CEL SCI CORP
Form S-1
August 30, 2006

As filed with the Securities and Exchange Commission on August __, 2006.

Registration No. 333-_____

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM S-1

Registration Statement
Under
THE SECURITIES ACT OF 1933

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

Colorado
(State or other jurisdiction of incorporation)

84-0916344	8229 Boone Blvd. #802 Vienna, Virginia 22182 (703) 506-9460
(IRS Employer I.D. number)	(Address, including zip code, and telephone Number) including area of principal executive offices)

Geert Kersten
8229 Boone Blvd. #802
Vienna, Virginia 22182
(703) 506-9460
(Name and address, including zip code, and telephone number, including area code, of agent for service)

Copies of all communications, including all communications sent to the agent for service, should be sent to:

William T. Hart, Esq.
Hart & Trinen
1624 Washington Street
Denver, Colorado 80203
(303) 839-0061

APPROXIMATE DATE OF COMMENCEMENT OF PROPOSED SALE TO THE PUBLIC:
As soon as practicable after the effective date of this Registration Statement

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box. [ ]

If any of the securities being registered on this Form are to be offered on a

delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box. [X]

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration for the same offering. [ ]

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. [ ]

If delivery of the prospectus is expected to be made pursuant to Rule 434, please check the following box. [ ]

CALCULATION OF REGISTRATION FEE

Title of each Class of Securities to be Registered	Securities to be Registered	Proposed Maximum Offering Price Per Share (3)	Proposed Maximum Aggregate Offering Price	Amount of Registration Fee
Common stock (1)	14,862,790	$0.61	$9,066,302	$ 970.09
Common stock (2)	11,351,162	$0.61	$6,924,209	$ 740.89
Total	26,213,952		$15,990,510	$1,710.98

(1) Represents shares to be sold by selling shareholders.
(2) Represents shares issuable to the selling shareholders as payment of interest or principal on the Series K Convertible Notes.
(3) Offering price computed in accordance with Rule 457(c).

Pursuant to Rule 416, this Registration Statement includes such indeterminate number of additional securities as may be required for issuance upon the exercise of the warrants as a result of any adjustment in the number of securities issuable by reason of stock splits or similar capital reorganizations.

The registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

PROSPECTUS

CEL-SCI CORPORATION

Common Stock

By means of this prospectus fifteen shareholders of CEL-SCI Corporation are offering to sell approximately 15,000,000 shares of CEL-SCI's common stock, which shares may be issued upon the conversion of Series K notes sold by CEL-SCI as well as shares of common stock issuable upon the exercise of CEL-SCI's Series K warrants. The actual number of shares issuable upon the conversion of the Series K promissory notes or upon the exercise of the Series K warrants may increase as the result of future sales of CEL-SCI's common stock at prices below either the note conversion price or warrant exercise price, as the case may be, or the market price of CEL-SCI's common stock. See "Description of Securities" for information concerning the terms of the Series K notes and the Series K warrants. The selling shareholders may be considered "underwriters" as that term is defined in the Securities Act of 1933.

By means of this prospectus CEL-SCI may also issue shares of its common stock to the holders of the Series K notes as payment of interest or principal. The actual number of shares which may be issued as payment of interest or principal may increase if the price of CEL-SCI's common stock is below the then applicable conversion price of the Series K notes.

CEL-SCI's common stock is quoted on the American Stock Exchange under the symbol "CVM." On August 25, 2006 the closing price for one share of the CEL-SCI's common stock was $0.61.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a criminal offense.

These securities are speculative and involve a high degree of risk. For a description of certain important factors that should be considered by prospective investors, see "Risk Factors" beginning on page 5 of this Prospectus

The date of this prospectus is August __, 2006

PROSPECTUS SUMMARY

THIS SUMMARY IS QUALIFIED BY THE MORE DETAILED INFORMATION APPEARING ELSEWHERE IN THIS PROSPECTUS.

CEL-SCI

CEL-SCI is involved in the research and development of drugs for cancer and infectious diseases. CEL-SCI's lead product Multikine(R) is being developed as a cancer drug. In 2005 the Canadian regulatory agency, the Biologics and Genetic Therapies Directorate (B&GTD), concurred with the initiation of a global

Phase III clinical trial in head and neck cancer patients using Multikine. The formal "no objection" letter from the B&GTD to the Clinical Trial Application (CTA) enables CEL-SCI to initiate the Canadian arm of the Phase III Multikine trial.

About 500 patients will be enrolled worldwide in the Phase III trial. The protocol is designed to develop conclusive evidence of the efficacy of Multikine in the treatment of advanced primary squamous 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 enhance the local/regional control of the disease, reduce the rate of disease progression and extend the time of progression free survival in patients with advanced oral squamous cell carcinoma.

Head and neck cancer is an aggressive cancer that affects about 500,000 people per annum worldwide.

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 treatment of cancer.

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 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.

(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.

In May 2006 CEL-SCI the presented long-term survival data from its Phase II clinical trial in patients with head and neck cancer (oral squamous cell carcinoma -- OSCC) treated with its anti-cancer drug Multikine(R). The addition of Multikine as first-line treatment prior to the standard of care treatment resulted in a 33-40% improvement in the median survival at 3 1/2 years post-surgery, when compared to the results of 39 OSCC clinical trials published in the scientific literature between 1987 and 2004. The data were presented at the "Vaccine Discovery and Commercialization" conference in Philadelphia, PA.

The long-term survival data were collected by the treating physicians in a follow-up study of 22 patients with advanced untreated primary tumors, who were enrolled in the Multikine Phase II clinical trial. The Multikine treatment regimen was administered to these patients prior to the standard of care treatment (i.e., surgery + radiation or surgery + chemo-radiation). Informed consent was obtained from all patients in the clinical trial and from 19 patients for the long-term follow-up study. Investigational Review Board / Ethics Committee approval was provided before the initiation of the clinical trial and again for the data collection in the follow-up study. The follow-up study questionnaire assessed the overall survival and the local regional control of the Multikine treated patients in this Phase II trial.

Documented data were available for 19 of the 22 patients in the follow-up portion of this clinical trial. Of the three patients who could not be evaluated in the follow-up study, one patient was known to be alive, but failed to give informed consent, and the other two were lost to follow-up. One patient died the day after definitive surgery, unrelated to Multikine therapy.

The median overall survival (calculated by including death from any cause of patients in the trial, even deaths not related to the disease) of the 19 evaluable patients in the follow-up portion of this clinical trial was 63% at a median follow-up of 40 months post-surgery. The results of the published scientific literature (39 OSCC clinical trials published between 1987 and 2004) document that survival at 3 1/2 years is approximately 47% following standard of care treatment. The addition of Multikine to the standard of care treatment resulted in a 33% increase in overall survival over the results published in the literature.

The median survival of patients in this clinical trial was 67% at a median follow-up of 42 months post-surgery, excluding the one patient with immediate post-operative death. The same 39 scientific publications indicate that survival at 3 1/2 years is approximately 47% following standard of care treatment. The addition of Multikine to the standard of care treatment resulted in an increase in survival of 40% over the results published in the literature.

