advanced primary head & neck cancer. Since Multikine is not tumor specific, it may also be applicable in many other solid tumors.

Significant accounting policies are as follows:

- a. Principles of Consolidation--The consolidated financial statements include the accounts of the Company and its wholly owned subsidiary, Viral Technologies, Inc. (VTI). All significant intercompany transactions have been eliminated upon consolidation. Certain amounts from 2009 consolidated financial statements have been reclassified to conform to 2010 consolidated financial statement presentation. One such reclassification is the reclassification of derivative instruments of \$35,113,970 from current liabilities to long-term liabilities on the September 30, 2009 consolidated balance sheet.
- b. Cash and Cash Equivalents--For purposes of the statements of cash flows, cash and cash equivalents consists principally of unrestricted cash on deposit and short-term money market funds. The Company considers all highly liquid investments with a maturity when purchased of less than three months, as cash and cash equivalents.
- c. Restricted Cash--The restricted cash is money held in escrow pursuant to the lease agreement for the manufacturing facility.
- d. Prepaid Expenses and Inventory--Prepaid expenses consist of expenses which benefit a substantial period of time. Inventory consists of manufacturing production advances and bulk purchases of laboratory supplies to be consumed in the manufacturing of the Company's product for clinical studies.
- e. Deposits--The deposit on September 30, 2009 was for the manufacturing facility (\$1,575,000) required by the lease agreement, but was refunded in February 2010, after the Company met the cash requirements of the lease.

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- f. Research and Office Equipment and Leasehold Improvements--Research and office equipment is recorded at cost and depreciated using the straight-line method over estimated useful lives of five to seven years. Leasehold improvements are depreciated over the shorter of the estimated useful life of the asset or the terms of the lease. Repairs and maintenance which do not extend the life of the asset are expensed when incurred. The fixed assets are reviewed on a quarterly basis to determine if any of the assets are impaired. Depreciation expense for the years ended September 30, 2010, 2009 and 2008 totaled \$437,629, \$330,820, and \$133,604, respectively. During the years ended September 30, 2010, 2009 and 2008, equipment with a net book value of \$2,323, \$270 and \$595 was retired.
- g. Patents--Patent expenditures are capitalized and amortized using the straight-line method over the shorter of the expected useful life or the

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legal life of the patent (17 years). In the event changes in technology or other circumstances impair the value or life of the patent, appropriate adjustment in the asset value and period of amortization is made. An impairment loss is recognized when estimated future undiscounted cash flows expected to result from the use of the asset, and from disposition, is less than the carrying value of the asset. The amount of the impairment loss is the difference between the estimated fair value of the asset and its carrying value. During the years ended September 30, 2010, 2009 and 2008, the Company recorded patent impairment charges of \$13,877, \$138,525, and \$8,114, respectively, for the net book value of patents abandoned during the year. These amounts are included in general and administrative expenses. Amortization expense for the years ended September 30, 2010, 2009 and 2008 totaled \$78,488, \$86,385, and \$81,456, respectively. The Company estimates that amortization expense will be approximately \$71,200 for each of the next five years, totalling \$356,000.

- h. Deferred Rent-- Interest on the deferred rent is calculated at 3% on the funds deposited on the manufacturing facility and for September 30, 2010, is included in the deferred rent. This interest income will be used to offset future rent. On September 30, 2010, the Company has included in deferred rent the following: 1) deposit on the manufacturing facility (\$3,150,000); 2) the fair value of the warrants issued to lessor (\$1,481,040); 3) additional investment (\$2,889,409); 4) deposit on the cost of the leasehold improvements for the manufacturing facility (\$1,786,591), 5) amortization of deferred rent (\$1,682,053); and 6) accrued interest on deposit (\$194,535).

On September 30, 2009, the Company has included in deferred rent the following: 1) deposit on the manufacturing facility (\$3,150,000); 2) the fair value of the warrants issued to lessor (\$1,731,667); 3) additional investment (\$2,864,698); 4) deposit on the cost of the leasehold improvements for the manufacturing facility (\$1,786,591); 5) amortization of deferred rent (\$882,338); and 6) accrued interest on deposit (\$92,687).

- i. Deferred Rent (liability)--The deferred rent (liability) is amortized on a straight-line basis over the term of the lease with the offset going against rent expense.
- j. Derivative Instruments--The Company entered into financing arrangements that consisted of freestanding derivative instruments or were hybrid instruments that contained embedded derivative features. The Company accounted for these

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arrangement in accordance with Codification 815-10-50, "Accounting for Derivative Instruments and Hedging Activities", "Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock". In accordance with accounting principles generally accepted in the United States ("GAAP"), derivative instruments and hybrid instruments are recognized as either assets or liabilities in the statement of financial position and are measured at fair value with gains or losses recognized in earnings or other comprehensive income depending on the nature of the derivative or hybrid instruments. Embedded derivatives that are not clearly and closely related to the host contract are bifurcated and recognized at fair value with changes in fair value recognized as either a gain or loss in earnings if they can be reliably measured. When the fair value of embedded derivative features cannot be reliably measured, the Company measures and reports the entire hybrid instrument at fair value with changes in fair value recognized as either a gain or loss in earnings. The Company determined the fair value of derivative instruments and hybrid instruments based on available market data using appropriate valuation models, giving consideration to all of the rights and obligations of each instrument and

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precluding the use of "blockage" discounts or premiums in determining the fair value of a large block of financial instruments. Fair value under these conditions does not necessarily represent fair value determined using valuation standards that give consideration to blockage discounts and other factors that may be considered by market participants in establishing fair value. The convertible debt associated with the Series K convertible notes was all either repaid or converted into the Company's common stock before September 30, 2009. The remaining warrants associated with Series K are valued at \$5,372,598 on September 30, 2009 and are shown in the balance sheet in long term liabilities. Warrants exercised during the year ended September 30, 2010 totaled \$534,088 in funds received by the Company. In addition, the Company recognized a gain of \$280,223 on the exercise of the Series K warrants. Outstanding warrants associated with Series K are valued at \$1,002,502 at September 30, 2010. The Company recorded a gain of \$2,856,355 on the remaining Series K for the year ending September 30, 2010.

The Company issued other warrants during the year ended September 30, 2009 that are accounted for as derivative liabilities. See Note 6. At September 30, 2009, the fair value of these derivative instruments totaled \$29,741,372 and is shown on the balance sheet in long term liabilities. At September 30, 2010, the fair value of these derivative instruments totaled \$4,037,067. There were 8,813,088 Series A warrants exercised during the year ended September 30, 2010, that brought in \$4,406,544 in funds to the Company. In addition, the Company recognized a gain of \$8,433,451 on the exercise of the Series A warrants. The fair value of these derivative liabilities will be adjusted at the end of each interim accounting period as well as at the end of each fiscal year as long as they are outstanding. The Company recorded a gain of \$12,993,883 on the remaining Series A through E warrants for the year ending September 30, 2010.

Also included in derivative liabilities are warrants issued to investors in August 2008. These warrants were valued at \$1,906,482 on September 30, 2010, which resulted in a gain of \$4,279,860 for the year ended September 30, 2010.

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- k. Research and Development Grant Revenues--The Company's grant arrangements are handled on a reimbursement basis. Grant revenues under the arrangements are recognized as grant revenue when costs are incurred. The Company is currently not receiving funds from any grants.
- l. Research and Development Costs--Research and development expenditures are expensed as incurred. Total research and development costs, excluding depreciation, were \$11,911,626, \$6,011,750, and \$4,101,563 for the years ended September 30, 2010, 2009 and 2008.
- m. Net Income (Loss) Per Common Share--Net income (loss) per common share is computed by dividing the net income (loss) by the weighted average number of common shares outstanding during the period. Potentially dilutive common stock equivalents, including convertible preferred stock, convertible debt and options to purchase common stock, are included in the calculation unless the result is antidilutive.
- n. Concentration of Credit Risk--Financial instruments, which potentially subject the Company to concentrations of credit risk, consist of cash and cash equivalents. The Company maintains its cash and cash equivalents with high quality financial institutions. At times, these accounts may exceed federally insured limits. The Company has not experienced any losses in such bank accounts. The Company believes it is not exposed to significant credit risk related to cash and cash equivalents.



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- o. Income Taxes-- The Company has net operating loss carryforwards at September 30, 2010 of approximately \$115 million. The Company uses the asset and liability method of accounting for income taxes. Under the asset and liability method, deferred tax assets and liabilities are recognized for future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating and tax loss carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. The Company records a valuation allowance to reduce the deferred tax assets to the amount that is more likely than not to be recognized.
  
- p. Use of Estimates--The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. Accounting for derivatives is based upon valuations of derivative instruments determined using various valuation techniques including the Black-Scholes and binomial pricing methodologies. The Company considers such valuations to be significant estimates.

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- q. Recent Accounting Pronouncements--In March 2008, the FASB issued Codification 815-20-50-1, "Disclosures about Derivative Instruments and Hedging Activities - an amendment of FASB Statement No. 133", which changes disclosure requirements for derivative instruments and hedging activities. The statement is effective for periods ending on or after November 15, 2008, with early application encouraged. The Company has adopted this topic with no impact on its consolidated financial statements.

In June 2008, the FASB issued EITF 07-5, "Determining Whether an Instrument (or Embedded Feature) Is Indexed to a Company's Own Stock". EITF 07-5 is now known as Codification 815-40-15-7 and it supersedes EITF 01-6 and provides revised guidance for, "...the determination of whether an instrument (or an embedded feature) is indexed to an entity's own stock, which is the first part of the scope exception in paragraph 11(a) of Statement 133, now known as Codification 815-10-50. If an instrument (or an embedded feature) that has the characteristics of a derivative instrument under Codification 815-10-50 is indexed to an entity's own stock, it is still necessary to evaluate whether it is classified in stockholders' equity (or would be classified in stockholders' equity if it were a freestanding instrument)." Specifically, Codification 815-40-15-7 provides a two-step process:

- Step 1: Evaluate the instrument's contingent exercise provisions, if any.
- Step 2: Evaluate the instrument's settlement provisions.

