

Edgar Filing: CEL SCI CORP - Form POS AM

CEL SCI CORP  
Form POS AM  
February 11, 2005

As filed with the Securities and Exchange Commission on February \_\_, 2005.

Registration No. 333-102639

SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

FORM S-1

POST-EFFECTIVE  
AMENDMENT NO. 2

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)

8229 Boone Blvd. #802  
Vienna, Virginia 22182  
(703) 506-9460

84-0916344

-----  
(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. [ ]

## Edgar Filing: CEL SCI CORP - Form POS AM

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<br>Class of<br>Security<br>to be<br>Registered | Securities<br>to be<br>Registered | Proposed<br>Maximum<br>Offering<br>Price Per<br>Share (3) | Proposed<br>Maximum<br>Aggregate<br>Offering<br>Price | Amount of<br>Registration<br>Fee |
|--|-----------------------------------|---|---|----------------------------------|
| -----  | -----                             | -----   | -----   | -----                            |
| Common stock (2)   | 1,100,000                         |   |   |                                  |

- 
- (1) Offering price computed in accordance with Rule 457(c).
  - (2) Shares of common stock to be sold by the selling shareholder.
  - (3) A fee of \$315 was paid when this Registration Statement was originally filed.

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 the anti-dilution provisions of the Series H Warrants.

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  
550,000 shares of Common Stock

By means of this prospectus SDS Merchant Fund, L.P. is offering to sell up to 550,000 shares of the common stock of CEL-SCI Corporation which shares may be issued upon the exercise of CEL-SCI's Series H warrants. The shares issuable

## Edgar Filing: CEL SCI CORP - Form POS AM

upon the exercise of the Series H warrants may increase as the result of future sales of CEL-SCI's common stock at prices below either the warrant exercise price or the market value of CEL-SCI's common stock. See "Comparative Share Data" for information concerning the terms of the Series H warrants. SDS Merchant Fund is an "underwriter" as that term is defined in the Securities Act of 1933.

The securities offered by this prospectus are speculative and involve a high degree of risk and should be purchased only by persons who can afford to lose their entire investment. Prospective investors should consider certain important factors described under "Risk Factors" beginning on page \_\_\_ of this prospectus.

These Securities Have Not Been Approved or Disapproved by the Securities and Exchange Commission Nor has the Commission Passed Upon the Accuracy or Adequacy of This Prospectus. Any Representation to the Contrary is a Criminal Offense.

CEL-SCI's common stock is traded on the American Stock Exchange. On January \_\_, 2005 the closing price of CEL-SCI's common stock on the American Stock Exchange was \$\_\_\_.

The date of this prospectus is January \_\_, 2005

### PROSPECTUS SUMMARY

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

#### CEL-SCI

CEL-SCI Corporation was formed as a Colorado corporation in 1983. CEL-SCI is involved in the research and development of certain drugs and vaccines. CEL-SCI manufactures MULTIKINE(R), its first, and main product, using CEL-SCI's proprietary cell culture technologies. CEL-SCI is testing MULTIKINE to determine if it is effective in creating an anti-cancer immune response in head and neck cancer 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

## Edgar Filing: CEL SCI CORP - Form POS AM

US Navy collaborations, CEL-1000 is now being tested against 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 January 10, 2005, 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 \$(90,750,000) at September 30, 2004 and expects to incur substantial losses for the foreseeable future.

2

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

### THE OFFERING

#### Securities Offered:

By means of this prospectus SDS Merchant Fund is offering to sell up to 550,000 shares of CEL-SCI's common stock issuable upon the exercise of CEL-SCI's Series H warrants. CEL-SCI refers to SDS Merchant Fund as the selling shareholder in this prospectus.

**Common Stock Outstanding:** As of January 10, 2005 CEL-SCI had outstanding 72,269,231 shares of common stock. The number of outstanding shares does not give effect to shares which may be issued upon the exercise of options or warrants held by SDS Merchant Fund or other persons. If all outstanding options and warrants were exercised CEL-SCI would have 86,219,765 outstanding shares of common stock. See "Comparative Share Data".

**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.

## Edgar Filing: CEL SCI CORP - Form POS AM

AMEX Symbol: CVM

### Summary Financial Data

| Results of Operations:                               | Years Ended September 30, |                |
|--|---------------------------|----------------|
|  | 2004                      | 2003           |
|  | -----                     | -----          |
| Grant Revenue and Other:                             | \$ 325,479                | \$ 318,304     |
| Expenses:  |                           |                |
| Research and Development                             | 1,941,630                 | 1,915,501      |
| Depreciation and Amortization                        | 198,269                   | 199,117        |
| General and Administrative                           | 2,310,279                 | 2,287,019      |
| Interest Income                                      | (51,817)                  | (52,502)       |
| Interest Expense                                     | 126,840                   | 2,340,667      |
|  | -----                     | -----          |
| Net Loss   | (4,199,722)               | (6,371,498)    |
| Net Loss Attributable to<br>Common Stockholders      | \$ (4,199,722)            | \$ (6,480,319) |
|  | =====                     | =====          |
| <br>Net loss per common share<br>(basic and diluted) | <br>\$ (0.06)             | <br>\$ (0.13)  |
|  | =====                     | =====          |
| <br>Weighted average common shares<br>outstanding    | <br>67,273,133            | <br>50,961,457 |
|  | =====                     | =====          |