Multikine first-line treatment also resulted in a 2-year local regional control (LRC) rate of 79%, as compared to the median 2-year LRC of 73% reported in the same 39 scientific publications. Multikine treatment resulted in an improvement over the published local regional control rate. It is clinically recognized that recurrence of disease in head & neck cancer is associated with a very poor prognosis.

Multikine treatment did not result in any severe adverse events (SAE) in this Phase II clinical trial. No SAEs related to Multikine have been reported in other trials conducted with Multikine either.

The data from CEL-SCI's Multikine Phase II clinical trial are thought to be directly applicable to CEL-SCI's planned global Phase III clinical trial, as the Multikine treatment regimen planned in the Phase III trial is identical to that of the Multikine treatment in the trial reported here. Furthermore, the planned endpoints of the Phase III trial are local regional control, disease-free survival and overall survival, all of which have shown improvement compared to historical controls, following Multikine first-line treatment over the current available treatments for these patients.

CEL-SCI also owns a pre-clinical technology called L.E.A.P.S. (Ligand Epitope Antigen Presentation System). The lead product derived from this technology is the CEL-1000 peptide which has shown protection in animals against herpes, malaria and cancer. With the help of government grants and US Army and US Navy collaborations, CEL-1000 is now being tested against avian flu, viral encephalitis, West Nile Virus, SARS, Vaccinia, Smallpox, herpes, malaria and other agents. If the bio-terrorism tests are successful, CEL-SCI is likely to push CEL-1000 for potential bio-terrorism disease indications to gain accelerated approval.

Before human testing can begin with respect to a drug or biological product, preclinical studies are conducted in laboratory animals to evaluate the potential efficacy and the safety of a product. Human clinical studies generally involve a three-phase process. The initial clinical evaluation, Phase I,

consists of administering the product and testing for safe and tolerable dosage levels. Phase II trials continue the evaluation of safety and determine the appropriate dosage for the product, identify possible side effects and risks in a larger group of subjects, and provide preliminary indications of efficacy. Phase III trials consist of testing for actual clinical efficacy within an expanded group of patients at geographically dispersed test sites.

CEL-SCI has funded the costs associated with the clinical trials relating to CEL-SCI's technologies, research expenditures and CEL-SCI's administrative expenses with the public and private sales of shares of CEL-SCI's common stock and borrowings from third parties, including affiliates of CEL-SCI.

All of CEL-SCI's products are in the development stage. As of June 30, 2006, CEL-SCI was not receiving any revenues from the sale of MULTIKINE or any other products which CEL-SCI was developing.

CEL-SCI does not expect to develop commercial products for several years, if at all. CEL-SCI has had operating losses since its inception, had an accumulated deficit of approximately $(102,621,000) at June 30, 2006 and expects to incur substantial losses for the foreseeable future.

CEL-SCI's executive offices are located at 8229 Boone Blvd., #802, Vienna, Virginia 22182, and its telephone number is (703) 506-9460.

CEL-SCI's common stock is quoted on the American Stock Exchange under the symbol "CVM".

THE OFFERING

By means of this prospectus fifteen shareholders of CEL-SCI Corporation are offering to sell approximately 15,000,000 shares of CEL-SCI's common stock which shares may be issued upon the conversion of Series K promissory notes sold by CEL-SCI as well as shares of common stock issuable upon the exercise of CEL-SCI's Series K warrants. The actual number of shares issuable upon the conversion of the Series K notes or upon the exercise of the Series K warrants may increase as the result of future sales of CEL-SCI's common stock at prices below either the note conversion price or warrant exercise price, as the case may be, or the market price of CEL-SCI's common stock. See "Description of Securities" for information concerning the terms of the Series K notes and the Series K warrants. The selling shareholders may be considered "underwriters" as that term is defined in the Securities Act of 1933.

By means of this prospectus CEL-SCI may also issue shares of its common stock to the holders of the Series K notes as payment of interest and principal.

As of August 15, 2006, CEL-SCI had 81,578,488 outstanding shares of common stock. The number of outstanding shares does not give effect to shares which may be issued upon the conversion of CEL-SCI's Series K notes, as payment of interest or principal on the Series K notes, the exercise of CEL-SCI's Series K warrants or the exercise of other outstanding warrants or options. See "Comparative Share Data".

Use of Proceeds

CEL-SCI will not receive any proceeds from the sale of the shares by the selling shareholders. However, CEL-SCI will receive proceeds upon the exercise of Series K warrants. CEL-SCI expects to use substantially all the net proceeds for general and administrative expenses, research and clinical trials.

Risk Factors

The purchase of the securities offered by this prospectus involves a high degree of risk. Risk factors include the lack of revenues and history of loss, need for additional capital and need for FDA approval. See the "Risk Factors" section of this prospectus for additional Risk Factors.

Forward Looking Statements

This prospectus contains various forward-looking statements that are based on CEL-SCI's beliefs as well as assumptions made by and information currently available to CEL-SCI. When used in this prospectus, the words "believe", "expect", "anticipate", "estimate" and similar expressions are intended to identify forward-looking statements. Such statements may include statements regarding seeking business opportunities, payment of operating expenses, and the like, and are subject to certain risks, uncertainties and assumptions which could cause actual results to differ materially from projections or estimates. Factors which could cause actual results to differ materially are discussed at length under the heading "Risk Factors". Should one or more of the enumerated

risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those anticipated, estimated or projected. Investors should not place undue reliance on forward-looking statements, all of which speak only as of the date made.

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 June 30, 2006 CEL-SCI incurred net losses of approximately $(102,621,000). 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 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. Although CEL-SCI's equity line of credit agreement is expected to be a source of funding, the amounts which CEL-SCI is able to draw from the equity line during each drawdown period are limited and may not satisfy CEL-SCI's capital needs.

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. CEL-SCI is unable to estimate the future costs of clinical trials since CEL-SCI has not yet met with the FDA to discuss the design of future clinical trials; and until the scope of future clinical trials is known, CEL-SCI will not be able to price any trials with clinical trial organizations.

Over the past three years CEL-SCI's research and development expenditures have decreased, due in part to the capital available to CEL-SCI. 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.

To raise additional capital CEL-SCI will most likely 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.

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.

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 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.

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. Although CEL-SCI believes its insurance coverage of $1,000,000 per claim is adequate, the defense or settlement of any product liability claim could adversely affect CEL-SCI even if the defense and settlement costs did not exceed CEL-SCI's insurance coverage.

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, by the FDA in the United States and by comparable agencies in most foreign countries. Before obtaining marketing approval, CEL-SCI's 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 a Phase III program for Multikine. The clinical trials of CEL-SCI's product candidates may not be completed on

schedule, and 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. It is possible that the FDA will require CEL-SCI to conduct additional studies to demonstrate that the Multikine that it plans to use for its Phase III program is the same as the product previously tested in CEL-SCI's phase II studies. Even if CEL-SCI believes the data collected from its clinical trials are sufficient, the FDA has substantial discretion in the approval process and may disagree with CEL-SCI's interpretation of the data. CEL-SCI can make no assurances that the FDA will not require CEL-SCI to conduct more Phase II studies before beginning Phase III trials. 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.