Codification 815-40-15-7 was effective for the Company as of January 1, 2009 and was applied to outstanding instruments as of October 1, 2009.

Based on this analysis, the Company has determined that some of its warrants are subject to Codification 815-10-50 and must be revalued at the end of

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every reporting period, with changes to the fair value of the warrants to be accounted for as derivative gains or losses in the income statement. For further discussion, see Note 10.

In September 2008, the FASB issued Codification 815-10-50-1A, "Disclosures about Credit Derivatives and Certain Guarantees: An Amendment of FASB Statement No. 133 and FASB Interpretation No. 45; and Clarification of the Effective Date of FASB Statement No. 161". This codification applies to credit derivatives within the scope of ASC 815 and hybrid instruments that have embedded credit derivatives. It deals with disclosures related to these derivatives and is effective for reporting periods ending after November 15, 2008. It also clarifies the effective date of Codification 815-20-50-1 as any reporting period beginning after November 15, 2008. The impact of the adoption of this codification did not have a material effect on the Company's consolidated financial statements.

In April 2009, the FASB issued Codification 825-10-65-1, "Interim Disclosures about Fair Value of Financial Instruments". This topic amends FASB Statement No. 107, "Disclosures about Fair Values of Financial Instruments", to require disclosures about fair values of financial instruments for interim reporting periods of publicly traded companies as well as in annual financial statements. This topic became effective for interim and annual reporting periods ending after June 15, 2009. The Company

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adopted this codification for the period ended June 30, 2009. There was no significant impact from this adoption on the Company's consolidated financial statement.

In May 2009, the FASB issued Codification 855-10-50, "Subsequent Events" which establishes general standards of accounting for and disclosure of events that occur after the balance sheet date but before the financial statements are issued or are available to be issued. The Statement sets forth the period after the balance sheet date during which management of a reporting entity should evaluate events or transactions that may occur for potential recognition or disclosure in the financial statements, the circumstances under which an entity should recognize events or transactions occurring after the balance sheet date in its financial statements and the disclosures that an entity should make about events or transactions that occurred after the balance sheet date. This topic became effective for the Company for the period ended June 30, 2009. The impact of the adoption was not significant.

In January 2010, the FASB amended Codification 820-10, "Improving Disclosures about Fair Value Measurement", effective for interim periods beginning after December 15, 2009. This amendment changes disclosures required for interim and annual periods with respect to fair value measurements. The Company has adopted the change in the disclosure requirements and the effect was immaterial.

- r. Stock-Based Compensation-- The Company recognized expense of \$1,316,399 for options issued or vested during the fiscal year ended September 30, 2010, expense of \$1,699,448 for options issued or vested during the fiscal year ended September 30, 2009 and expense of \$561,387 for options issued or vested during the fiscal year ending September 30, 2008. This expense was recorded as general and administrative expense. The Company received a total of \$36,330 and \$282,841 from the exercise of options during the year ended September 30, 2010 and 2009, respectively. The following table summarizes stock option activity for the year ended September 30, 2010.

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Non-Qualified Stock Option Plan

	Outstanding			Exercisable		
	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value	Number of Shares	Weighted Average Exercise Price
Outstanding at October 1, 2009	19,578,091	\$ 0.48	7.70	23,979,937	7,400,431	\$ 0.61
Vested						
Granted	1,453,450	\$ 0.57	9.74	106,592	812,669	\$ 0.53
Exercised	(18,625)	\$ 0.31	8.31	6,224	(18,625)	\$ 0.31
Forfeited	(4,500)	\$ 0.77				
Expired	(30,502)	\$ 1.05			(30,502)	\$ 1.05
Outstanding at September 30, 2010	20,977,914	\$ 0.49	7.18	4,209,476	8,163,973	\$ 0.62

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Incentive Stock Option Plan

	Outstanding			Exercisable		
	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value	Number of Shares	Weighted Average Exercise Price
Outstanding at October 1, 2009	9,598,874	\$ 0.39	7.03	12,859,317	8,548,876	\$ 0.38
Vested						
Granted	1,100,000	\$ 0.61	9.76	31,000	449,999	\$ 0.49
Exercised	(71,333)	\$ 0.43	1.74	22,400	(71,333)	\$ 0.43
Expired	(34,500)	\$ 2.25			(34,500)	\$ 2.25

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Outstanding at  
September 30, 2010    10,593,041    \$ 0.40    6.65    3,101,582    8,893,042    \$ 0.38

The total intrinsic value of options exercised during the fiscal years 2010, 2009 and 2008 was \$32,999, \$242,634 and \$5,784, respectively.

The weighted average fair value at the date of grant for options granted during fiscal years 2010, 2009 and 2008 was \$0.52, \$0.28 and \$0.51, respectively.

A summary of the status of the Company's non-vested options as of September 30, 2010 is presented below:

Non-qualified Stock Option Plan:

	Weighted Number of Shares	Average Price
	-----	-----
Nonvested at October 1, 2007	1,439,986	\$0.51
Vested	(616,328)	
Granted	1,039,000	
Forfeited	(9,332)	
	-----	
Nonvested at September 30, 2008	1,853,326	\$0.61
Vested	(1,566,280)	
Granted	11,895,614	\$0.31
Forfeited	(5,000)	
	-----	

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Nonvested at September 30, 2009	12,177,660	\$0.40
Vested	(812,669)	
Granted	1,453,450	\$0.50
Forfeited	(4,500)	
	-----	
Nonvested at September 30, 2010	12,813,941	\$0.40
	=====	

Incentive Stock Option Plan:

	Weighted Number of Shares	Average Price
	-----	-----
Nonvested at October 1, 2007	603,332	\$0.49
Vested	(280,001)	
Granted	300,000	
Forfeited	-	
	-----	
Nonvested at September 30, 2008	623,331	\$ 0.62
Vested	(4,556,108)	
Granted	4,982,775	\$0.22

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Forfeited	-	
	-----	
Nonvested at September 30, 2009	1,049,998	\$0.45
Vested	(449,999)	
Granted	1,100,000	\$0.55
Forfeited	-	
	-----	
Nonvested at September 30, 2010	1,699,999	\$0.54
	=====	

In fiscal year 2010, the Company issued 2,553,450 stock options to employees and directors at a fair value of \$1,333,831, (\$0.52 fair value per option), at a weighted average exercise price of \$0.59 per share. In fiscal year 2009, the Company issued 16,878,389 stock options to employees and directors at a fair value of \$4,725,949, (\$0.28 fair value per option), at a weighted average exercise price of \$0.343 per share. In fiscal year 2008, the Company issued 1,339,000 stock options to employees and directors at a fair value of \$677,661, at a weighted average exercise price of \$0.51 per share. On September 30, 2010, the Company had 14,513,940 options that were unvested at a fair value of \$5,333,797, which is a weighted average fair value of \$0.37 per share with a weighted average remaining vesting life of 1.87 years. The fair value of each option grant was estimated on the date of grant using the Black-Scholes option-pricing model with the following assumptions:

	2010	2009	2008
	----	----	----
Expected stock price volatility	98.6-104.5%	79.5-80.2%	79-81%
Risk-free interest rate	2.54-4.01%	2.82-3.72%	3.68-4.53%
Expected life of options	9.63-10 Years	10 Years	10 Years
Expected dividend yield	-	-	-

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The Company's stock options are not transferable, and the actual value of the stock options that an employee may realize, if any, will depend on the excess of the market price on the date of exercise over the exercise price. The Company has based its assumption for stock price volatility on the variance of daily closing prices of the Company's stock. The risk-free rate of return used for fiscal years 2010, 2009 and 2008 equals the yield on ten-year zero-coupon U.S. Treasury issues on the grant date. Historical data was used to estimate option exercise and employee termination within the valuation model. The expected term of options represents the period of time that options granted are expected to be outstanding and has been determined based on an analysis of historical exercise behavior. No discount was applied to the value of the grants for non-transferability or risk of forfeiture.

2. SERIES K CONVERTIBLE DEBT

In August 2006, the Company issued \$8,300,000 million in aggregate principal amount of convertible notes (the "Series K Notes") together with warrants to purchase 4,825,581 shares of the Company's common stock (the "Series K Warrants"). Additionally, in connection with issuance of the Series K Notes and Series K Warrants, the placement agent received a fee of \$498,000 and 386,047 fully vested warrants (the "Placement Agent Warrants") to purchase shares of the Company's common stock. Net proceeds were \$7,731,290, net of \$568,710 in direct transaction costs, including the placement agent fee. The Series K convertible debt has all either been repaid or converted into shares of the Company's common stock as of

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September 2009.

### Features of the Convertible Debt Instrument and Warrants

The Series K Notes were convertible into 9,651,163 shares of the Company's common stock at the option of the holder at any time prior to maturity at a conversion price of \$0.86 per share, subject to adjustment for certain events described below. The Series K Warrants were exercisable over a five-year period from February 4, 2007 through February 4, 2012 at \$0.95 per share.

The Series K Notes bore interest at the greater of 8% or LIBOR plus 300 basis points, and were required to be repaid in thirty equal monthly installments of \$95,000 beginning on March 4, 2007 and continuing through September 4, 2010. The remaining principal balance of \$950,000 was required to be repaid on August 4, 2011; however, holders of the Series K Notes were allowed to require the repayment of the entire remaining principal balance at any time after August 4, 2009. Interest had been payable quarterly beginning in September 30, 2006. Each payment of principal and accrued interest could be settled in cash or in shares of common stock at the option of the Company. The number of shares deliverable under the share-settlement option was determined based on the lower of (a) \$0.86 per share, as adjusted pursuant to the terms of the Series K Notes or (b) 90% applied to the arithmetic average of the volume-weighted-average trading prices for the twenty day period immediately preceding each share settlement.

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The conversion price of the Series K Notes and exercise price of the Series K Warrants were each subject to certain anti-dilution protections, including for stock splits, stock dividends, change in control events and dilutive issuances of common stock or common stock equivalents, such as stock options, at an effective price per share that is lower than the then conversion price. In the event of a dilutive issuance of common stock or common stock equivalents, the conversion price and exercise price would be reduced to equal the lower per share price of the subsequent transaction.