### Balance Sheet Data:

|                          | September 30, |            |
|--------------------------|---------------|------------|
|                          | 2004          | 2003       |
|                          | -----         | -----      |
| Working Capital          | \$ 4,592,331  | \$ 531,742 |
| Total Assets             | 5,513,810     | 2,915,206  |
| Convertible Debt *       | --            | 32,882     |
| Note Payable - Covance * | --            | 184,330    |
| Note Payable - Cambrex*  | --            | 656,076    |
| Total Liabilities        | 215,981       | 1,690,100  |
| Stockholders' Equity     | 5,297,829     | 1,225,106  |

\* Included in Total Liabilities.

### 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

## Edgar Filing: CEL SCI CORP - Form POS AM

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 this offering involves the risks described below, which could adversely affect the price of CEL-SCI's common stock. In addition to the other information contained in this prospectus, the following factors should be considered carefully in evaluating an investment in the shares offered by this prospectus.

#### RISKS RELATED TO CEL-SCI

Since CEL-SCI Has Earned Only Limited Revenues and Has a History of Losses, CEL-SCI Will Require Additional Capital to Remain in Operation.

CEL-SCI has had only limited revenues since it was formed in 1983. Since the date of its formation and through September 30, 2004 CEL-SCI incurred net losses of approximately \$(90,750,000). During the years ended September 30, 2002, 2003 and 2004 CEL-SCI suffered losses of \$(8,342,244), \$(6,371,498) and \$(4,199,722) respectively. CEL-SCI has relied principally upon the proceeds of

4

public and private sales of securities and convertible notes to finance its activities to date. All of CEL-SCI's potential products are in the early stages of development, and any commercial sale of these products will be many years away. 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.

## Edgar Filing: CEL SCI CORP - Form POS AM

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

5

common stock. Since April 2001 CEL-SCI has sold approximately 34,000,000 shares of its common stock to private investors at prices that were between 7% and 30% below the market price of CEL-SCI's common stock at the time of sale.

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 \$2,000,000 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

## Edgar Filing: CEL SCI CORP - Form POS AM

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.

6

### 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. For example, MULTIKINE is now being made by a process that was different from the process tested in many of CEL-SCI's clinical studies to date. 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. In this regard, the FDA is aware of Phase II clinical study results from US and Canadian studies, but not results from foreign trials. The foreign data comprises approximately 75% of the subjects participating in CEL-SCI's Phase II program. CEL-SCI can make no assurances that the FDA will accept the data from its foreign studies or that the agency would 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, 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



## Edgar Filing: CEL SCI CORP - Form POS AM

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.

7

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 is continuing, for example, to develop MULTIKINE to decrease or further characterize the amount of DNA in MULTIKINE and to develop ways of better measuring the amount of DNA in the product. CEL-SCI can make no assurances that it will succeed in decreasing the amount of DNA in MULTIKINE to a level that is acceptable for product approval or that it can develop a method of measuring the amount of DNA that the FDA accepts as suitable for approving the marketing of the product.

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:

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

CEL-SCI and any 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 entered into 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, injunction, fines, or be forced to remove a product from the market or experience other adverse consequences, including restrictions or delays in obtaining regulatory marketing approval, which could materially harm CEL-SCI's financial results, reputation and stock price. Additionally, CEL-SCI may not be able to obtain the labeling claims necessary or desirable for product promotion. CEL-SCI may also be required to undertake post-marketing trials. In addition, if CEL-SCI or other parties identify adverse effects after any of CEL-SCI's products are on the market, or if manufacturing problems occur, regulatory approval may be withdrawn 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 pharmaceutical and biotechnology companies are developing products for the prevention or treatment of cancer and infectious diseases including Introgen Therapeutics, Inc. and ImClone Systems, Inc. which are currently developing drugs for head and neck cancer. Both Introgen and ImClone, as well as many other companies working on drugs designed to prevent, cure or treat cancer, have substantial financial, research and development, and marketing resources and are capable of providing significant long-term competition either by establishing

## Edgar Filing: CEL SCI CORP - Form POS AM

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 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 trade secrets and later issued patents will protect the technology associated with MULTIKINE.

### RISKS RELATED TO THIS OFFERING

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 twelve months ended December 31, 2004 CEL-SCI's stock price has ranged from a low of \$0.46 per share to a high of \$1.88 per share. Factors such as fluctuations in CEL-SCI's operating results, announcements of technological innovations or new therapeutic products by CEL-SCI or its competitors, governmental regulation, developments in patent or other proprietary rights, public concern as to the safety of products developed by CEL-SCI or other biotechnology and pharmaceutical companies, and general market conditions may have a significant effect on the future market price of CEL-SCI's common stock.