The requirements governing the conduct of clinical trials, manufacturing, and marketing of CEL-SCI's product candidates, including Multikine, outside the United States vary widely 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. 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.

In addition to conducting further clinical studies of Multikine and CEL-SCI's other product candidates, CEL-SCI also must undertake the development

of its manufacturing process and optimize its product formulations.

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.

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

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

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

CEL-SCI and any third-party manufacturers or suppliers must continually adhere to federal regulations setting forth requirements, known as current Good Manufacturing Practices, or cGMPs, and their foreign equivalents, which are enforced by the FDA and other national regulatory bodies through their facilities inspection programs. If CEL-SCI's facilities, or the facilities of its manufacturers or suppliers, cannot pass a pre-approval plant inspection, the FDA will not approve the marketing application of CEL-SCI's product candidates. In complying with cGMP and foreign regulatory requirements, CEL-SCI and any of its potential third-party manufacturers or suppliers will be obligated to expend time, money and effort in production, record-keeping and quality control to ensure that its products meet applicable specifications and other requirements. State regulatory agencies and the regulatory agencies of other countries have similar requirements.

CEL-SCI has an agreement with Cambrex Bio Science, Inc. whereby Cambrex

agreed to provide CEL-SCI with a facility for the periodic manufacturing of Multikine in accordance with the cGMPs established by FDA regulations. This agreement expires on December 31, 2006. If the Cambrex facility were not available for the production of Multikine, CEL-SCI estimates that it would take approximately six to ten months to find or build an alternative manufacturing facility for Multikine. CEL-SCI does not know what cost it would incur to obtain an alternative source of Multikine.

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 criminal prosecution, seizure, injuction, 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 and 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 our 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 cure or treat cancer and have substantial financial, research and development, and marketing resources and are capable of providing significant long-term competition either by establishing in-house research groups or by forming collaborative ventures with other entities. In addition, smaller companies and non-profit institutions are active in research relating to cancer and infectious diseases and are expected to become more active in the future.

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

Certain aspects of CEL-SCI's technologies are covered by U.S. and foreign patents. In addition, CEL-SCI has a number of new patent applications pending. There is no assurance that the applications still pending or which may be filed in the future will result in the issuance of any patents. Furthermore, there is no assurance as to the breadth and degree of protection any issued patents might afford CEL-SCI. Disputes may arise between CEL-SCI and others as to the scope and validity of these or other patents. Any defense of the patents could prove costly and time consuming and there can be no assurance that CEL-SCI will be in a position, or will deem it advisable, to carry on such a defense. 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. CEL-SCI's first Multikine patent expired in 2000. Since CEL-SCI does not know if it will ever be able to sell Multikine on a commercial basis, CEL-SCI cannot predict what effect the expiration of this patent will have on CEL-SCI. Notwithstanding the above, CEL-SCI believes that later issued patents and trade secrets will protect the technology associated with Multikine.

Risks Related to CEL-SCI's Common Stock

Since the market price for CEL-SCI's common stock is volatile, investors in this offering 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 year ended September 30, 2005 CEL-SCI's stock price has ranged from a low of $0.46 per share to a high of $1.08 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 conversion of the Series K notes, the payment of interest or principal on the Series K notes, the exercise of the Series K warrants, or the exercise of other outstanding options and warrants, 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 August 15, 2006 allow the holders to acquire up to approximately 20,300,000 additional shares of its common stock. Until the options and warrants expire, or the convertible notes are paid, or the options or warrants expire, 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 convertible notes, options and warrants may convert or exercise these securities

at a time when CEL-SCI could obtain additional capital on terms more favorable than those provided by the options. 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 the warrants described above, or the perception that such sales could occur, may adversely affect the market price of CEL-SCI's common stock.

COMPARATIVE SHARE DATA

	Number of Shares	Note Reference
Shares outstanding as of August 15, 2006:	81,578,488	
Shares to be sold in this Offering:		
Shares issuable upon conversion of Series K notes	9,651,162	A
Shares issuable upon exercise of Series K warrants	5,211,628	A
Shares issuable as payment of interest on the Series K notes	1,700,000	A
Shares issuable as payment of principal on the Series K notes	9,651,162	A

Other Shares Which May Be Issued:

The following table lists additional shares of CEL-SCI's common stock which may be issued as of August 15, 2006 as the result of the exercise of other outstanding options or warrants issued by CEL-SCI:

	Number of Shares	Note Reference
Shares issuable upon the exercise of warrants held by private investors	5,007,744	B
Shares issuable upon exercise of options granted to CEL-SCI's officers, directors, employees, consultants, and third parties	10,034,795	C

A. On August 4, 2006, CEL-SCI sold Series K convertible notes, plus Series K warrants, to independent private investors for $8,300,000. The notes bear interest annually at the greater of 8% or 6 month LIBOR plus 3% per year. The

Notes are due and payable on August 4, 2011 and are secured by substantially all of CEL-SCI's assets.

At the holder's option the Series K notes are convertible into shares of the Company's common stock at a conversion price of $0.86.

The Series K warrants allow the holders to purchase up to 4,825,581 shares of CEL-SCI's common stock at a price of $0.95 per share at any time between February 4, 2007 and February 4, 2012.

The actual number of shares issuable upon the conversion of the Series K promissory notes or upon the exercise of the Series K warrants may increase as the result of future sales of CEL-SCI's common stock at prices below either the note conversion price or warrant exercise price, as the case may be, or the market price of CEL-SCI's common stock.

At CEL-SCI's election, and under certain conditions, CEL-SCI may use shares of its common stock to make interest or principal payments on the Series K notes. The actual number of shares which may be issued as payment of interest or principal may increase if the price of CEL-SCI's common stock is below the then applicable conversion price of the Series K notes.

To the extent CEL-SCI uses its shares to make principal payments on the notes, the number of shares which may be issued upon the conversion of the notes may be less due to reduction in the outstanding principal balance of the notes.

The actual number of shares which will ultimately be issued upon the payment or conversion of the Series K notes and the exercise of the Series K warrants (if any) will vary depending upon a number of factors, including the price at which CEL-SCI sells any additional shares of its common stock prior to the date the Series K notes are paid or converted or the date the Series K warrants are exercised or expire. See "Description of Securities" for more detailed information concerning the Series K notes and warrants.