### Accounting for the Convertible Debt Instrument and Warrants

The Company accounted for the Series K Warrants as derivative liabilities in accordance with Codification 815-10. The Company determined that the Series K Notes constituted a hybrid instrument that had the characteristics of a debt host contract containing several embedded derivative features that would require bifurcation and separate accounting as a derivative instrument pursuant to the provisions of the topic. The Company determined that certain of these features cannot be reliably measured and, in accordance with the requirements of the topic, measured the entire hybrid instrument at fair value with changes in fair value recognized as either a gain or loss.

Upon issuance of the Series K Notes and Series K Warrants, the Company allocated proceeds received to the Series K Notes and the Series K Warrants on a relative fair value basis. As a result of such allocation, the Company determined the initial carrying value of the Series K Notes to be \$6,565,528. The Series K Notes were immediately marked to fair value resulting in a derivative liability in the amount of \$9,728,793 and the Company recognized a charge of \$3,163,265, which was recorded as costs associated with convertible debt. As of September 30, 2008, the fair value

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of the Series K Notes was \$1,943,240, and the Company recognized a total gain of \$1,799,393 on the convertible debt and associated warrants during the year ended September 30, 2008. A debt discount in the amount of \$1,734,472 was amortized to interest expense using the effective interest method over the expected term of the Series K Notes. During the year ended September 30, 2009, the Company recorded interest expense of \$193,980 in related amortization of the debt discount. During the year ended September 30, 2008, the Company recorded interest expense of \$249,106 in related amortization of the debt discount over the term of the Series K Notes.

Upon issuance, the Series K Warrants and Placement Agent Warrants did not meet the requirements for equity classification set forth in Codification 815-10-50, "Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock," because such warrants (a) must be settled in registered shares and (b) are subject to substantial liquidated damages if the Company is unable to maintain the effectiveness of the resale registration of the shares. Therefore such warrants were accounted for as freestanding derivative instruments pursuant to the provisions of Codification 815-10. Accordingly, the Company allocated \$2,570,138 of the initial proceeds to the Series K Warrants and immediately marked them to fair value resulting in a derivative liability of \$2,570,138 and recognized a charge of \$835,666, which was recorded as costs associated with convertible debt. As of September 30, 2008, the fair value of the Series K Warrants was \$995,793. The Company paid \$568,710 in cash transaction costs and incurred another \$223,907 in costs based upon the fair value of the Placement Agent Warrants, which was recorded as costs associated with convertible debt. Such costs were expensed immediately as

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part of fair value adjustments required in connection with the convertible debt instrument and the Company's irrevocable election to initially and subsequently measure the Series K Notes at fair value. As of September 30, 2008, the fair value of the Placement Agent Warrants was \$79,664. In connection with the June 2009 financing, the Series K notes and warrants were repriced to \$0.40. As of September 30, 2009, the fair value of the remaining investor and broker warrants was \$5,372,598. During the fiscal year ended September 30, 2010, 1,335,221 Series K warrants were exercised, on which the Company recognized a gain on conversion of \$280,223. When the warrants were exercised, \$1,233,518 of the Series K warrants was converted from derivative liabilities to equity. At September 30, 2010, the fair value of the remaining investor and broker warrants was \$1,002,502.

During the year ended September 30, 2009, all remaining convertible debt was converted into common stock or was repaid in accordance with the terms of the agreement. \$24,375 was repaid at 120% and \$1,206,341 in convertible debt was converted into 3,015,852 shares of common stock during the year ended September 30, 2009.

### 3. OPERATIONS AND FINANCING

The Company has incurred significant costs since its inception in connection with the acquisition of certain patented and unpatented proprietary technology and know-how relating to the human immunological defense system, patent applications, research and development, administrative costs, construction of laboratory facilities, and clinical trials. The Company has funded such costs with proceeds from the public and private sale of its common and preferred stock. The Company will be required to raise additional capital or find additional long-term financing in order to continue with its research efforts. To date, the Company has not generated any revenue from product sales. The ability of the Company to complete the necessary clinical

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trials and obtain Federal Drug Administration (FDA) approval for the sale of products to be developed on a commercial basis is uncertain. Ultimately, the Company must complete the development of its products, obtain the appropriate regulatory approvals and obtain sufficient revenues to support its cost structure.

The Company has two partners who have agreed to participate in and pay for part of the Phase III clinical trial for Multikine. Since the Company was able to raise substantial capital during 2009, the Company is currently preparing the Phase III trial for Multikine. The net cost of the clinical trial is currently being negotiated, but is assumed to be about \$25 - \$26 million. The Company believes that its capital will allow it to enroll the patients in the Phase III clinical trial. The Company will need to raise additional funds, either through its existing warrants/options, through a debt or equity financing or a partnering arrangement, to complete the Phase III trial and bring Multikine to market. There can be no assurances the Company will be successful in raising additional funds.

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#### 4. RESEARCH AND OFFICE EQUIPMENT

Research and office equipment at September 30, 2010 and 2009, consists of the following:

	2010 ----	2009 ----
Research equipment	\$3,647,684	\$3,292,472
Furniture and equipment	116,996	122,957
Leasehold improvements	126,910	44,419
	-----	-----
	3,891,590	3,459,848
Less: Accumulated depreciation and amortization	(2,626,759)	(2,259,237)
	-----	-----
Net research and office equipment	\$1,264,831	\$1,200,611
	=====	=====

#### 5. INCOME TAXES

At September 30, 2010, the Company had a federal net operating loss carryforward of approximately \$115 million expiring from 2011 through 2030. In addition, the Company has a general business credit as a result of the credit for increasing research activities of approximately \$2,341,000 at September 30, 2010 and 2009. These tax credits begin expiring after twenty years from the year in which the credit was generated. The components of the deferred taxes at September 30, 2010 and 2009 are comprised of the following:

	2010 ----	2009 ----
Net operating loss	\$45,940,445	\$39,491,048
R&D credit	2,340,614	2,340,614
Amortization of debt discount	--	658,406
Codification 718-10-30-3	1,243,647	683,245
Derivative loss	--	8,919,951
Vacation and other	83,593	9,127
Deferred rent	970,224	-



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Total deferred tax assets	50,578,523	52,102,392
Derivative gain	(2,133,259)	-
Depreciation	(80,026)	-
Total deferred tax liability	(2,213,285)	-
Valuation allowance	(48,365,238)	(52,102,392)
Net deferred tax asset	\$ -	\$ -

In assessing the realization of the deferred tax assets, management considered whether it was more likely than not that some portion or all of the deferred tax asset will be realized. The ultimate realization of the deferred tax assets is dependent upon the generation of future taxable

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income. Management has considered the history of the Company's operating losses and believes that the realization of the benefit of the deferred tax assets cannot be determined. In addition, under the Internal Revenue Code Section 382, the Company's ability to utilize these net operating loss carryforwards may be limited or eliminated in the event of a change in ownership in the future. Internal Revenue Code Section 382 generally defines a change in ownership as the situation where there has been a more than 50 percent change in ownership of the value of the Company within the last three years.

The Company's effective tax rate is different from the applicable federal statutory tax rate. The reconciliation of these rates for the years ended September 30 is as follows:

	2010	2009	2008
	----	----	----
Federal Rate	34.0%	34.0%	34.0%
State tax rate, net of federal benefit	5.91%	3.96%	3.96%
R&D credit	0%	2.01%	5.06%
RT&D credit true-up	0%	(0.40%)	0%
Nondeductible expenses	0.02%	(0%)	(0.04%)
Valuation allowance	(39.93%)	(39.57%)	(42.98%)
Effective tax rate	0.0%	0.0%	0.0%

The Company adopted the provisions of Codification 740-10, "Accounting for Uncertainty in Income Taxes" on October 1, 2007 which requires financial statement benefits be recognized for positions taken for tax return purposes, when it is more likely than not that the position will be sustained. The Company has concluded that it has properly filed its tax returns and does not believe that any of the positions it has taken would result in a disallowance of any of these tax positions. Therefore, the Company has concluded that adoption of ASC 740-10 had no impact on its financial positions. No interest or penalties have been accrued as a result of adoption of this requirement. In the United States, the Company is still open to examination from 2006 forward.

6. STOCK OPTIONS, BONUS PLAN AND WARRANTS

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Non-Qualified Stock Option Plans --At September 30, 2010, the Company has collectively authorized the issuance of 33,760,000 shares of common stock under its Non-Qualified Stock Option Plans. Options typically vest over a three-year period and expire no later than ten years after the grant date. Terms of the options are to be determined by the Company's Compensation Committee, which administers the plans. The Company's employees, directors, officers, and consultants or advisors are eligible to be granted options under the Non-Qualified Stock Option Plans.

Information regarding the Company's Non-Qualified Stock Option Plans is summarized as follows:

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	Outstanding		Exercisable	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Options outstanding, October 1, 2007	7,462,698	\$0.69	5,972,712	\$0.67
Options granted	1,039,000	\$0.60		
Options exercised	(50,467)	\$0.29		
Options forfeited	(43,966)	\$0.96		
	-----			
Options outstanding, September 30, 2008	8,407,265	\$0.68	6,553,939	\$ 0.64
Options granted	12,538,114	\$0.38		
Options exercised	(162,253)	\$0.38		
Options forfeited	(462,535)	\$0.82		
	-----			
Options outstanding, September 30, 2009	20,320,591	\$0.49	8,142,931	\$0.64
Options granted	1,453,450	\$0.56		
Options exercised	(18,625)	\$0.31		
Options forfeited	(35,002)	\$0.97		
	-----			
Options outstanding, September 30, 2010	21,720,414	\$0.50	8,906,473	\$0.65
	=====			

In December 2007, the Company extended the expiration date on 1,680,533 options from the Nonqualified Stock Option Plans with exercise prices ranging from \$1.05 to \$1.94. The options originally would have expired between February 2008 and October 2008 and were extended for five years to expiration dates ranging from February 2013 to October 2013. This extension was considered a new measurement date with respect to the modified options. At the date of modification, the additional cost of the options was \$410,471. As of September 30, 2010, all of these options remain outstanding.