Shares issuable upon the exercise of options and warrants, or as a result of sales made in connection with the equity line of credit 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 has outstanding options and warrants which allow the holders to acquire up to 13,950,534 additional shares of CEL-SCI's common stock. Until the

## Edgar Filing: CEL SCI CORP - Form POS AM

options and 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 the options and warrants may exercise or convert these securities at a time when CEL-SCI could obtain additional capital on terms more favorable than those provided by the options. The exercise of the options and warrants will dilute the voting interest of the owners of presently outstanding shares of CEL-SCI's common stock.

CEL-SCI has filed registration statements with the Securities and Exchange Commission so that the 13,950,534 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.

See the "Comparative Share Data" section of this prospectus for more information concerning CEL-SCI's outstanding options and warrants.

### Equity Line of Credit

An unknown number of shares of common stock are issuable under an equity line of credit arrangement to Rubicon Group Ltd. As CEL-SCI sells shares of its common stock to Rubicon Group under the equity line of credit, and Rubicon Group sells the common stock to third parties, the price of CEL-SCI's common stock may decrease due to the additional shares in the market. If CEL-SCI decides to draw down on the equity line of credit as the price of its common stock decreases, CEL-SCI will be required to issue more shares of its common stock for any given dollar amount invested by Rubicon Group, subject to the minimum selling price specified by CEL-SCI. The more shares that are issued under the equity line of credit, the more CEL-SCI's then outstanding shares will be diluted and the more CEL-SCI's stock price may decrease. Any decline in the price of CEL-SCI's common stock may encourage short sales, which could place further downward pressure on the price of CEL-SCI's common stock. Short selling is a practice of selling shares which are not owned by a seller with the expectation that the market price of the shares will decline in value after the sale.

As consideration for extending the equity line of credit, CEL-SCI granted Rubicon Group warrants to purchase 395,726 shares of common stock at any time prior to September 16, 2008 at a price of \$0.83 per share. Rubicon Group is not obligated to exercise any warrants.

CEL-SCI has filed a registration statement with the Securities and Exchange Commission so that the shares purchased by the Rubicon Group may be resold in the public market.

11

### COMPARATIVE SHARE DATA

|  | Number of<br>Shares | Note<br>Reference |
|--|---------------------|-------------------|
| Shares outstanding as of January 10, 2005          | 72,269,231          |                   |
| Shares to be sold in this Offering:                |                     |                   |
| Shares issuable upon exercise of Series H warrants | 550,000             | A, C              |

The number of shares outstanding as of January 10, 2005 excludes shares

## Edgar Filing: CEL SCI CORP - Form POS AM

which may be issued upon the exercise of other options or warrants issued by CEL-SCI or in connection with CEL-SCI's equity line of credit. See table below.

### Other Shares Which May Be Issued:

The following table lists additional shares of CEL-SCI's common stock which may be issued as the result of the exercise of other outstanding options or warrants issued by CEL-SCI or pursuant to the equity line of credit agreement:

|   | Number of<br>Shares | Note<br>Reference |
|---|---------------------|-------------------|
| Shares issuable upon exercise of warrants held by private investors   | 2,564,761           | B, C              |
| Shares issuable pursuant to equity line of credit:  | Unknown             | D                 |
| Shares issuable upon exercise of equity line warrants   | 395,726             | D                 |
| Shares issuable upon exercise of options and warrants granted to CEL-SCI's officers, directors, employees, consultants, and third parties | 10,290,047          | E                 |
| Shares issuable upon exercise of options granted to investor relations consultants  | 150,000             | F                 |

A. In January and July 2003, CEL-SCI sold Series H convertible notes, plus Series H warrants, to a group of private investors for \$1,350,000. At the holder's option the notes were convertible into shares of CEL-SCI's common stock equal in number to the amount determined by dividing each \$1,000 of note principal to be converted by the Conversion Price. The Conversion Price was 76% of the average of the 3 lowest daily trading prices of CEL-SCI's common stock on

12

the American Stock Exchange during the 15 trading days immediately prior to the conversion date.

As of the date of this prospectus all of the Series H notes had been converted into 3,233,229 shares of CEL-SCI's common stock and Series H warrants to purchase 550,000 shares had been exercised.

The Series H warrants initially allowed the holders to purchase up to 1,100,000 shares of CEL-SCI's common stock at a price of \$0.25 per share at any time prior to January 7, 2010.

Every three months after December 26, 2004 the exercise price of the Series H warrants will be adjusted to an amount equal to 84% of the average of the 3 lowest daily trading prices of CEL-SCI's common stock on the American Stock Exchange during the 15 trading days immediately prior to the three month adjustment date, provided that the adjusted price is lower than the warrant exercise price on that date.

B. In August 2003, the Company issued warrants to a private investor. The warrants permit the holder to purchase 23,758 shares of CEL-SCI's common stock at a price of \$0.77 per share at any time prior to August 17, 2006.