B. Between August 2001 and May 2006 CEL-SCI sold shares of its common stock in private transactions.. In some cases, warrants were issued as part of the financings. The names of the warrant holders and the terms of the warrants are shown below:

Warrant Holder	Issue Date	Shares Issuable Upon Exercise of Warrants	Exercise Price	Expiration Date
Lamey Corporation	8/17/2001	272,108	$ 1.75	7/1/2007
Karen Carson	2/15/2005	15,000	$ 0.73	2/15/2015
Lucci Financial Group	10/14/2005	80,000	$ 1.00	10/14/2010
Lucci Financial Group	10/14/2005	80,000	$ 2.00	10/14/2010
Mooring Capital	8/16/2003	23,758	$ 0.77	8/17/2006
Eastern Biotech	5/30/2003	400,000	$ 0.47	5/30/2008
Bristol Capital LLC	9/16/2003	197,863	$ 0.83	9/16/2008
Longview Fund, LP	12/1/2003	70,588	$ 1.32	12/1/2006
Longview International Equity Fund, LP	12/1/2003	70,588	$ 1.32	12/1/2006
Longview Equity Fund, LP	12/1/2003	105,882	$ 1.32	12/1/2006
Capital Ventures				

International	12/1/2003	176,460	$	1.32	12/1/2006
Enable Growth Partners	12/1/2003	35,294	$	1.32	12/1/2006
Robert Schacter	12/1/2003	48,400	$	1.32	12/1/2006
Thomas Griesel	12/1/2003	12,115	$	1.32	12/1/2006
Eric Sloane	12/1/2003	26,000	$	1.32	12/1/2006
Financial West Group	12/1/2003	4,500	$	1.32	12/1/2006

Cher Ami Holdings	12/1/2003	441,176	$	0.56	12/1/2007
Wachovia Capital	5/4/2004	76,642	$	1.37	5/4/2009
Cher Ami Holdings	7/18/2005	375,000	$	0.65	7/18/2009
Jenna Holdings	10/31/2005	271,370	$	0.55	10/24/2010
Cher Ami Holdings	2/9/2006	150,000	$	0.56	2/9/2011
Riviera Ventures Inc.	4/1/2006	375,000	$	0.73	3/31/2007
Lucci Financial Group	4/12/2006	100,000	$	1.50	4/12/2009
Eastern Biotech	4/17/2006	800,000	$	1.25	6/30/08
Cher Ami Holdings	5/18/2006	800,000	$	0.82	5/17/11

C. The options are exercisable at prices ranging from $0.16 to $6.25 per share. CEL-SCI may also grant options to purchase additional shares under its Incentive Stock Option and Non-Qualified Stock Option Plans.

The shares referred to in Note C are being offered for sale by means of separate registration statements which have been filed with the Securities and Exchange Commission.

MARKET FOR CEL-SCI'S COMMON STOCK

As of August 15, 2006 there were approximately 2,500 record holders of CEL-SCI's common stock. CEL-SCI's common stock is traded on 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 American Stock Exchange. The market quotations reflect inter-dealer prices, without retail mark-up, mark-down or commissions and may not necessarily represent actual transactions.

Quarter Ending	High	Low
12/31/03	$1.75	$0.91
3/31/04	$1.45	$0.86
6/30/04	$1.30	$0.67
9/30/04	$0.89	$0.52
12/31/04	$0.67	$0.46
3/31/05	$1.08	$0.62
6/30/05	$0.73	$0.48
9/30/05	$0.60	$0.46
12/31/05	$0.69	$0.45
3/31/06	$1.06	$0.49
6/30/06	$1.74	$0.71

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 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.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATION

The following selected financial data and discussion should be read in conjunction with the Consolidated Financial Statements and Notes thereto appearing elsewhere in this prospectus. As discussed in Note 2 to the consolidated financial statements, CEL-SCI's financial statements have been restated. The accompanying management's discussion and analysis gives effect to that restatement.

	For the years ended September 30,				
Statements of Operations	2005	2004 (1)	2003 (1)	2002 (1)	2001 (1)
Grant revenue and other	$ 269,925	$ 325,479	$ 318,304	$ 384,939	$ 293,871
Other expenses:					
Research and development	2,229,729	1,941,630	1,915,501	4,699,909	7,762,213
Depreciation and amortization	190,420	198,269	199,117	226,514	209,121
General and administrative	1,930,543	2,310,279	2,287,019	1,754,332	3,432,437
Gain (loss) on derivative instruments	363,028	1,174,660	(2,319,005)	5,053,156	55,739
Other income	625,472	-	-	-	-
Other costs of financing	-	-	(270,664)	-	(235,563)
Interest income	52,660	51,817	52,502	85,322	376,221
Interest expense	-	(53,855)	(1,365,675)	(4,517,716)	(7,326,556)

Net loss	(3,039,607)	(2,952,077)	(7,986,175)	(5,675,054)	(18,240,059)
Net loss per common share					
Basic	$ (0.04)	$ (0.04)	$ (0.16)	$ (0.20)	$ (0.84)
Diluted	$ (0.05)	$ (0.06)	$ (0.19)	$ (0.24)	$ (0.84)

Weighted average common shares outstanding					
Basic	72,703,395	67,273,133	50,961,457	28,746,341	21,824,273
Diluted	73,581,925	68,924,099	51,127,439	31,788,281	21,824,273

	Nine Months Ended June 30,	
	2006	2005
REVENUES:		
Grant revenue and other	$ 106,370	$ 223,395
EXPENSES:		
Research and development, excluding depreciation of $55,532 and $49,999 include below	1,290,843	1,824,044
Depreciation and amortization	130,143	149,590
General and administrative	2,353,956	1,537,454
GAIN (LOSS) ON DERIVATIVE INSTRUMENTS	13,130	211,715
INTEREST INCOME	33,203	43,309
NET LOSS	$ (3,622,239)	$ (3,032,669)
NET LOSS PER COMMON SHARE (BASIC)	$ (0.05)	$ (0.04)
NET LOSS PER COMMON SHARE (DILUTED)	$ (0.05)	$ (0.04)
WEIGHTED AVERAGE COMMON SHARES OUTSTANDING (BASIC AND DILUTED)	78,076,239	72,316,654

(1) The results for fiscal years 2001 through 2004 were restated (see Note 2 to the Consolidated Financial Statements).

Balance Sheets:

	September 30,				
	2005	2004 (1)	2003 (1)	2002 (1)	2001 (1)
Working capital (deficit)	$2,238,297	$4,592,332	$ 205,815	$(1,366,925)	$2,758,122
Total assets	3,092,352	5,513,810	2,915,206	3,771,258	4,508,920
Convertible debt (2)	-	-	194,109	1,673,504	-
Note payable - Covance (2)	-	-	184,330	-	-
Note payable -					

Cambrex (2)	-	-	664,910	1,135,017	-
Series E preferred stock (2)	-	-	-	2,001,591	6,692,922
Derivative instruments - current (2)	1,280	-	319,295	4	4,559
Derivative instruments - noncurrent (2)	811,180	1,175,488	2,517,131	314,844	556,348
Total liabilities	987,313	1,391,468	4,694,385	6,115,876	7,806,174
Stockholders' equity (deficit)	2,105,039	4,122,342	(1,779,179)	(2,344,618)	(3,297,254)

	June 30, 2006
Working capital	$1,843,951
Total Assets	2,728,056
Current Liabilities	252,467
Total Liabilities	255,467
Stockholders' Equity	2,472,589

(1) The results for fiscal years 2001 through 2004 were restated (see Note 2 to the Consolidated Financial Statements).
(2) Included in total liabilities.

No dividends have been declared on CEL-SCI's common stock.