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In April 2009, the Company extended the expiration date on 147,000 options from the Nonqualified Stock Option Plans with the exercise prices ranging from \$1.05 to \$1.87. The options originally would have expired between May 2009 and September 2009 and were extended for three years to expiration dates ranging from May 2012 to September 2012. This extension was considered a new measurement date with respect to the modified options. At the date of modification, the additional cost of the options was \$2,904. As of September 30, 2010, all of these options remain outstanding.

In January 2010, the Company extended the expiration date on 181,666 options from the Nonqualified Stock Option Plans with the exercise prices ranging from \$1.05 to \$1.76. The options originally would have expired between February 2010 and November 2010 and were extended for three years to expiration dates ranging from February 2013 to November 2013. This extension was considered a new measurement date with respect to the modified options. At the date of modification, the additional cost of the options was \$72,632. As of September 30, 2010, all of these options remain outstanding.

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Incentive Stock Option Plan--At September 30, 2010, the Company has collectively authorized the issuance of 17,100,000 shares of common stock under its Incentive Stock Option Plans. Options vest over a one-year to three-year period and expire no later than ten years after the grant date. Terms of the options are to be determined by the Company's Compensation Committee, which administers the plans. Only the Company's employees and directors are eligible to be granted options under the Incentive Stock Option Plans.

Information regarding the Company's Incentive Stock Option Plans is summarized as follows:

	Outstanding		Exercisable	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
	-----	-----	-----	-----
Options outstanding, October 1, 2007	4,601,933	\$0.64	3,998,601	\$0.63
Options granted	300,000	\$0.62		
Options exercised	-			
Options forfeited	(156,667)	\$3.83		
	-----			
Options outstanding, September 30, 2008	4,745,266	\$0.53	4,121,935	\$0.52
Options granted	4,982,775	\$0.27		
Options exercised	(100,000)	\$1.13		
Options forfeited	(29,167)	\$1.70		
	-----			
Options outstanding, September 30, 2009	9,598,874	\$0.39	8,548,876	\$0.38
	=====			

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Options granted	1,100,000	\$0.61	
Options exercised	(71,333)	\$0.43	
Options forfeited	(34,500)	\$2.25	
	-----		
Options outstanding, September 30, 2010	10,593,041	\$0.50	8,893,042      \$0.65
	=====		

In December 2007, the Company extended the expiration date on 225,100 options from the Incentive Stock Option Plans with exercise prices ranging from \$1.05 to \$1.94. The options originally would have expired between February 2008 and December 2008 and were extended for five years to expiration dates ranging from February 2013 to December 2013. This extension was considered a new measurement date with respect to the modified options. At the date of modification, the additional cost of the options was \$54,537. As of September 30, 2010, all of these options remain outstanding.

In April 2009, the Company extended the expiration date on 153,000 options from the Incentive Stock Option Plans with the exercise price of \$1.05. The options originally would have expired between April 2009 and December 2009 and were extended for three years to expiration dates ranging from April 2012

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to December 2012. This extension was considered a new measurement date with respect to the modified options. At the date of modification, the additional cost of the options was \$3,238. As of September 30, 2010, all of these options remain outstanding.

In January 2010, the Company extended the expiration date on 337,166 options from the Incentive Stock Option Plans with the exercise prices ranging from \$1.05 to \$1.18. The options originally would have expired between February 2010 and December 2010 and were extended for three years to expiration dates ranging from February 2013 to December 2013. This extension was considered a new measurement date with respect to the modified options. At the date of modification, the additional cost of the options was \$139,812. As of September 30, 2010, all of these options remain outstanding

### Other Options and Warrants

The Company accounts for options to non-employees in accordance with Codification 505-50-05-5, "Equity Based Payments to Non-Employees". The warrants are valued using the Black-Scholes methodology and are either expensed as the warrants are vested or as a debit and a credit to additional paid-in capital if an equity transaction. If the warrants are expensed, they are revalued each quarter before they are fully vested and the difference in the value of the warrants is recorded in the consolidated statement of operations. Warrants issued in connection with some financings are classified as derivative liabilities due to their terms. See Note 10 for further discussion of the derivative liabilities. Details of the other transactions follow.

In November and December 2007, the Company extended the expiration date of 2,016,176 investor and consultant warrants. The options and warrants were due to expire from December 1, 2007 through December 31, 2008. All options and warrants were extended for an additional five years from the original expiration date. The cost of the extension of investor warrants of \$424,815 was recorded as a debit to accumulated deficit (dividend) and a credit to additional paid-in capital. The cost of the extension of the consultant

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warrants of \$99,181 was recorded as a debit to general and administrative expense and a credit to additional paid-in capital. The additional cost of the extension of investor and consultant warrants was determined using the Black Scholes method.

Expected stock risk volatility	72%
Risk-free interest rate	3.67%
Expected life of warrant	5.17-5.5 Years

In January 2009, as part of an amended lease agreement on the manufacturing facility, the Company repriced 3,000,000 warrants issued to the lessor in July 2007 at \$1.25 per share and which were to expire on July 12, 2013. These warrants were repriced at \$0.75 per share and expire on January 26, 2014. The cost of this repricing and extension of the warrants was \$70,515 and was accounted for as a debit to the deferred rent asset and a credit to additional paid-in capital. In addition, 787,500 additional warrants were given to the lessor of the manufacturing facility on the same date, exercisable at a price of \$0.75 per share, and will expire on January 26, 2014. The cost of these warrants was \$45,207 and was accounted for as a debit to the deferred rent asset and a credit to additional paid-in capital. The cost of the warrant extension and the new warrants was determined using the Black Scholes method using the following assumptions.

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Expected stock risk volatility	61.63%
Risk-free interest rate	1.52%
Expected life of warrant	5 Years

In March 2009, as further consideration for its rights under the licensing agreement, Byron Biopharma purchased 3,750,000 Units from the Company at a price of \$0.20 per Unit. Each Unit consisted of one share of the Company's common stock and two warrants. Each warrant entitles the holder to purchase one share of the Company's common stock at a price of \$0.25 per share. The warrants are exercisable at any time prior to March 6, 2016. The fair value of the warrants was calculated to be \$1,015,771 using the Black Scholes method with the following assumptions and was recorded as both a debit and a credit to additional paid-in capital.

Expected stock risk volatility	83.12%
Risk-free interest rate	2.30%
Expected life of warrant	7 Years

Between March 31 and June 30, 2009, 2,296,875 new warrants were issued to the leaseholder on the manufacturing facility in consideration for the deferment of rent payments. The cost of these new warrants of \$251,172 was recorded as a debit to research and development and a credit to additional paid in capital. The cost the new warrants was determined using the Black Scholes method using the following assumptions.

Expected stock risk volatility	63.03 - 64.46%
Risk-free interest rate	1.82 - 2.13%
Expected life of warrant	5 Years

In June 2009, 2,075,084 warrants issued to two investors in connection with a financing in August 2008 were reset from \$0.75 to \$0.40. The additional cost of the warrants of \$123,013 was recorded as a debit and a credit to additional paid in capital. In addition, the investors were issued 1,815,698 warrants exercisable at \$0.40 per share at a cost of \$404,460. The additional cost of the warrants was recorded as a debit and a credit to paid in capital. The costs were determined using the Black Scholes method using the following

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assumptions.

Expected stock risk volatility	63.75%
Risk-free interest rate	2.13%
Expected life of warrant	5.17 Years

In June 2009, the Company issued 10,284,060 warrants exercisable at \$0.50 per share in connection with the June financing. The cost of the warrants of \$2,775,021 was recorded as a debit and a credit to additional paid in capital. See Note 11.

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Expected stock risk volatility	62.59%
Risk-free interest rate	2.13-2.71%
Expected life of warrant	5 Years

In connection with the reset of the conversion price of the Series K notes and the exercise price of the warrants from \$0.75 to \$0.40 after the June 2009 financing, the Series K note holders received 5,348,357 additional warrants. The cost of these additional warrants is included in the fair value of the remaining warrants at September 30, 2010. See Note 2.

In June 2009, the Company issued 1,648,244 warrants exercisable at \$0.40 per share to the holder of a note from the Company. These warrants were valued at \$65,796 using the Black Scholes method. In July 2009, the Company issued 1,849,295 warrants exercisable at \$0.50 per share to the holder of the note that was amended for the second time. These warrants were valued at \$341,454 using the Black Scholes method. The first warrants were recorded as a discount to the loan and a credit to additional paid-in capital. The second warrants were recorded as a debit to derivative loss of \$831,230, a premium of \$341,454 on the loan and a credit to additional paid in capital of \$489,776. The first warrants were amortized as interest expense at the time of the second amendment. On the second amendment, \$338,172 of the premium was amortized as a reduction to interest expense as of September 30, 2009. The balance of the premium of \$3,282 was amortized as a reduction to interest expense in October 2009. The following assumptions were used to value these warrants:

	June 2009	July 2009
Expected stock risk volatility	90%	90%
Risk-free interest rate	2.4%	2.4%
Expected life of warrant	5 Years	5 Years

In July 2009, 375,000 warrants held by an investor were extended for two years. The additional value of the warrants of \$24,061 was calculated using the Black Scholes method using the following assumptions. This cost was accounted for as a debit and a credit to additional paid in capital.

	Original Warrants	Extended Warrants
Expected stock risk volatility	57.14%	57.14%
Risk-free interest rate	1.76%	1.76%
Expected life of warrant	0.08 Year	2.08 Years

In July 2009, 192,500 options were issued with exercise prices between \$0.40 and \$0.60 per share to three consultants, for past services, at a cost of \$35,911 using the Black Scholes method. The options were accounted for as a

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debit to general and administrative expense and a credit to additional paid

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in capital. Also in July 2009, the Company issued 200,000 options to a consultant with an exercise price of \$0.38 per share. The cost of these options, \$43,702, was calculated using the Black Scholes method using the following assumptions and accounted for as a debit to research and development and a credit to additional paid in capital.