## Edgar Filing: CEL SCI CORP - Form POS AM

In July and September 2002, CEL-SCI sold Series G convertible notes, plus Series G warrants, to a group of private investors for \$1,300,000. As of June 30, 2003 all of the Series G notes had been converted into 8,390,746 shares of CEL-SCI's common stock. As of September 30, 2004 the Series G warrants allowed the holders to purchase up to 450,000 shares of CEL-SCI's common stock at a price of \$0.145 per share at any time prior to July 12, 2009. Every three months after December 9, 2004, the exercise price of the Series G warrants will be adjusted to an amount equal to 84% of the average of the 3 lowest daily trading prices of CEL-SCI's common stock on the American Stock Exchange during the 20 trading days immediately prior to the three month adjustment date, provided that the adjusted price is lower than the warrant exercise price on that date.

In May 2003 CEL-SCI sold shares of its common stock plus Series I warrants to a strategic partner, at prices equal to or above the then current price of CEL-SCI's common stock. The Series I warrants allow the holder to purchase 1,100,000 shares of CEL-SCI's common stock at a price of \$0.47 per share at any time prior to May 30, 2008.

On December 1, 2003, CEL-SCI sold 2,999,964 shares of its common stock, to a group of private institutional investors for approximately \$2,550,000, or \$0.85 per share. As part of this transaction, the investors in the private offering received Series J warrants which allow the investors to purchase 991,003 shares of CEL-SCI's common stock at a price of \$1.32 per share at any time prior to December 1, 2006.

C. If CEL-SCI sells any additional shares of common stock, or any securities convertible into common stock at a price below the then applicable exercise price of the Series G or H warrants, the warrant exercise price will be lowered to the price at which the shares were sold or the lowest price at which the

13

securities are convertible, as the case may be. If the warrant exercise price is adjusted, the number of shares of common stock issuable upon the exercise of the warrant will be increased by the product of the number of shares of common stock issuable upon the exercise of the warrant immediately prior to the sale multiplied by the percentage by which the warrant exercise price is reduced.

If CEL-SCI sells any additional shares of common stock, or any securities convertible into common stock at a price below the market price of CEL-SCI's common stock, the exercise price of the Series G or H warrants will be lowered by a percentage equal to the price at which the shares were sold or the lowest price at which the securities are convertible, as the case may be, divided by the then prevailing market price of CEL-SCI's common stock. If the warrant exercise price is adjusted, the number of shares of common stock issuable upon the exercise of the warrant will be increased by the product of the number of shares of common stock issuable upon the exercise of the warrant immediately prior to the sale multiplied by the percentage determined by dividing the price at which the shares were sold by the market price of CEL-SCI's common stock on the date of sale.

However, neither the exercise price of the Series G or H warrants nor the shares issuable upon the exercise of the Series G or H warrants will be adjusted as the result of shares issued in connection with a Permitted Financing. A Permitted Financing involves shares of common stock issued or sold:

- o in connection with a merger or acquisition or a strategic partnership;
- o upon the exercise of options or the issuance of common stock to CEL-SCI's employees, officers, directors, consultants and vendors in accordance with

## Edgar Filing: CEL SCI CORP - Form POS AM

CEL-SCI's equity incentive policies;

- o pursuant to the conversion or exercise of securities which were outstanding prior to July 12, 2002 in the case of the Series G warrants and January 7, 2003 in the case of the Series H warrants;
- o to key officers of CEL-SCI in lieu of their respective salaries.

D. An unknown number of shares of common stock are issuable under the equity line of credit agreement between CEL-SCI and Rubicon Group Ltd. As consideration for extending the equity line of credit, CEL-SCI granted Rubicon Group Ltd. warrants to purchase 395,726 shares of common stock at a price of \$0.83 per share at any time prior to September 16, 2008.

Under the equity line of credit agreement, Rubicon Group Ltd. has agreed to provide CEL-SCI with up to \$10,000,000 of funding prior to September 16, 2005. During this period, CEL-SCI may request a drawdown under the equity line of credit by selling shares of its common stock to Rubicon Group Ltd. and Rubicon Group Ltd. will be obligated to purchase the shares. CEL-SCI may request a drawdown once every 24 trading days, although CEL-SCI is under no obligation to request any drawdowns under the equity line of credit.

14

During the 22 trading days following a drawdown request, CEL-SCI will calculate the amount of shares it will sell to Rubicon Group Ltd. and the purchase price per share. The purchase price per share of common stock will be based on the daily volume weighted average price of CEL-SCI's common stock during each of the 22 trading days immediately following the drawdown date, less a discount of 11%.

CEL-SCI may request a drawdown by faxing a drawdown notice to Rubicon Group Ltd., stating the amount of the drawdown and the lowest daily volume weighted average price, if any, at which CEL-SCI is willing to sell the shares. The lowest volume weighted average price will be set by CEL-SCI's Chief Executive Officer in his sole and absolute discretion.

If CEL-SCI sets a minimum price which is too high and CEL-SCI's stock price does not consistently meet that level during the 22 trading days after its drawdown request, the amount CEL-SCI can draw and the number of shares CEL-SCI will sell to Rubicon Group Ltd. will be reduced. On the other hand, if CEL-SCI sets a minimum price which is too low and its stock price falls significantly but stays above the minimum price, CEL-SCI will have to issue a greater number of shares to Rubicon Group Ltd. based on the reduced market price.

As of January 10, 2005 CEL-SCI had received net proceeds of \$335,910 from the sale of 307,082 shares of common stock pursuant to the terms of the equity line of credit.