CEL-SCI's net losses for each fiscal quarter during the two years ended September 30, 2005 were:

Quarter	Net income (loss)	Net income (loss) per share - Basic	Net income (loss) per share - Diluted
12/31/2003	$ (1,381,433) (1)	$ (0.02) (1)	$(0.02) (1)
3/31/2004	(1,404,976) (1)	(0.02) (1)	(0.02) (1)
6/30/2004	353,647 (1)	0.01 (1)	(0.01) (1)
9/30/2004	(519,315) (1)	(0.01) (1)	(0.01) (1)
12/31/2004	$ (1,229,443) (2)	$ (0.02) (2)	(0.02) (2)
3/31/2005	(1,149,440) (2)	(0.02) (2)	(0.02) (2)
6/30/2005	(653,786) (2)	(0.01) (2)	(0.01) (2)
9/30/2005	(6,938)	--	--

(1) The results for fiscal years 2001 through 2004 were restated (see Note 2 to the Consolidated Financial Statements).
(2) The results for the quarterly periods in fiscal year 2005 have been restated.

OVERVIEW

CEL-SCI's most advanced product, Multikine, manufactured using the Company's proprietary cell culture technologies, is 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 idea of Multikine is to make current cancer treatments 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 (500,000 new cases per annum). Since Multikine is not tumor specific, it may also be applicable in many other solid tumors.

CEL-SCI also owns a pre-clinical technology called L.E.A.P.S. (Ligand Epitope Antigen Presentation System). The lead product derived from this technology is the CEL-1000 peptide which has shown protection in animals against herpes, malaria and cancer. With the help of government grants, NIAID and US

Army and US Navy collaborations, CEL-1000 is now being tested against avian flu, viral encephalitis, West Nile Virus, SARS, Vaccinia, Smallpox, herpes, malaria and other agents. If the bio-terrorism tests are successful, CEL-SCI is likely to push CEL-1000 for potential bio-terrorism disease indications to gain accelerated approval.

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

Nine Months ended June 30, 2006

"Grant revenues and other" decreased by $117,025 during the nine months ended June 30, 2006, compared to the same period of the previous year, due to the winding down of the work funded by the grants in the summer of 2005. CEL-SCI is continuing to apply for grants to support its work. Grant revenues and others remained about the same for the three months ended June 30, 2006 as it was for the three months ended June 30, 2005.

During the nine-month period ended June 30, 2006, research and development expenses decreased by $533,201. During the three-month period ended June 30, 2006, research and development expenses decreased by $108,956. In the previous year, expenses were higher because the Company was doing work in support of the Phase III application for Multikine.

During the three and nine-month periods ended June 30, 2006, general and administrative expenses increased by $428,751 and $816,502, respectively. This change was due to: 1) costs related to the restatement of the financial statements ($185,800 and $318,750, respectively); 2) an increase in public relations and corporate presentation expenses ($239,850 and $408,850, respectively); and 3) the employee stock option expense required by SFAS 123R ($39,100 and $142,700, respectively).

Interest income during the nine months ended June, 2006 decreased by $10,106. The decrease was due to a decline in the balances in the interest bearing accounts. Interest income during the three months ended June 30, 2006 decreased by $1,214 for the same reason.

The gain on derivative instruments of $13,130 for the nine months ended June 30, 2006, compared to a loss of $211,715 for the same period of 2005 was the result of reclassification to equity of all derivative instruments except the Series E warrants on December 27, 2005. The gain on derivative instruments of $1,615 during the three months ended June 30, 2006 compared to a gain of $319,570 for the same period in 2005 was the result of the reclassification to equity of all derivative instruments except the Series E warrants.

Fiscal 2005

"Grant revenues and other" decreased by $55,554 during the year ended September 30, 2005, compared to 2004. This was due to the winding down of the work funded by the grants in 2005. CEL-SCI is continuing to apply for grants to support its work.

During the year ended September 30, 2005, research and development expenses increased by $288,099. The increase in research and development expense was due largely to an increase in work related to CEL-SCI's Phase III application for Multikine.

During the year ended September 30, 2005, general and administrative expenses decreased by $379,736. The decrease was mostly due to a decrease in public relations and corporate presentation expenses, filing fees, travel expenses, accounting fees and legal fees, as CEL-SCI's efforts were primarily focused on the submission of the Phase III clinical trial application for Multikine.

CEL-SCI received $625,472 in settlement of a lawsuit in which CEL-SCI was not a party. The litigation involved a shareholder and three former investors in CEL-SCI. The lawsuit sought to recover short-swing profits allegedly obtained by the defendants, their investment advisor and the investment advisor's principal acting together as a group in trading CEL-SCI securities.

Interest income during the year ended September 30, 2005 increased by $843 as a result of higher balances in interest bearing accounts during the year. Interest expense decreased to zero as a result of the conversion of the remaining convertible debt in October 2003. Interest expense for the year ended September 30, 2004 is primarily for interest related to the convertible debt payable to Cambrex Biosciences, Inc. and Covance AG.

Gain on derivative instruments for the year ended September 30, 2005 decreased by $811,632 due to a decrease in the number of derivative instruments outstanding during the year as a result of expiration of certain agreements or reclassifications of certain instruments to equity.

Fiscal 2004

Grant revenue and other during fiscal year 2004 remained at approximately the same level as fiscal year 2003 as work continued on the four grants received during the fiscal year 2003. Interest income also remained approximately at the same level.

Research and development expense increased by approximately $26,000 as CEL-SCI's research and development costs on L.E.A.P.S. increased during fiscal

2004.

General and administrative expenses increased by approximately $23,000 this year. CEL-SCI's cost reduction program continues. This reduction was substantially offset by an increase in audit and audit-related fees and an increase in filing and registration fees.

CEL-SCI recognized a gain of $1,174,660 on derivative instruments during fiscal year 2004 compared to a loss of $2,319,005 for the year ended September 30, 2003. This was due primarily to a decrease in the trading price of CEL-SCI's

common stock which is a significant component of fair value of CEL-SCI's derivative instruments. Also, during fiscal year 2004, several derivative instruments met the criteria for equity classification after which they were no longer marked to market.

Other costs of financing decreased by $270,664 during fiscal year 2004 since CEL-SCI did not enter into an equity line of credit financing arrangement during the year.

Research and Development Expenses

During the five years ended September 30, 2005 CEL-SCI's research and development efforts involved Multikine, L.E.A.P.S. and an AIDS vaccine. The table below shows the research and development expenses associated with each project during this five-year period.

	2005	2004	2003	2002	2001
MULTIKINE	$1,911,615	$1,539,454	$1,653,904	$4,405,678	$7,365,305
L.E.A.P.S.	318,114	402,176	261,597	244,769	280,766
AIDS Vaccine	--	--	--	43,462	94,642
Other	--	--	--	6,000	21,500
TOTAL	$2,229,729	$1,941,630	$1,915,501	$4,699,909	$7,762,213

CEL-SCI believes that it has compiled sufficient data and clinical information to justify a Phase III clinical trial which would be designed to prove the clinical benefit from Multikine as an addition to established anti-cancer therapies. In 2005, CEL-SCI submitted a protocol to the FDA and the Canadian regulatory agency, the Biologics and Genetic Therapies Directorate for Phase III clinical trials. CEL-SCI is unable to estimate the future costs of research and clinical trials involving Multikine since CEL-SCI has not yet finalized the protocol with the FDA. Until the scope of these trials is known, CEL-SCI will not be able to price any future trials.