Expected stock risk volatility	66.74%
Risk-free interest rate	2.71%
Expected life of warrant	5 Years

In July 2009, the Company issued warrants to a private investor. The 167,500 warrants were issued with an exercise price of \$0.50 per share and valued at \$43,550 using the Black Scholes method using the following assumptions. The cost of the warrants was accounted for as a debit to additional paid in capital and a credit to derivative liabilities.

Expected stock risk volatility	90%
Risk-free interest rate	2.90%
Expected life of warrant	5.5 Years

In July 2009, 100,000 warrants were extended for one year. The cost of the extension of \$3,134 was calculated using the Black Scholes method using the following assumptions. The cost was accounted for as a debit to general and administrative expenses and a credit to additional paid in capital.

	Original Warrants	Extended Warrants
Expected stock risk volatility	57.14%	57.14%
Risk-free interest rate	1.76%	1.76%
Expected life of warrant	0.17 Year	1.17 Years

In August 2009, the Company received additional financing. In connection with the financing, the Company issued 4,850,501 warrants exercisable at \$0.55 per share. The cost of the warrants of \$1,455,150 was calculated using the Black Scholes method using the following assumptions and was recorded as a debit to additional paid in capital and a credit to derivative liabilities. See Note 11.

Expected stock risk volatility	90%
Risk-free interest rate	2.59%
Expected life of warrant	5.51 Years

Also in August 2009, the Company completed an offering to the original Series K investors. Issued with an exercise price of \$0.55 per share, the 541,717 warrants were valued at \$249,190 using the Black Scholes method using the following assumptions. The warrants were accounted for as a debit to additional paid in capital and a credit to derivative liabilities.

Expected stock risk volatility	90 %
Risk-free interest rate	2.61%
Expected life of warrant	5.5 Years

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In September 2009, the Company received a \$2,000,000 loan. In connection with the loan, the Company issued 500,000 warrants with an exercise price of \$0.68 per share. The cost of the warrants of \$245,000 was recorded as a debit to discount on note payable and a credit to additional paid in capital. This cost was amortized to interest expense when the loan was repaid. See Note 11.

Expected stock risk volatility	90%
Risk-free interest rate	2.54%
Expected life of warrant	5.5 Years

In September 2009, the Company issued 4,714,284 warrants with an exercise price of \$1.50 per share in connection with a financing. The cost of the warrants of \$3,488,570 was calculated using the Black Scholes method using the following assumptions and was recorded as a debit and a credit to additional paid in capital. See Note 11. In addition, 714,286 warrants were issued with an exercise price of \$1.75 per share to the placement agent on the transaction. The cost of \$664,286 was calculated using the Black Scholes method using the following assumptions and was accounted for as a debit to additional paid in capital and a credit to derivative liabilities.

	Financing Warrants	Placement Agent Warrants
Expected stock risk volatility	110%	110%
Risk-free interest rate	1.01%	2.42%
Expected life of warrant	2 Years	4.91 Years

In accordance with Codification 815-40-15-7, derivative liabilities must be revalued at the end of each interim period and at the end of the fiscal year, as long as they remain outstanding. As of September 30, 2009, the fair value of these new derivative liabilities totaled \$29,741,372. As of September 30, 2010, the value of the remaining derivative liabilities totaled \$5,943,549.

In August 2010, 70,000 options owned by an investor were extended for two years at a cost of \$15,477. This cost was calculated using the Black Scholes method and was accounted for as a credit to additional paid in capital and a debit to general and administrative expense. The calculation used the following assumptions.

	Prior to Extension	After Extension
Expected stock risk volatility	102%	102%
Risk-free interest rate	0.15%	0.49%
Expected life of warrant	0 Years	2 Years

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**Stock Bonus Plans** -- At September 30, 2010, the Company had been authorized to issue up to 11,940,000 shares of common stock under its Stock Bonus Plans. All employees, directors, officers, consultants, and advisors are eligible to be granted shares. During the year ended September 30, 2008, 205,125 shares were issued to the Company's 401(k) plan for a cost of \$108,590. During the year ended September 30, 2009, 91,766 shares were issued to the Company's 401(k) plan for a cost of \$57,829. During the year ended September 30, 2010, 182,233 shares were issued to the Company's 401(k) plan for a cost of \$112,325.

**Stock Compensation Plan**-- At September 30, 2010, 9,500,000 shares were



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authorized for use in the Company's stock compensation plan. During the year ended September 30, 2008, 1,789,451 shares were issued at the weighted average \$0.62 per share for a total cost of \$1,324,474. During the year ended September 30, 2009, 1,324,385 shares were issued at the weighted average of \$0.24 per share for a total cost of \$312,016. During the year ended September 30, 2010, no shares were issued from the Stock Compensation Plan.

### 7. EMPLOYEE BENEFIT PLAN

The Company maintains a defined contribution retirement plan, qualifying under Section 401(k) of the Internal Revenue Code, subject to the Employee Retirement Income Security Act of 1974, as amended, and covering substantially all Company employees. Each participant's contribution is matched by the Company with shares of common stock that have a value equal to 100% of the participant's contribution, not to exceed the lesser of \$10,000 or 6% of the participant's total compensation. The Company's contribution of common stock is valued each quarter based upon the closing bid price of the Company's common stock. The expense for the years ended September 30, 2010, 2009, and 2008, in connection with this Plan was \$123,500, \$61,517, and \$110,670, respectively.

### 8. COMMITMENTS AND CONTINGENCIES

Operating Leases—The future minimum annual rental payments due under noncancelable operating leases for office and laboratory space are as follows:

Year Ending September 30,	
2011	1,903,471
2012	1,896,205
2013	1,855,889
2014	1,579,931
2015	1,572,839
2016 and thereafter	26,441,949
	-----
Total minimum lease payments:	\$35,250,284
	=====

Rent expense for the years ended September 30, 2010, 2009, and 2008, was \$3,308,102, \$2,759,332, and \$253,526, respectively. Rent increased substantially during the fiscal year ended September 30, 2009 because the

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Company took delivery of the new building in October of 2008; see discussion below. These leases expire between June 2012 and August 2028.

In August 2007 the Company leased a building near Baltimore, Maryland. The building was be remodeled in accordance with the Company's specifications so that it can be used by the Company to manufacture Multikine for the Company's Phase III clinical trial and sales of the drug if approved by the FDA. The Company took possession of the building in October 2008.

The lease is for a term of twenty years and required annual base rent payments of \$1,575,000 during the first year of the lease. The annual base rent escalates each year at 3%. The Company is also required to pay all real and personal property taxes, insurance premiums, maintenance expenses, repair costs and utilities. The lease allows the Company, at its election, to extend the lease for two ten-year periods or to purchase the building at the end of the 20-year lease. The lease required the Company to pay \$3,150,000 towards

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the remodeling costs, which will be recouped by reductions in the annual base rent of \$303,228 in years six through twenty of the lease, subject to the Company maintaining compliance with the lease covenants. Included on the consolidated balance sheet is an asset of \$7,819,522 shown as deferred rent. \$7,068,184 of this asset is long term and the balance of \$751,338 is in current assets. Included in deferred rent are the following: 1) deposit on the manufacturing facility (\$3,150,000); 2) warrants issued to lessor (\$1,481,040); 3) additional investment (\$2,889,409); 4) deposit on the cost of the leasehold improvements for the manufacturing facility (\$1,786,591); 5) amortization of deferred rent (\$1,682,053); and 6) accrued interest on deposit (\$194,535). Also included on the consolidated balance sheet is restricted cash of \$21,357. In July 2008, the Company was required to deposit the equivalent of one year of base rent in accordance with the contract. The \$1,575,000 included in current assets on September 30, 2009 was required to be deposited when the amount of cash the Company had dropped below the amount stipulated in the lease. The Company received a refund of the deposit in February 2010, when the Company was again in compliance with the contract.

Employment Contracts--In April 2005, the Company entered into a three-year employment agreement with Maximilian de Clara, the Company's President. The employment agreement provided that the Company would pay Mr. de Clara an annual salary of \$363,000 during the term of the agreement. On September 8, 2006 Mr. de Clara's Employment Agreement was amended and extended to April 30, 2010. On August 30, 2010, Mr. de Clara's employment agreement, as amended on September 8, 2006, was extended to August 30, 2013.

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The employment agreement, as amended, also provided that on September 8, 2006, March 8, 2007, September 8, 2007, March 8, 2008, September 8, 2008 and March 8, 2009, each date being a "Payment Date", the Company issued Mr. de Clara shares of its common stock equal in number to the amount determined by dividing \$200,000 by the average closing price of the Company's common stock for the twenty trading days preceding the Payment Date. A total of 2,610,649 shares were issued to Mr. de Clara under this agreement.

The employment agreement provides that the Company will pay Mr. de Clara an annual salary of \$363,000 during the term of the agreement. In the event that there is a material reduction in his authority, duties or activities, or in the event there is a change in the control of the Company, then the agreement allows him to resign from his position at the Company and receive a lump-sum payment from the Company equal to 18 months salary. For purposes of the employment agreement, a change in the control of the Company means the sale of more than 50% of the outstanding shares of the Company's Common Stock, or a change in a majority of the Company's directors.

In September 2006, the Company agreed to extend its employment agreement with Geert R. Kersten, the Company's Chief Executive Officer, to September 2011. The employment agreement, which is essentially the same as Mr. Kersten's prior employment agreement, provides that during the term of the agreement the Company will pay Mr. Kersten an annual salary of \$370,585 plus any increases approved by the Board of Directors during the period of the employment agreement. In the event there is a change in the control of the Company, the agreement allows him to resign from his position at the Company and receive a lump-sum payment from the Company equal to 24 months of salary. For purposes of the employment agreement a change in the control of the Company means: (1) the merger of the Company with another entity if after such merger the shareholders of the Company do not own at least 50% of voting capital stock of the surviving corporation; (2) the sale of substantially all of the assets of the Company; (3) the acquisition by any person of more than 50% of the Company's common stock; or (4) a change in a majority of the

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Company's directors which has not been approved by the incumbent directors.