E. The options are exercisable at prices ranging from \$0.16 to \$11.00 per share. CEL-SCI may also grant options to purchase additional shares under its Incentive Stock Option and Non-Qualified Stock Option Plans.

F. CEL-SCI has granted options for the purchase of 150,000 shares of common stock to certain investor relations consultants in consideration for services provided to CEL-SCI. The options are exercisable at \$1.63 per share and expire June 1, 2006.

The shares referred to in Notes B, D and E are being, or will be, offered for sale by means of registration statements which have been filed with the

## Edgar Filing: CEL SCI CORP - Form POS AM

Securities and Exchange Commission.

### MARKET FOR CEL-SCI'S COMMON STOCK

As of January \_\_, 2005 there were approximately 2,550 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    |
|----------------|--------|--------|
| 12/31/02       | \$0.32 | \$0.19 |
| 3/31/03        | \$0.27 | \$0.15 |
| 6/30/03        | \$1.35 | \$0.20 |
| 9/30/03        | \$1.08 | \$0.61 |

15

|          |        |        |
|----------|--------|--------|
| 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 |

Holders of Common Stock are entitled to receive such dividends as may be declared by the Board of Directors out of funds legally available therefore 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.

### MANAGEMENTS DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATION



## Edgar Filing: CEL SCI CORP - Form POS AM

The following selected financial data should be read in conjunction with the more detailed financial statements, related notes and other financial information included in this prospectus. Certain amounts reported in previous years have been reclassified to conform to the classifications being used as of and for the year ended September 30, 2004.

16

|   | For the Years Ended September 30, |                |                |                 |                |
|---|-----------------------------------|----------------|----------------|-----------------|----------------|
|   | 2004                              | 2003           | 2002           | 2001            | 2000           |
|   | ----                              | ----           | ----           | ----            | ----           |
| Grant Revenue and Other:                      | \$ 325,479                        | \$ 318,304     | \$ 384,939     | \$ 293,871      | \$ 40,544      |
| Operating Expenses:                           |                                   |                |                |                 |                |
| Research and Development                      | 1,941,630                         | 1,915,501      | 4,699,909      | 7,762,213       | 5,186,066      |
| Depreciation and Amortization                 | 198,269                           | 199,117        | 226,514        | 209,121         | 220,999        |
| General and Administrative                    | 2,310,279                         | 2,287,019      | 1,754,332      | 3,432,437       | 3,513,888      |
| Interest Income                               | (51,817)                          | (52,502)       | (85,322)       | (376,221)       | (402,011)      |
| Interest Expense                              | 126,840                           | 2,340,667      | 2,131,750      | --              | --             |
| Net Loss                                      | \$ (4,199,722)                    | \$ (6,371,498) | \$ (8,342,244) | \$ (10,733,679) | \$ (8,478,399) |
| Net loss attributable to common stock holders | \$ (4,199,722)                    | \$ (6,480,319) | \$ (9,989,988) | \$ (11,104,251) | \$ (8,478,399) |
| Net loss per common share (basic and diluted) | \$ (0.06)                         | \$ (0.13)      | \$ (0.35)      | \$ (0.51)       | \$ (0.44)      |
| Weighted average common shares outstanding    | 67,273,133                        | 50,961,457     | 28,746,341     | 21,824,273      | 19,259,199     |

### Balance Sheet Data:

September 30,

|                          | 2004        | 2003       | 2002       | 2001        | 2000         |
|--------------------------|-------------|------------|------------|-------------|--------------|
|                          | ----        | ----       | ----       | ----        | ----         |
| Working Capital          | \$4,592,331 | \$ 531,742 | \$ 690,804 | \$2,801,299 | \$11,725,940 |
| Total Assets             | 5,513,810   | 2,915,206  | 3,771,258  | 4,508,920   | 13,808,882   |
| Convertible Debt *       | --          | 32,882     | 639,288    | --          | --           |
| Note Payable - Covance * | --          | 184,330    | --         | --          | --           |
| Note Payable - Cambrex * | --          | 656,076    | 1,135,017  | --          | --           |
| Total Liabilities        | 215,981     | 1,690,100  | 2,709,087  | 507,727     | 847,423      |
| Stockholders' Equity     | 5,297,829   | 1,225,106  | 1,062,171  | 4,001,193   | 12,961,459   |

\* 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

## Edgar Filing: CEL SCI CORP - Form POS AM

September 30, 2004 were:

| Quarter  | Net Loss       | Net Loss<br>per Share |
|----------|----------------|-----------------------|
| 12-31-02 | \$ (1,682,865) | \$ (0.04)             |
| 03-31-03 | \$ (1,032,181) | \$ (0.02)             |
| 06-30-03 | \$ (1,762,564) | \$ (0.03)             |
| 09-30-03 | \$ (1,893,888) | \$ (0.03)             |
| 12-31-03 | \$ (1,106,093) | \$ (0.02)             |
| 03-31-04 | \$ (1,205,273) | \$ (0.02)             |
| 06-30-04 | \$ (893,610)   | \$ (0.01)             |
| 09-30-04 | \$ (994,746)   | \$ (0.01)             |

17

### OVERVIEW

CEL-SCI's most advanced product, Multikine(R), 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. 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 and US Army and US Navy collaborations, CEL-1000 is now being tested against 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 its inception, CEL-SCI has financed operations through the issuance of equity securities, convertible notes, loans and certain research grants. CEL-SCI's expenses will likely exceed its revenues as it continues the development of Multikine and brings other drug candidates into clinical trials. Until such time as CEL-SCI becomes profitable, any or all of these financing vehicles or others may be utilized to assist CEL-SCI's capital requirements.