As explained in the section of this prospectus captioned "Business", as of February 28, 2006, CEL-SCI was involved in a number of pre-clinical studies with respect to its L.E.A.P.S. technology. As with Multikine, CEL-SCI does not know what obstacles it will encounter in future pre-clinical and clinical studies involving its L.E.A.P.S. technology. Consequently, CEL-SCI cannot predict with any certainty the funds required for future research and clinical trials and the timing of future research and development projects.

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

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

CEL-SCI discontinued its research efforts relating to the AIDS vaccine due to a lack of government funding in 2000.

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 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 Company-sponsored research and development, 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 fiscal 2003, CEL-SCI reduced its discretionary expenditures. In fiscal 2004 and 2005 expenditures remained at the 2003 levels. If necessary, CEL-SCI may reduce discretionary expenditures in fiscal 2006; however such reductions would further delay the development of CEL-SCI's products.

Multikine has an FDA approved shelf life of two years. Consequently, Multikine can only be used for two years after it is manufactured. Since the last batch of Multikine was manufactured over two years ago, CEL-SCI does not currently have any Multikine available for future clinical studies. As a result, CEL-SCI will be required to manufacture additional quantities of Multikine for future research and clinical studies. CEL-SCI anticipates that the Multikine needed for its planned Phase III clinical trial will be manufactured in several batches over a two to three year period at a cost of between $4 to $5 million. CEL-SCI's last batch of Multikine was used during the fall of 2002.

Series K Notes and Warrants

On August 4, 2006, CEL-SCI sold Series K convertible notes, plus Series K warrants, to independent private investors for $8,300,000. The notes bear

interest annually at the greater of 8% or 6 month LIBOR plus 3% per year. The Notes are due and payable on August 4, 2011 and are secured by substantially all of CEL-SCI's assets.

At the holder's option the Series K notes are convertible into shares of CEL-SCI's common stock at a conversion price of $0.86.

The Series K warrants allow the holders to purchase up to 5,211,628 shares of CEL-SCI's common stock at a price of $0.95 per share at any time between February 4, 2007 and February 4, 2012.

See "Description of Securities" for more detailed information concerning the Series K notes and warrants.

Future Capital Requirements

CEL-SCI plans to use its existing financial resources, and any proceeds received from the exercise of CEL-SCI's outstanding warrants or options to fund its capital requirements during the year ending September 30, 2006.

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, 2005 are as follows:

Contractual Obligations:		Years Ending September 30,		
	Total	2006	2007	2008
Operating Leases	$ 359,921	$156,067	$132,719	71,136
Employment Contracts	1,247,203	702,703	363,000	181,500
	$1,607,124	$858,770	$495,719	$252,636

It should be noted that substantial additional funds will be needed for more extensive clinical trials which will be necessary before CEL-SCI will be able to apply to the FDA for approval to sell any products which may be developed on a commercial basis throughout the United States. 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. It is the opinion of management that sufficient funds will be available from external financing and additional capital and/or expenditure reduction in order to meet CEL-SCI's liabilities and commitments as they come due during fiscal year 2006. Ultimately, CEL-SCI must complete the development of its products, obtain appropriate regulatory approvals and obtain sufficient revenues to support its cost structure.

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. However, certain accounting policies are particularly important to the portrayal of financial position and results of operations and require the application of 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 - In October 1996, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards No. 123, Accounting for Stock-Based Compensation (SFAS No. 123). This statement encouraged but did not require companies to account for employee stock compensation awards based on their estimated fair value at the grant date with the resulting cost charged to operations. CEL-SCI had elected to continue to account for its employee stock-based compensation using the intrinsic value method prescribed in Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees and related Interpretations". In December 2004 the FASB issued SFAS No. 123R, "Share-Based Payment". SFAS No. 123R requires companies to recognize expense associated with share based compensation arrangements, including employee stock options, using a fair value-based option pricing model. SFAS No. 123R 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 reflects compensation expense in the financial statements beginning October 1, 2005. The modified prospective transition method does not require restatement of prior periods to reflect the impact of SFAS No. 123R. As such, compensation expense will be recognized for awards that were granted, modified, repurchased or cancelled on or after October 1, 2005 as well as for the portion of awards previously granted that vested during the period ended June 30, 2006. For the nine months ended June 30, 2006, CEL-SCI recorded $142,690 in general and administrative expense for the cost of employee options. The Company's options vest over a three-year period from the date of grant. After one year, the stock is one-third vested, with an additional one-third vesting after two years and the final one-third vesting at the end of the three-year period. There were no options granted during the nine-month period ended June 30, 2006. Options are granted with an exercise price equal to the closing bid price of the Company's stock on the day before the grant. CEL-SCI determines the fair value of the employee compensation using the Black Scholes method of valuation. No corresponding expense was recorded for the nine months ended June 30, 2005 because the statement did not require the cost to be recorded in that period. Under SFAS 148, "Accounting for Stock-Based Compensation - Transition and Disclosure", which was in effect during the nine months ended June 30, 2005, CEL-SCI's net loss and net loss per common share would have been increased to the pro forma amounts indicated below:

	Nine Months Ended June 30, 2005	Three Months Ended June 30, 2005
Net loss:		
As reported and amended	$ (3,244,384)	$ (973,356)

Add: Total stock-based employee compensation expense determined under fair-value-based method for all awards, net of related tax effects	(419,789)	(144,949)
Pro forma net loss, as amended	$ (3,664,173)	$ (1,118,305)
Net loss per share, as reported and amended	$0.04	$0.01
Pro forma net loss per share	$0.05	$0.02

Options to non-employees are accounted for in accordance with FASB's Emerging Issues Task Force (EITF) Issue 96-18 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 every fiscal quarter. This review requires that CEL-SCI make assumptions regarding the value of these assets and the changes in circumstances that would affect the carrying value of these assets. If such analysis indicates that a possible impairment may exist, CEL-SCI is then required to estimate the fair value of the asset and, as deemed appropriate, expense all or a portion of the asset. The determination of fair value includes numerous uncertainties, such as the impact of competition on future value. CEL-SCI believes that it has made reasonable estimates and judgments in determining whether its long-lived assets have been impaired; however, if there is a material change in the assumptions used in its determination of fair values or if there is a material change in economic conditions or circumstances influencing fair value, CEL-SCI could be required to recognize certain impairment charges in the future. As a result of the reviews, no changes in asset values were required.

Prepaid Expenses and Laboratory Supplies--The majority of prepaid expenses consist 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 prepaid expenses 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. Other 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--The Company enters into financing arrangements that consist of freestanding derivative instruments or are hybrid instruments that contain embedded derivative features. The Company accounts for these arrangement in accordance with Statement of Financial Accounting Standards No. 133, "Accounting for Derivative Instruments and Hedging Activities", ("SFAS No. 133") and Emerging Issues Task Force Issue No. 00-19, "Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock", ("EITF 00-19"), 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 can not 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 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.