On August 30, 2010, the Company entered into a three-year employment agreement with Patricia B. Prichep, the Company's Senior Vice President of Operations. The employment agreement with Ms. Prichep provides that during the term of the agreement the Company will pay Ms. Prichep an annual salary of \$194,298 plus any increases approved by the Board of Directors during the period of the employment agreement.

On August 30, 2010, the Company also entered into a three-year employment agreement with Eyal Talor, Ph.D., the Company's Chief Scientific Officer. The employment agreement with Dr. Talor provides that during the term of the agreement the Company will pay Dr. Talor an annual salary of \$239,868 plus any increases approved by the Board of Directors during the period of the employment agreement.

In the event there is a change in the control of the Company, the employment agreements with Ms. Prichep and Dr. Talor allow Ms. Prichep and/or Dr. Talor (as the case may be) to resign from her or his position at the Company and receive a lump-sum payment from the Company equal to 18 months salary. For purposes of the employment agreements, a change in the control of the Company means: (1) the merger of the Company with another entity if after such merger the shareholders of the Company do not own at least 50% of voting capital stock of the surviving corporation; (2) the sale of substantially all of the assets of the Company; (3) the acquisition by any person of more than 50% of the Company's common stock; or (4) a change in a majority of the Company's directors which has not been approved by the incumbent directors.

The employment agreements with Ms. Prichep and Dr. Talor will also terminate upon the death of the employee, the employee's physical or mental disability, willful misconduct, an act of fraud against the Company, or a breach of the employment agreement by the employee. If the employment agreement is terminated for any of these reasons the employee, or her or his legal representatives, as the case may be, will be paid the salary provided by the employment agreement through the date of termination.

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The Company has an additional contract with a consultant for a nine month period ending in fiscal year 2011. This contract totals approximately \$45,000. Further, the Company has contingent obligations with other vendors for work that will be completed in relation to the Phase III trial. The timing of these obligations cannot be determined at this time. The amount of these obligations for the Phase III trial are approximately \$27 million with the net cost to the Company being between \$25 - \$26 million.

Iroquois Lawsuit - On October 21, 2009, Iroquois filed suit against the Company in the United States District Court for the Southern District of New York. In its lawsuit, Iroquois is seeking \$30 million in actual damages, \$90 million in punitive damages, the issuance of an additional 4,264,681 shares of the Company's common stock, the issuance of warrants to purchase an additional 6,460,757 shares of the Company's stock and a ruling by the court that the conversion price of the notes and the exercise price of the warrants are both \$0.20.

The Company believes that Iroquois's claims are without merit and has filed a motion with the District Court seeking the dismissal of Iroquois's lawsuit.

### 9. LOANS FROM OFFICER AND INVESTOR

Between December 2008 and June 2009, Maximilian de Clara, the Company's President and a director, loaned the Company \$1,104,057. The loan was

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initially payable at the end of March, 2009, but was extended to the end of June 2009. At the time the loan was due, and in accordance with the loan agreement, the Company issued Mr. de Clara warrants which entitle Mr. de Clara to purchase 1,648,244 shares of the Company's common stock at a price of \$0.40 per share. The warrant is exercisable at any time prior to December 24, 2014. Pursuant to Codification paragraph 470-50-40-17, the fair value of the warrants issuable under the first amendment was recorded as a discount on the note payable with a credit recorded to additional paid-in capital. The discount was amortized from April 30, 2009 through June 27, 2009. Although the loan was to be repaid from the proceeds of the Company's then recent financing, the Company's Directors deemed it beneficial not to repay the loan and negotiated a second extension of the loan with Mr. de Clara on terms similar to the June 2009 financing. Pursuant to the terms of the second extension the note is now due on July 6, 2014, but, at Mr. de Clara's option, the loan can be converted into shares of the Company's common stock. The number of shares which will be issued upon any conversion will be determined by dividing the amount to be converted by \$0.40. As further consideration for the second extension, Mr. de Clara received warrants which allow Mr. de Clara to purchase 1,849,295 shares of the Company's common stock at a price of \$0.50 per share at any time prior to January 6, 2015.

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The loan from Mr. de Clara bears interest at 15% per year and is secured by a second lien on substantially all of the Company's assets. The Company does not have the right to prepay the loan without Mr. de Clara's consent.

In accordance with Codification Subtopic 470-50, the second amendment to the loan was accounted for as an extinguishment of the first amendment debt. The extinguishment of the loan requires that the new loan be recorded at fair value and a gain or loss must be recognized. This resulted in a premium of \$341,454, which was amortized over the period from July 6, 2009, the date of the second amendment, to October 1, 2009. The loan holder may request repayment in full or in part at any time after October 1, 2009 on ten days notice. In October 2009, the balance of the remaining premium of \$3,282, was amortized to interest expense. Amortization of the premium was \$338,172 for the year ended September 30, 2009.

In early September 2009, the Company received a short term loan of \$2,000,000, with associated costs of \$73,880, from two investors. The Company repaid the loan at the end of September 2009, along with \$200,000 in interest. In addition, the Company issued 500,000 warrants at \$0.68 at a cost of \$245,000 in connection with the loan. This cost was recorded as a debit to discount on note payable and a credit to derivative liabilities. When the loan was repaid, this discount was written off as interest expense. On September 30, 2009, the fair value of the warrants was \$735,000. On September 30, 2010, the fair value of the warrants was \$220,000, and all of the warrants remain outstanding.

### 10. STOCKHOLDERS' EQUITY

On April 18, 2007, the Company completed a \$15 million private financing. Shares were sold at \$0.75, a premium over the closing price of the previous two weeks. The financing was accompanied by 10 million warrants with an exercise price of \$0.75 and 10 million warrants with an exercise price of \$2.00. The warrants are known as Series L and Series M warrants, respectively. The shares were registered in May 2007.

The financing resulted in the issuance of 19,999,998 shares of common stock to the investors. The warrants issued with the financing qualified for equity

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treatment. The Series L warrants were recorded as a debit and a credit to additional paid-in capital at a value of \$5,164,355 and the Series M warrants were recorded as a debit and a credit to additional paid-in capital at a fair value of \$434,300.

In September 2008, 2,250,000 of the original Series L warrants were repriced at \$0.56 and extended for one year to April 17, 2013. The increase in the value of the warrants of \$173,187 was recorded as a debit and a credit to additional paid-in capital in accordance with the original accounting for the Series L warrants.

As a result of the financing, and in accordance with the original Series K agreement, the Series K conversion price of the notes was repriced to \$0.75 from the original \$0.86 and the exercise price of the warrants were adjusted to \$0.75 from the original \$0.95. The Series K convertible debt and warrants were revalued with the new conversion price and were adjusted to their new fair value.

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On August 18, 2008, the Company sold 1,383,389 shares of common stock and 2,075,084 warrants in a private financing for \$1,037,542. The shares were sold at \$0.75, a significant premium over the closing price of the Company's common stock. The warrants were valued at \$891,336 and recorded as a debit and a credit to additional paid-in capital. Each warrant entitles the holder to purchase one share of the Company's common stock at a price of \$0.75 per share at any time prior to August 18, 2014. The shares have no registration rights.

On February 26, 2008, the Company issued a total of 258,000 shares of restricted common stock to two consultants at \$0.53 per share for a total cost of \$136,740 of which \$70,312 had been expensed at September 30, 2008. This stock was expensed over the period of the contracts with the consultants. In April 2008, an additional 258,000 shares of restricted common stock to two consultants were issued at \$0.69 for a total cost of \$178,020, of which \$86,984 had been expensed at September 30, 2008. The value of the stock was expensed over the remaining period of the contracts with the consultants.

During the fourth quarter of fiscal year 2008, an additional 1,173,000 shares were issued to consultants at prices ranging from \$0.55 to \$0.578. The total cost of \$649,994 was expensed to general and administrative expense. At September 30, 2008, \$111,452 had been expensed to general and administrative expense.

During the year ended September 30, 2009, the Company issued 3,316,438 shares of common stock in payment of invoices totaling \$1,561,343. Common stock was also issued to pay interest and principal on the convertible debt. See Note 2. In addition, the balance of the shares issued to the Company's president in September 2008 were expensed at a cost of \$200,000. An additional 1,030,928 shares were issued to the president in March 2009 at a cost of \$200,000. An additional 12,672 shares were issued to an employee for expenses. The shares were expensed at a cost of \$3,168.

In November 2008, the Company extended its licensing agreement for Multikine with Orient Europharma. The new agreement extends the Multikine collaboration to also cover South Korea, the Philippines, Australia and New Zealand. The licensing agreement initially focuses on the areas of head and neck cancer, nasopharyngeal cancer and potentially cervical cancer. The agreement expires 15 years after the commencement date which is defined as the date of the first commercial sale of Multikine in any country within the territory. In

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connection with the agreement, Orient Europharma purchased 1,282,051 shares of common stock at a cost of \$0.39 per share, for a total to the Company, after expenses, of \$499,982.

On December 30, 2008, the Company entered into an Equity Line of Credit agreement as a source of funding for the Company. For a two-year period, the agreement allows the Company, at its discretion, to sell up to \$5 million of the Company's common stock at the volume weighted average price of the day minus 9%. The Company may request a drawdown once every ten trading days, although the Company is under no obligation to request any draw-downs under the equity line of credit. The equity line of credit expires on January 6, 2011. There were no draw-downs during the years ended September 30, 2010 or 2009.

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On March 6, 2009, the Company entered into a licensing agreement with Byron Biopharma LLC ("Byron") under which the Company granted Byron an exclusive license to market and distribute the Company's cancer drug Multikine in the Republic of South Africa. The Company has existing licensing agreements for Multikine with Teva Pharmaceuticals and Orient Europharma. Pursuant to the agreement, Byron will be responsible for registering the product in South Africa. Once Multikine has been approved for sale, the Company will be responsible for manufacturing the product, while Byron will be responsible for sales in South Africa. Revenues will be divided equally between the Company and Byron. To maintain the license Byron, among other requirements, must make milestone payments to the Company totaling \$125,000 on or before March 15, 2010. This payment was received in March 2010. On March 30, 2009, and as further consideration for its rights under the licensing agreement, Byron purchased 3,750,000 Units from the Company at a price of \$0.20 per Unit. Each Unit consisted of one share of the Company's common stock and two warrants. Each warrant entitles the holder to purchase one share of the Company's common stock at a price of \$0.25 per share. The warrants are exercisable at any time prior to March 6, 2016. The shares of common stock included as a component of the Units were registered by the Company under the Securities Act of 1933. The Units were accounted for as an equity transaction using the Black Scholes method to value the warrants. The fair value of the warrants was calculated to be \$1,015,771 and was recorded as both a debit and a credit to additional paid-in capital.