### Results of Operations

#### Fiscal 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.

## Edgar Filing: CEL SCI CORP - Form POS AM

Fiscal 2003

Grant revenues and other was lower during the year ended September 30, 2003 due to the winding down of a project for which CEL-SCI received grant money. The grant for this project generated \$110,000 in revenue in fiscal year 2003 compared with \$380,000 in revenue in fiscal year 2002. However, CEL-SCI has received four additional grants, two grants in April 2003, one grant in May 2003, and one grant in September 2003 for other projects on which CEL-SCI is working. These grants generated approximately \$170,750 in revenue in fiscal year 2003. Research and development expenses declined because CEL-SCI completed its

18

current production of Multikine during fiscal year 2002. General and administrative expenses were higher during the year ended September 30, 2003 since there was a reversal in 2002 of a 2001 fiscal year charge of \$593,472 resulting from a decline in the intrinsic value of the options repriced to employees. Interest income during the year ended September 30, 2003 was less than it was during the same periods in fiscal year 2002 as a result of CEL-SCI's smaller cash position and lower interest rates on interest bearing accounts. During the years ended September 30, 2003 and 2002, interest expense was \$2,340,667 and \$2,131,750, respectively. Interest expense for all periods presented is primarily a non-cash item incurred to account for interest and amortization of the discounts and deferred financing costs related to convertible debt, the note payable to Covance AG and the convertible debt payable to Cambrex Biosciences, Inc.

### Research and Development Expenses

During the five years ended September 30, 2004 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.

|              | 2004<br>---- | 2003<br>---- | 2002<br>---- | 2001<br>---- | 2000<br>---- |
|--------------|--------------|--------------|--------------|--------------|--------------|
| MULTIKINE    | \$1,539,454  | \$1,653,904  | \$4,405,678  | \$7,365,305  | \$4,106,752  |
| L.E.A.P.S.   | 402,176      | 261,597      | 244,769      | 280,766      | 453,061      |
| AIDS Vaccine | --           | --           | 43,462       | 94,642       | 602,252      |
| Other        | --           | --           | 6,000        | 21,500       | 24,000       |
|              | -----        | -----        | -----        | -----        | -----        |
| TOTAL        | \$1,941,630  | \$1,915,501  | \$4,699,909  | \$7,762,213  | \$5,186,065  |
|              | =====        | =====        | =====        | =====        | =====        |

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. It is CEL-SCI's intention to meet with the FDA in early 2005 to discuss such a trial. CEL-SCI is unable to estimate the future costs of research and clinical trials involving Multikine since CEL-SCI has not yet met with the FDA to discuss the design of future clinical trials and until the scope of these trials is known, CEL-SCI will not be able to price any future trials.

As explained in Item 1 of this report, as of November 15, 2004 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.

## Edgar Filing: CEL SCI CORP - Form POS AM

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.

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

Clinical and other studies necessary to obtain regulatory approval of a new drug involve significant costs and require several years to complete. The extent

19

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.

### 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 expenditures remained at the 2003 levels. If necessary, CEL-SCI may reduce discretionary expenditures in fiscal 2005; 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.

### Equity Line of Credit

In order to provide a possible source of funding for CEL-SCI's current

## Edgar Filing: CEL SCI CORP - Form POS AM

activities and for the development of its current and planned products, CEL-SCI entered into an equity line of credit agreement with Rubicon Group Ltd.

20

Under the equity line of credit agreement, Rubicon Group has agreed to provide CEL-SCI with up to \$10,000,000 of funding during a two year period beginning on December 29, 2003. During this period, CEL-SCI may request a drawdown under the equity line of credit by selling shares of its common stock to Rubicon Group, and Rubicon Group will be obligated to purchase the shares. The minimum amount CEL-SCI can draw down at any one time is \$100,000, and the maximum amount CEL-SCI can draw down at any one time will be determined at the time of the drawdown request using a formula contained in the equity line of credit agreement. CEL-SCI may request a drawdown once every 22 trading days, although CEL-SCI is under no obligation to request any drawdowns under the equity line of credit.

During the 22 trading days following a drawdown request, CEL-SCI will calculate the number of shares it will sell to Rubicon Group and the purchase price per share. The purchase price per share of common stock will be based on the daily volume weighted average price of CEL-SCI's common stock during each of the 22 trading days immediately following the drawdown date, less a discount of 11%.