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 the years ended September 30, 2005, 2004 and 2003, CEL-SCI recognized a gain of $363,028, a gain of $1,174,660, and a loss of $2,319,005, 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 rate risk on investments is considered immaterial due to the dollar value of investments as of September 30, 2004 and June 30, 2005.)

Recent Accounting Pronouncements

In November 2004 the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards ("SFAS") No. 151, "Inventory Costs, an amendment of Accounting Research Bulletin (ARB) 43, Chapter 4, Inventory Pricing". This statement amends ARB 43, Chapter 4, to clarify accounting for abnormal amounts of idle facility expense, freight, handling costs and wasted material. SFAS No. 151 requires that those items be recognized as current-period charges in all circumstances. SFAS No. 151 is effective for fiscal years

beginning after June 15, 2005. CEL-SCI does not believe that the adoption of SFAS No. 151 will have a material effect on its financial position, results of operations or cash flows.

In December 2004 the FASB issued SFAS No. 123R, "Share-Based Payment". SFAS No. 123R requires companies to recognize expense associated with share based compensation arrangements, including employee stock options, using a fair value-based option pricing model. SFAS No. 123R 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 reflects compensation expense in the financial statements

beginning October 1, 2005. The modified prospective transition method does not require restatement of prior periods to reflect the impact of SFAS No. 123R. As such, compensation expense will be recognized for awards that were granted, modified, repurchased or cancelled on or after October 1, 2005 as well as for the portion of awards previously granted that vested during the period ended June 30, 2006.

On December 16, 2004, the FASB issued SFAS No. 153, "Exchange of Non-monetary Assets", an amendment of Accounting Principles Board ("APB") Opinion No. 29. Statement No. 153 replaces the exception from fair value measurement in APB No. 29, with a general exception from fair value measurement for exchanges of non-monetary assets that do not have commercial substance. The Statement is to be applied prospectively and is effective for non-monetary asset exchanges occurring in fiscal periods beginning after June 15, 2005. CEL-SCI does not believe that SFAS No. 153 will have a material impact on its results of operations or cash flows.

In March 2005, the FASB issued FIN No. 47, "Accounting for Conditional Asset Retirement Obligations - an Interpretation of FASB Statement No. 143". The interpretation clarifies terms used in FASB Statement No. 143 and is effective no later than the end of fiscals ending after December 15, 2005. CEL-SCI does not believe that FIN No. 47 will have a material impact on its results of operations or cash flows.

In May 2005, the FASB issued SFAS No. 154, "Accounting Changes and Error Corrections--A replacement of APB Opinion No. 20 and FASB Statement No. 3". The statement requires that retrospective application of a change in accounting principle be limited to the direct effects of the change and is part of a broader effort by the FASB to improve the comparability of cross-border financial reporting by working with the International Accounting Standards Board (IASB) toward development of a single set of high-quality accounting standards.

In February 2006, the FASB issued SFAS No. 155, "Hybrid Instruments". The statement amends SFAS No. 133 and SFAS No. 140, "Accounting for Transfers and Servicing of Financial Assets and Extinguishments of Liabilities". The statement also resolves issues addressed in Statement 133 Implementation Issue No. D1, "Application of Statement 133 to Beneficial Interests in Securitized Financial Assets." The statement: a) permits fair value remeasurement for any hybrid financial instrument that contains an embedded derivative that otherwise would require bifurcation, b) clarifies which interest-only strips and principal-only strips are not subject to the requirements of SFAS No. 133, c) establishes a requirement to evaluate interests in securitized financial assets to identify interests that are freestanding derivatives or that are hybrid financial instruments that contain an embedded derivative requiring bifurcation, d) clarifies that concentrations of credit risk in the form of subordination are not embedded derivatives, and e) amends Statement 140 to eliminate the

prohibition on a qualifying special purpose entity from holding a derivative financial instrument that pertains to a beneficial interest other than another derivative financial instrument. CEL-SCI does not believe that SFAS No. 155 will have a material impact on its results of operations or cash flows.

In March 2006, FASB issued SFAS No. 156, "Accounting for Servicing of Financial Assets - an amendment of FASB Statement No. 140". The statement requires: 1) an entity to recognize a servicing asset or servicing liability each time it undertakes an obligation to service a financial asset; 2) requires all separately recognized servicing assets and servicing liabilities to be

initially measured at fair value; 3) permits an entity to choose either the amortization method or the fair value measurement method for measuring the asset or liability; 4) permits a one-time reclassification of available-for-sale securities to trading securities; and 5) requires separate presentation of servicing assets and servicing liabilities subsequently measured at fair value in the statement of financial position. Since CEL-SCI has no servicing assets or servicing liabilities, CEL-SCI believes that there will be no impact on its results of operations or cash flows. The statement is effective for fiscal years beginning after September 15, 2006.

BUSINESS

CEL-SCI Corporation was formed as a Colorado corporation in 1983. CEL-SCI's principal office is located at 8229 Boone Boulevard, Suite 802, Vienna, VA 22182. CEL-SCI's telephone number is 703-506-9460 and its web site is 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 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 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 (500,000 new cases per annum). Since Multikine is not tumor specific, it may also be applicable in many other solid tumors.

In August 2005, the Canadian regulatory agency, the Biologics and Genetic Therapies Directorate, concurred with the initiation of a global Phase III clinical trial in head and neck cancer patients using Multikine. The formal "no objection" letter from the Biologics and Genetic Therapies Directorate to the Clinical Trial Application (CTA) enables CEL-SCI to initiate the Canadian arm of the Phase III Multikine trial.

About 500 patients will be enrolled worldwide in the Phase III trial. The protocol is designed to develop conclusive evidence of the efficacy of Multikine in the treatment of advanced primary squamous 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 enhance the local/regional control of the disease, reduce the rate of disease progression

and extend the time of progression-free survival in patients with advanced oral squamous cell carcinoma.

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 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.

(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.

CEL-SCI also owns a pre-clinical technology called L.E.A.P.S.TM (Ligand

Epitope Antigen Presentation System). The lead product derived from this technology is the CEL-1000 peptide which has shown protection in animals against herpes, malaria, viral encephalitis and cancer. With the help of government grants, NIAID and US Army and US Navy collaborations, CEL-1000 is now being

tested against avian flu, viral encephalitis, West Nile Virus, SARS, Vaccinia, Smallpox, herpes, malaria and other agents.

MULTIKINE

Multikine has been tested in 200 patients in clinical trials conducted in the U.S., Canada, Europe and Israel. Most of these patients were head and neck cancer patients, but some studies were also conducted in prostate cancer patients, HIV-infected patients and HIV-infected women with Human Papilloma Virus ("HPV")-induced cervical dysplasia, the precursor stage before the development of cervical cancer. The safety profile was found to be very good and CEL-SCI believes that the clinical data suggests that further studies are warranted.

The function of the immunological system is to protect the body against infectious agents, including viruses, bacteria, parasites and malignant (cancer) cells. An individual's ability to respond to infectious agents and to other substances (antigens) recognized as foreign by the body's immune system is critical to health and survival. When the immune response is adequate, infection is usually combated effectively and recovery follows. Severe infection can occur when the immune response is inadequate. Such immune deficiency can be present from birth but, in adult life, it is frequently acquired as a result of intense sickness or as a result of the administration of chemotherapeutic drugs and/or radiation. It is also recognized that, as people reach middle age and thereafter, the immune system grows weaker.