In late June and early July of 2009, the Company raised \$6,139,739, less associated costs of \$296,576. The Company issued 15,349,346 shares at \$0.40 per share to the investors. The Company also issued 10,284,060 warrants, exercisable at \$0.50 per share to the investors at a fair value of \$2,775,021 and this cost is shown on the balance sheet as a derivative liability. As of September 30, 2009, the fair value of the warrants was \$15,223,759. During the year ended September 30, 2010, 8,813,088 warrants were exercised. As of September 30, 2010, the fair value of the 1,470,972 remaining warrants was \$676,647.

As a result of the June 2009 financing, the conversion price of the Series K notes and the exercise price of the Series K warrants were reduced to \$0.40 per share because the shares sold by the Company were below the conversion price of the notes and the exercise price of the warrants. Also in conjunction with the June 2009 financing, the exercise price of warrants issued in a prior financing was reset to \$0.40 per share, resulting in the issuance of an additional 1,166,667 shares of common stock. The issuance of these shares was accounted for as a dividend of \$466,667 for the year ended September 30, 2009.

On July 27, 2009, 215,000 shares were issued to employees at \$0.39. These

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shares will vest at specified milestones; 20% of them had vested by September 30, 2009. During the year ended September 30, 2009, \$16,770 of the cost was expensed. There was no additional vesting for these shares for the year ended September 30, 2010. In addition, on August 5, 2009, 65,785 shares were issued at \$0.38 to the Board of Directors. The cost of \$24,998 was expensed during the year ended September 30, 2009.

In late August of 2009, the Company raised an additional \$4,852,995, less associated costs of \$248,037. The Company issued 10,784,435 shares at \$0.45 per share to the investors. The Company also issued 5,392,217 warrants at \$0.55 per share to the investors at a fair value of \$1,704,340 and this cost

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is shown on the balance sheet as a derivative liability on September 30, 2009. As of September 30, 2009, the fair value of these warrants was \$8,088,328. On September 30, 2010, these warrants are shown as a derivative liability of \$2,480,420. No warrants were exercised during the year ended September 30, 2010.

In September of 2009, the Company raised an additional \$20,000,000, less associated costs of \$1,423,743. The Company issued 14,285,715 shares at \$1.40 per share to the investors. The Company also issued 4,714,284 warrants, exercisable at \$1.50 per share to the investors at a fair value of \$3,488,570. The Company also issued 714,286 warrants, exercisable at \$1.75 per share to the placement agent at a fair value of \$642,857. The cost of the warrants is shown on the balance sheet as a derivative liability. As of September 30, 2009, the fair value of these warrants was \$5,694,285. As of September 30, 2010, the fair value of these warrants is shown as a derivative liability of \$660,000. No warrants were exercised during the year ended September 30, 2010.

During the year ended September 30, 2010, there were an additional 2,011,174 warrants and options exercised for 2,011,174 shares of common stock at prices ranging from \$0.56 to \$0.75. The Company received a total of \$1,413,307 from the exercise of warrants and options during the year ended September 30, 2010.

During the year ended September 30, 2009, 3,316,438 shares of common stock were issued in payment of invoices totaling \$1,561,343. During the year ended September 30, 2010, 465,158 shares of common stock were issued in payment of invoices totaling \$1,241,026.

In accordance with Codification 815-40-15-7, derivative liabilities must be revalued at the end of each interim period and at the end of the fiscal year, as long as they remain outstanding. Series A through E warrants that do not qualify for equity accounting must be accounted for as a derivative liability since the warrant agreements provide the holders with the right, at their option, to require the Company to a cash settlement of the warrant at Black-Scholes value in the event of a Fundamental Transaction, as defined in the warrant agreements. Since the occurrence of a Fundamental Transaction is not entirely within the Company's control, there exist circumstances that would require net-cash settlement of the warrants while holders of shares would not receive a cash settlement. As of September 30, 2009, the fair value of these derivative liabilities was \$29,741,372. As of September 30, 2010, and after the exercise of warrants discussed above, the fair value of these derivative liabilities was \$4,037,067.

During the fiscal year ended September 30, 2010, 8,813,088 of Series A warrants were exercised, resulting on a gain on derivative instruments of

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\$8,433,451. When the warrants were exercised, the value of these warrants was converted from derivative liabilities to equity, and the Series A warrants transferred to equity totaled \$4,276,972.

On October 1, 2009, the Company reviewed all outstanding warrants in accordance with the requirements of Codification 815-40, "Determining Whether an Instrument (or Embedded Feature) is Indexed to an Entity's Own Stock". This topic provides that an entity should use a two-step approach to evaluate

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whether an equity-linked financial instrument (or embedded feature) is indexed to its own stock, including evaluating the instrument's contingent exercise and settlement provisions. Two warrant agreements provide for adjustments to the purchase price for certain dilutive events, which includes an adjustment to the warrant exercise price in the event that the Company makes certain equity offerings in the future at a price lower than the exercise price of the warrants. Under the provisions of Codification 815-40, the warrants are not considered indexed to the Company's stock because future equity offerings or sales of the Company's stock are not an input to the fair value of a "fixed-for-fixed" option on equity shares, and equity classification is therefore precluded. Accordingly, effective October 1, 2009, 3,890,782 warrants issued in August 2008 were determined to be subject to the requirements of this topic and were valued using the Black-Scholes formula as of October 1, 2009 at \$6,186,343. Effective October 1, 2009, the warrants are recognized as a liability in the Company's condensed consolidated balance sheet at fair value with a corresponding adjustment to accumulated deficit and will be marked-to-market each reporting period during which they are exercisable. The warrants were revalued on September 30, 2010, at \$1,906,482. The assumptions used in the fair value calculation for the warrants as of October 1, 2009 and September 30, 2010 are as follows:

	October 1, 2009	September 30, 2010
	-----	-----
Expected stock price volatility	95%	100%
Risk-free interest rate	2.151%	0.919%
Expected life of warrant	4.88 years	3.88 years

On March 12, 2010, the Company temporarily reduced the exercise price of the Series M warrants, originally issued on April 18, 2007. The exercise price was reduced from \$2.00 to \$0.75. At any time prior to June 16, 2010, investors could have exercised the Series M warrants at a price of \$0.75 per share. For every two Series M warrants exercised prior to June 16, 2010, the investor would have received one Series F warrant. Each Series F warrant would have allowed the holder to purchase one share of the Company's common stock at a price of \$2.50 per share at any time on or before June 15, 2014. After June 15, 2010 the exercise price of the Series M warrants reverted back to the \$2.00 per share. Any person exercising a Series M warrant after June 15, 2010 would not receive any Series F warrants. The Series M warrants expire on April 17, 2012. An analysis of the modification to the warrants determined that the modification increased the value of the warrants by \$1,432,456. The adjustment was recorded as a debit and a credit to additional paid-in capital. There were no exercises of the Series M warrants at the reduced price and the exercise price of the Series M warrants reverted back to \$2.00 on June 16, 2010.

On August 3, 2010, the Company's Board of Directors approved an amendment to the terms of the Series M warrants held by an investor. The investor is the owner of 8,800,000 warrants priced at \$2.00 per share. The investor may now purchase 6,000,000 shares of the Company's common stock (reduced from



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8,800,000) at a price of \$0.60 per share. In approving the amendment, the Company's Directors determined that reducing the number of outstanding warrants would be beneficial. An analysis of the modification to the warrants determined that the modification increased the value of the warrants by \$100,000. The adjustment was recorded as a debit and a credit to additional paid-in capital. As of September 30, 2010, all of these warrants remained outstanding.

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### 11. FAIR VALUE MEASUREMENTS

Effective October 1, 2008, the Company adopted the provisions of Codification 820-10, "Fair Value Measurements", which defines fair value, establishes a framework for measuring fair value and expands disclosures about such measurements that are permitted or required under other accounting pronouncements. While topic 820-10 may change the method of calculating fair value, it does not require any new fair value measurements. The adoption of Codification 820-10 did not have a material impact on the Company's results of operations, financial position or cash flows.

In accordance with the topic, the Company determines fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The Company generally applies the income approach to determine fair value. This method uses valuation techniques to convert future amounts to a single present amount. The measurement is based on the value indicated by current market expectations about those future amounts.

Codification 820-10 establishes a fair value hierarchy that prioritizes the inputs used to measure fair value. The hierarchy gives the highest priority to active markets for identical assets and liabilities (Level 1 measurement) and the lowest priority to unobservable inputs (Level 3 measurement). The Company classifies fair value balances based on the observability of those inputs. The three levels of the fair value hierarchy are as follows:

- o Level 1 - Observable inputs such as quoted prices in active markets for identical assets or liabilities.
- o Level 2 - Inputs other than quoted prices that are observable for the asset or liability, either directly or indirectly. These include quoted prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active and amounts derived from valuation models where all significant inputs are observable in active markets.
- o Level 3 - Unobservable inputs that reflect management's assumptions.

For disclosure purposes, assets and liabilities are classified in their entirety in the fair value hierarchy level based on the lowest level of input that is significant to the overall fair value measurement. The Company's assessment of the significance of a particular input to the fair value measurement requires judgment and may affect the placement within the fair value hierarchy levels.