The following summarizes the drawdowns requested by CEL-SCI under the equity line of credit during the year ended September 30, 2004.

| Date of Sale<br>----- | Shares Sold<br>----- | Average Sale Price Per Share<br>----- | Net Proceeds to CEL-SCI<br>----- |
|-----------------------|----------------------|---------------------------------------|----------------------------------|
| 01/27/04              | 101,308              | \$1.09                                | \$109,000                        |
| 02/11/04              | 92,722               | \$1.19                                | \$109,000                        |
| 03/02/04              | 74,760               | \$1.07                                | \$ 79,000                        |
| 03/12/04              | 38,292               | \$1.04                                | \$ 39,000                        |

The net proceeds to CEL-SCI are net of a \$1,000 fee paid to an escrow agent.

### Shelf Offering

In May 2004, CEL-SCI completed an offering of 6,402,439 shares of registered common stock at \$0.82 per share to one institutional investor. This sale resulted in gross proceeds of \$5,250,000 and associated costs of \$498,452. The stock was offered pursuant to a shelf registration statement and Wachovia Capital Markets, LLC acted as the placement agent for the offering. CEL-SCI is using the proceeds of the offering to advance the clinical development of Multikine for the treatment of cancer. In connection with this financing, 76,642 warrants were issued to Wachovia at a price of \$1.37. The warrants expire May 4, 2009. The warrants were valued using the Black-Scholes valuation method and an expense of \$38,127 was recorded to additional paid-in capital as a cost related to obtaining capital during the year ended September 30, 2004.

21

### Future Capital Requirements

## Edgar Filing: CEL SCI CORP - Form POS AM

CEL-SCI plans to use its existing financial resources, the proceeds from the sale of its common stock, and proceeds from the sale of common stock under the equity line of credit agreement to fund its capital requirements during the year ending September 30, 2005.

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, 2004 are as follows:

| Contractual Obligations: | Years Ending September 30, |           |           |          |
|--------------------------|----------------------------|-----------|-----------|----------|
| Total                    | 2005                       | 2006      | 2007      |          |
| -----                    | ----                       | ----      | ----      | ----     |
| Operating Leases         | \$281,481                  | \$139,209 | \$ 71,136 | \$71,136 |
| Employment Contracts     | 891,788                    | 552,085   | 339,703   | --       |
|                          | \$1,173,269                | \$691,294 | \$410,839 | \$71,136 |
|                          | =====                      | =====     | =====     | =====    |

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 2005. 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.

### Covance AG

On October 8, 2002, CEL-SCI signed an agreement with Covance AG (Covance), a Swiss Corporation. Pursuant to the agreement, amounts owed to Covance totaling \$199,928 as of June 30, 2003 were converted to a note payable. The note was payable on January 2, 2004. Interest was payable monthly at an annual rate of 8%. Until the entire amount was paid to Covance, Covance was entitled to receive 2% of any draw-down of CEL-SCI's equity credit line, 2% of any net funds received from outside financings of less than \$1 million, 3% of any net funds received from outside financings greater than \$1 million but less than \$2 million and 4% of any net funds received from outside financings greater than \$2 million. During the year ended September 30, 2003, CEL-SCI paid \$15,598 on the Covance note. The note was paid in full in December 2003.

### Eastern Biotech

In May 2003, CEL-SCI entered into an agreement with Eastern Biotech which

## Edgar Filing: CEL SCI CORP - Form POS AM

provided Eastern Biotech with the following (i) the exclusive right to distribute Multikine and CEL-1000 in Greece, Serbia and Croatia, (ii) a royalty equal to 1% of CEL-SCI's net sales of Multikine and CEL-1000 prior to May 30, 2033, (iii) 1,100,000 shares of CEL-SCI's common stock and, (iv) warrants which allow Eastern Biotech to purchase an additional 1,100,000 shares of CEL-SCI's common stock at a price of \$0.47 per share at any time prior to May 30, 2008. In consideration for the above Eastern Biotech paid CEL-SCI \$500,000. Because the Company did not register these shares prior to September 30, 2003, the royalty percentage increased to 2%. If Eastern Biotech did not meet certain clinical development milestones within one year, it would lose the right to sell both products in these three countries. As of June 1, 2004, Eastern Biotech lost its exclusive right to market, distribute and sell Multikine in accordance with the agreement.

### Cambrex Bio Science Promissory Note

In November 2001, CEL-SCI gave a promissory note to Cambrex Bio Sciences, Inc., the owner of the manufacturing facility used by CEL-SCI to produce Multikine for CEL-SCI's clinical trials. The promissory note was in the principal amount of \$1,172,517 which represented the cost of CEL-SCI's use of the Cambrex manufacturing facility for the three months ended January 10, 2002. The amount due Cambrex bore interest at the prime interest rate, plus 3%, which was adjusted monthly. As of December 1, 2003 the prime interest rate was 4% and the interest rate on the amount due Cambrex was 7%. Pursuant to the agreement, CEL-SCI surrendered a cash deposit and transferred title to certain equipment to Cambrex, which reduced the amount due by \$225,000. Until the note was paid in full, CEL-SCI agreed to pay Cambrex 10% of all amounts received by CEL-SCI, net of financing costs, from any future financings, including amounts received by CEL-SCI from its equity line of credit. Cambrex, at its option, could convert all or part of the amount due Cambrex into shares of CEL-SCI's common stock. The number of shares to be issued to Cambrex upon any conversion of the note was to be determined by dividing that portion of the note to be converted by the Conversion Price. The "Conversion Price" was an amount equal to 90% of the average closing prices of CEL-SCI's common stock for the three trading days immediately prior to the conversion date. However, the Conversion Price could not be less than \$0.22.