Two classes of white blood cells, macrophages and lymphocytes, are believed to be primarily responsible for immunity. Macrophages are large cells whose principal immune activity is to digest and destroy infectious agents. Lymphocytes are divided into two sub-classes. One sub-class of lymphocytes, B-cells, produces antibodies in response to antigens. Antibodies have unique combining sites (specificities) that recognize the shape of particular antigens and bind with them. The combination of an antibody with an antigen sets in motion a chain of events which may neutralize the effects of the foreign substance. The other sub-class of lymphocytes, T-cells, regulates immune responses. T-cells, for example, amplify or suppress antibody formation by B-cells, and can also directly destroy "foreign" cells by activating "killer cells."

It is generally recognized that the interplay among T-cells, B-cells and the macrophages determines the strength and breadth of the body's response to infection. It is believed that the activities of T-cells, B-cells and macrophages are controlled, to a large extent, by a specific group of hormones called cytokines. Cytokines regulate and modify the various functions of both T-cells and B-cells. There are many cytokines, each of which is thought to have distinctive chemical and functional properties. IL-2 is but one of these cytokines and it is on IL-2 and its synergy with other cytokines that CEL-SCI has focused its attention. Scientific and medical investigation has established that IL-2 enhances immune responses by causing activated T-cells to proliferate. Without such proliferation no immune response can be mounted. Other cytokines support T-cell and B-cell proliferation. However, IL-2 is the only known cytokine which causes the proliferation of T-cells. IL-2 is also known to

activate B-cells in the absence of B-cell growth factors.

Although IL-2 is one of the best characterized cytokines with anticancer potential, CEL-SCI is of the opinion that to have optimum therapeutic value, IL-2 should be administered not as a single substance but rather as a mixture of IL-2 and certain cytokines, i.e. as a "cocktail". This approach, which was

pioneered by CEL-SCI, makes use of the synergism between these cytokines. It should be noted, however, that neither the Food and Drug Administration (FDA) nor any other agency has determined that CEL-SCI's Multikine product will be effective against any form of cancer.

Research and human clinical trials sponsored by CEL-SCI have indicated a correlation between administration of Multikine to cancer patients and immunological responses. On the basis of these experimental results, CEL-SCI believes that Multikine may have application for the treatment of solid tumors in humans.

Between 1985 and 1988 Multikine was tested at St. Thomas Hospital in London, UK in forty-eight patients with various types of cancers. Multikine was shown to be safe when used by these patients.

In November 1990, the Florida Department of Health and Rehabilitative Services ("DHRS") gave the physicians at a southern Florida medical institution approval to start a clinical cancer trial in Florida using CEL-SCI's Multikine product. The focus of the trial was unresectable head and neck cancer.

In 1991, four patients with regionally advanced squamous cell cancer of the head and neck were treated with CEL-SCI's Multikine product. The patients had previously received radical surgery followed by radiation therapy but developed recurrent tumors at multiple sites in the neck and were diagnosed with terminal cancer.

Significant tumor reduction occurred in three of the four patients as a result of the treatment with Multikine. Negligible side effects, such as injection site soreness and headaches, were observed and the patients were treated as outpatients. Notwithstanding the above, it should be noted that these trials were only preliminary and were only conducted on a small number of patients. It remains to be seen if Multikine will be effective in treating any form of cancer.

These results caused CEL-SCI to embark on a major manufacturing program for Multikine with the goal of being able to produce a drug that would meet the stringent regulatory requirements for advanced human studies. This program included building a pilot scale manufacturing facility.

The objective of CEL-SCI scientists is to use Multikine as an adjunct (additive) therapy to the existing treatment of previously untreated head & neck cancer patients with the goal of reducing cancer recurrence and ultimately increasing survival. However, pursuant to FDA regulations, CEL-SCI was required to test the drug first for safety in locally recurrent, locally metastatic head and neck cancer patients who had failed other cancer therapies. This dose escalation study was started in 1995 at several centers in Canada and the US where 16 patients were enrolled at 4 different dosage levels. The study ended in 1998 and showed Multikine to be safe and well tolerated at all dose levels.

Because CEL-SCI scientists have determined that patients with previously untreated disease would most likely benefit more from Multikine treatment,

CEL-SCI started a safety trial in Canada in 1997 in advanced primary head & neck cancer patients who had just recently been diagnosed with head & neck cancer. This study ultimately enrolled 28 patients, also at 4 different dosage levels,

and ended in late 1999. Halfway through this study, CEL-SCI launched a number of phase II studies in advanced primary head & neck cancer to determine the best dosage, best route of administration and best frequency of administration of Multikine. Those studies involved 19 patients in Israel (1997 - 2000), 30 patients in Poland and the Czech Republic (1999 - 2000), and 94 patients (half treated with Multikine and the other half disease-matched cancer patients served as control) in Hungary (1999 - 2003). The Hungarian trial compared the control group (receiving only conventional cancer therapy) to the Multikine treated patients (receiving Multikine prior to conventional therapy) by histopathology and immunohistochemistry. The results of these studies were published in peer-reviewed scientific journals and/or presented at scientific meetings. The studies that have not yet been published were conducted in support of Multikine's safety and clinical utility.

The above studies, which are all completed, indicate that Multikine was safe and well tolerated at all dose levels investigated. The studies also showed partial and complete tumor responses following Multikine treatment at the best treatment regimen combinations as well as tumor necrosis (destruction) and fibrosis (as determined by histopathology).

While CEL-SCI scientists believe partial and complete tumor responses to be very important, they also believe that other findings with Multikine in these studies are equally important since they may serve to enhance existing cancer therapies, thereby affecting the clinical outcome of the cancer patient's treatment.

The initial results of the Hungarian study were published in December 2003. Data from a Phase I/II clinical trial in fifty-four (54) advanced primary head and neck cancer patients (half treated, half control), the first part of the Hungarian study, were published in The Laryngoscope, December 2003, Vol.113 (12). The title of the article is "The Effect of Leukocyte Interleukin Injection (MULTIKINE) on the Peritumoral and Intratumoral Subpopulation of Mononuclear Cells and on Tumor Epithelia: A Possible New Approach to Augmenting Sensitivity to Radiation Therapy and Chemotherapy in Oral Cancer - A Multi Center Phase I/II Clinical Trial".

The data demonstrates that treatment with Multikine rendered a high proportion of the tumor cell population highly susceptible to radiation therapy. This finding represents a major advance in the treatment of cancer since, under current standard therapy, only about 5%-10% of the cancer cells are thought to be susceptible to radiation therapy at any one point in time.

The increased sensitivity of the Multikine-treated tumors to radiation was derived from a dramatic increase in the number of proliferating (those that are in cell cycle) cancer cells. Following Multikine treatment, the great majority of the tumor cells were in a proliferative state, as measured by the well-established cell proliferation marker Ki67. The control patients (not treated with Multikine) had only low expression (near background) of the same proliferation marker (Ki67) in this study. These findings were statistically significant (p