The table below sets forth the assets and liabilities measured at fair value on a recurring basis, by input level, in the condensed consolidated balance sheet at September 30, 2010:

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	Quoted Prices in Active Markets for Identical Assets or Liabilities (Level 1) -----	Significant Other Observable Inputs (Level 2) -----	Significant Unobservable Inputs (Level 3) -----	To
Derivative Instruments	\$ - =====	\$ - =====	\$ 6,946,051 =====	\$6,94 =====

The table below sets forth the assets and liabilities measured at fair value on a recurring basis, by input level, in the condensed consolidated balance sheet at September 30, 2009:

	Quoted Prices in Active Markets for Identical Assets or Liabilities (Level 1) -----	Significant Other Observable Inputs (Level 2) -----	Significant Unobservable Inputs (Level 3) -----	To
Derivative Instruments	\$ - =====	\$ - =====	\$35,113,970 =====	\$35, =====

The following sets forth the reconciliation of beginning and ending balances related to fair value measurements using significant unobservable inputs (Level 3), as of September 30, 2010 and 2009:

	2010 ----	2009 ----
Beginning balance	\$35,113,970	\$3,018,697
Transfers in	6,186,343	8,877,217
Transfers out	(5,510,490)	(5,273,594)
Realized and unrealized gains/losses recorded in Earnings	(28,843,772)	28,491,650
Ending balance	\$ 6,946,051 =====	\$35,113,970 =====

The fair values of the Company's derivative instruments disclosed above are primarily derived from valuation models where significant inputs such as historical price and volatility of the Company's stock as well as U.S. Treasury Bill rates are observable in active markets.

12. NET INCOME (LOSS) PER COMMON SHARE

Basic earnings per share (EPS) excludes dilution and is computed by dividing net income by the weighted average of common shares outstanding for the period. Diluted EPS reflects the potential dilution that could occur if securities or other common stock equivalents (convertible preferred stock, convertible debt, warrants to purchase common stock and common stock options) were exercised or converted into common stock. The following table provides a reconciliation of the numerators and denominators of the basic and diluted per-share computations:

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	2010 ----	2009 ----	2008 ----
Net income (loss) - available to common shareholders-basic	\$ 8,950,973	\$ (41,400,758)	\$ (8,128,230)
Add: Conversion of note payable	162,326	-	-
Less: Conversion of derivative instruments	(20,130,098)	-	-
	-----	-----	-----
Net income (loss) - diluted	\$ (11,016,799)	\$ (31,830,304)	\$ (8,128,230)
Weighted average number of shares - basic	202,102,859	133,535,050	117,060,866
Incremental shares from:			
Potentially dilutive shares	21,414,912	-	-
Conversion of note payable	2,760,142	-	-
	-----	-----	-----
Weighted average number of shares - diluted	226,277,913	133,535,050	117,060,866
	=====	=====	=====
Earnings per share - basic	\$ 0.04	\$ (0.31)	\$ (0.07)
	=====	=====	=====
Earnings per share - diluted	\$ (0.05)	\$ (0.31)	\$ (0.07)
	=====	=====	=====

Included in the above computations of weighted-average shares for diluted net loss per share were options and warrants to purchase 21,414,912 shares of common stock as of September 30, 2010. Excluded from the above computations of weighted-average shares for diluted net loss per share were options and warrants to purchase 23,384,797, and 14,488,124 shares of common stock as of September 30, 2009 and 2008, respectively. These securities were excluded because their inclusion would have an anti-dilutive effect on net loss per share.

13. SEGMENT REPORTING

Codification 280-10, "Disclosure about Segments of an Enterprise and Related Information" establishes standards for reporting information regarding operating segments in annual financial statements and requires selected information for those segments to be presented in interim financial reports issued to stockholders. This topic also establishes standards for related disclosures about products and services and geographic areas. Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker, or decision-making group, in making decisions how to allocate resources and assess performance. The Company's chief decision maker, as defined under this topic, is the Chief Executive Officer. To date, the Company has viewed its operations as principally one segment, the research and development of certain drugs and vaccines. As a result, the financial information disclosed herein materially represents all of the financial information related to the Company's principal operating segment.

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14. QUARTERLY INFORMATION (UNAUDITED)

The following quarterly data are derived from the Company's consolidated statements of operations.

Financial Data

Fiscal 2010

	Three months ended December 31, 2009	Three months ended March 31, 2010	Three months ended June 30, 2010	Three months ended September 30, 2010	Year Ended September 2010
Revenue	\$ 30,000	\$ 30,600	\$ 30,900	\$ 61,800	\$ 153,000
Operating expenses	4,282,849	5,350,958	3,424,959	5,654,787	18,713,553
Non operating expenses (income)	(72,099)	(56,167)	(38,423)	(33,221)	(199,910)
Gain/loss on derivative instruments	23,340,267	4,519,672	2,754,512	(1,770,679)	28,843,772
Modification of warrants	-	(1,432,456)	-	(100,000)	(1,532,456)
Net loss available to common shareholders	\$19,159,517	\$ (2,176,975)	\$ (601,124)	\$ (7,430,445)	\$ 8,950,007
Net loss per share-basic	\$ 0.10	\$ (0.01)	\$ 0.00	\$ (0.04)	\$ 0.00
Weighted average shares-basic	194,959,814	204,173,750	204,592,051	204,757,898	202,102,000
Net loss per share-diluted	\$ 0.02	\$ (0.03)	\$ (0.01)	\$ (0.04)	\$ (0.01)
Weighted average shares-diluted	256,198,162	258,251,010	231,827,525	228,932,952	226,277,000

Fiscal 2009

	Three months ended December 31, 2008	Three months ended March 31, 2009	Three months ended June 30, 2009	Three months ended September 30, 2009	Year Ended September 2009
Revenue	\$ -	\$ 19,643	\$ 30,450	\$ 30,000	\$ 80,093
Operating expenses	2,551,823	2,384,760	3,243,576	3,920,391	12,100,550
Non operating expenses (income)	(13,379)	16,717	376,445	18,140	397,933

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Gain/loss on derivative instruments	391,689	264,554	(2,649,493)	(26,498,400)	(28,491,
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Net loss	(2,173,513)	(2,117,280)	(6,239,064)	(30,380,173)	(40,910,
Modification of warrants	-	-	(466,667)	(24,061)	(490,
	-----	-----	-----	-----	-----
Net loss available to common shareholders	(2,173,513)	(2,117,280)	\$ (6,705,731)	\$ (30,404,234)	\$ (41,400,
	=====	=====	=====	=====	=====
Net loss per share-basic	\$ (0.02)	\$ (0.02)	\$ (0.05)	\$ (0.19)	\$ (0
	=====	=====	=====	=====	=====
Net loss per share-diluted	\$ (0.02)	\$ (0.02)	\$ (0.05)	\$ (0.19)	\$ (0
	=====	=====	=====	=====	=====
Weighted average shares-basic and diluted	122,215,334	124,701,667	130,076,656	156,916,920	133,535,

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The Company has experienced large swings in its quarterly gains and losses in 2010 and 2009. These swings are caused by the changes in the fair value of the convertible debt each quarter. These changes in the fair value of the debt are recorded on the consolidated statements of operations. In addition, the cost of options granted to consultants has affected the quarterly losses recorded by the Company.

15. SUBSEQUENT EVENTS

In accordance with Codification 855-50, "Subsequent Events", the Company has reviewed subsequent events through the date of the filing. The Company received a \$733,437 grant under The Patient Protection and Affordable Care Act of 2010 (PPACA). The grant was related to three of the Company's projects, including the Phase III trial of Multikine. The PPACA provides small and mid-sized biotech, pharmaceutical and medical device companies with up to a 50% tax credit for investments in qualified therapeutic discoveries for tax years 2009 and 2010, or a grant for the same amount tax-free. The tax credit/grant program covers research and development costs from 2009 and 2010 for all qualified "therapeutic discovery projects."

On December 10, 2010, the Company entered into a sales agreement with McNicoll Lewis & Vlak LLC (MLV) relating to shares of common stock which have been registered by means of a shelf registration statement filed in July 2009. The Company may offer and sell shares of its common stock, having an aggregate offering price of up to \$30 million, from time to time through MLV acting as agent and/or principal.

Sales of the Company's common stock, if any, may be made in sales deemed to be "at-the-market" equity offerings as defined in Rule 415 promulgated under the Securities Act of 1933, as amended, including sales made directly on or through the NYSE Amex, the existing trading market for the Company's common stock, sales made to or through a market maker other than on an exchange or otherwise, in negotiated transactions at market prices prevailing at the time of sale or at prices related to such prevailing market prices, and/or any other method permitted by law. MLV will act as sales agent on a best efforts basis. The Company is not required to sell any shares to McNicoll Lewis & Vlak and McNicoll Lewis & Vlak is not required to sell any shares on the

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Company's behalf or purchase any of its shares for its own account.

McNicoll Lewis & Vlak will be entitled to a commission in an amount equal to the greater of 3% of the gross proceeds from each sale of the shares, or \$0.025 for each share sold, provided, that, in no event will McNicoll Lewis & Vlak receive a commission greater than 8.0% of the gross proceeds from the sale of the shares. In connection with the sale of the common stock on behalf of the Company, McNicoll Lewis & Vlak may be deemed to be an "underwriter" within the meaning of the Securities Act of 1933, as amended, and the compensation of McNicoll Lewis & Vlak may be deemed to be underwriting commissions or discounts.

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### SIGNATURES

In accordance with Section 13 or 15(a) of the Exchange Act, the Registrant has caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized on the 10th day of December 2010.

CEL-SCI CORPORATION

By: /s/ Maximilian de Clara

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Maximilian de Clara, President

Pursuant to the requirements of the Securities Act of 1934, this Report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Maximilian de Clara ----- Maximilian de Clara	Director	December 10, 2010
/s/ Geert R. Kersten ----- Geert R. Kersten	Chief Executive, Principal Accounting, Principal Financial Officer and a Director	December 10, 2010
/s/ Alexander G. Esterhazy ----- Alexander G. Esterhazy	Director	December 10, 2010
/s/ C, Richard Kinsolving ----- Dr. C. Richard Kinsolving	Director	December 10, 2010
/s/ Peter R. Young ----- Dr. Peter R. Young	Director	December 10, 2010

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EXHIBITS