During the quarter ended December 31, 2003, CEL-SCI paid \$692,010 of principal plus accrued interest of \$59,450 to Cambrex, thereby fully repaying the remaining balance of the note. No part of the note was converted into shares of CEL-SCI's common stock.

### Convertible Notes

In December 2001 and January 2002, CEL-SCI sold Series F convertible notes, plus Series F warrants, to a group of private investors for \$1,600,000. As of December 1, 2002 all of the Series F notes had been converted into 6,592,461 shares of CEL-SCI's common stock.

In July and September 2002, CEL-SCI sold Series G convertible notes, plus Series G warrants, to a group of private investors for \$1,300,000. As of June 30, 2003 all of the Series G notes had been converted into 8,390,746 shares of CEL-SCI's common stock.

In January and July 2003, CEL-SCI sold Series H convertible notes, plus Series H warrants, to a group of private investors for \$1,350,000. As of December 1, 2003 all of the Series H notes had been converted into 3,233,229 shares of CEL-SCI's common stock.

## Edgar Filing: CEL SCI CORP - Form POS AM

### 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. Our 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 would be 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 encourages but does 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 has 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 2002, the FASB issued SFAS No. 148, "Accounting for Stock-Based Compensation - Transaction and Disclosure" which amends SFAS No. 123. SFAS No. 148 provided alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation and requires more prominent and more frequent disclosures in the financial statements of the effects of stock-based compensation. The provisions of SFAS No. 148 are effective for periods beginning after December 15, 2002. The Company has elected to continue to account for its employee stock-based compensation using the intrinsic value method.

**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 our long-lived assets have been impaired; however, if there is a material change in the assumptions used in our 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 are expected.



## Edgar Filing: CEL SCI CORP - Form POS AM

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.

Convertible Notes - Convertible notes were issued during the year ended September 30, 2002. CEL-SCI initially offset a portion of the notes with a discount representing the relative fair value of the warrants and a beneficial conversion feature discount. This discount is amortized to interest expense over the period the notes are outstanding and is accelerated pro-rata as the notes are converted. The fair value of the warrants and the beneficial conversion discount are calculated based on available market data using appropriate valuation models. These valuations require that CEL-SCI make assumptions and estimates regarding the convertible notes and warrants. Management uses its judgment, as well as outside sources, to determine these assumptions and estimates.

### 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 has no derivative financial instruments. Further, there is 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.

### 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 ARB 43, Chapter 4". 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

25

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 compensation expense in an amount equal to the fair value of the share-based payment (stock options and restricted stock) issued to employees. SFAS No. 123R applies to all transactions involving issuance of equity by a company in exchange for goods and services, including employees. SFAS No. 123R is effective for fiscal periods beginning after June 15, 2005. CEL-SCI has not determined the impact of adopting SFAS No. 123R.

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, which differed from the International Accounting Standards

## Edgar Filing: CEL SCI CORP - Form POS AM

Board's ("IASB") method of accounting for exchanges of similar productive assets. 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.

### 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](http://www.cel-sci.com). CEL-SCI makes its electronic filings with the Securities and Exchange Commission (SEC), including its annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to these reports available on its website free of charge as soon as practicable after they are filed or furnished to the SEC.

### OVERVIEW

CEL-SCI's most advanced product, Multikine(R), 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. 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 a recently completed clinical trial involving 54 matched cancer patients, treatment with Multikine prior to surgical intervention rendered the residual tumor cells much more susceptible to follow-on treatment with radiation, and possibly chemotherapy. This data was published in December 2003. A second finding involving another 39 matched cancer patients demonstrated that Multikine pre-treatment increased the percent and absolute number of immune cells infiltrating into the tumor bed, causing tumor cell destruction and

26

necrosis. This finding was presented at The American Society of Clinical Oncology (ASCO) in June 2004. The data pointed to a reversal of the CD4/CD8 immune cell ratios in the tumors, resulting in a 42% response rate after only 3 weeks of the non-toxic treatment with Multikine.

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 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.

### MULTIKINE

Multikine has been tested in 220 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

## Edgar Filing: CEL SCI CORP - Form POS AM

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

27

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

## Edgar Filing: CEL SCI CORP - Form POS AM

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.

28

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, surgery plus radiation therapy) to the Multikine treated patients (receiving Multikine prior to conventional therapy) by histopathology and immunohistochemistry. The results of

## Edgar Filing: CEL SCI CORP - Form POS AM

these studies were published in peer-reviewed scientific journals and/or presented at scientific meetings. The studies that have not yet been published were either conducted in support of Multikine's safety and clinical utility or will be published in the future.

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). Additional findings regarding Multikine treatment of head & neck cancer are expected to be presented/published in 2005.

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".

29

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