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CEL SCI CORP
Form 424B3
August 09, 2010

Rule 424(b)(3)
File
#333-160794

PROSPECTUS SUPPLEMENT
(to Prospectus dated August 4, 2010)

CEL-SCI CORPORATION
Common Stock and Warrants

By means of this prospectus CEL-SCI Corporation is offering to sell up to 6,000,000 shares of its common stock to Laksya Ventures.

Laksya Ventures is the owner of Cel-Sci's Series M Warrants which, prior to August 3, 2010, allowed Laksya to purchase 8,800,000 shares of Cel-Sci's common stock at a price of \$2.00 per share.

On August 3, 2010 Cel-Sci's directors approved an amendment to the terms of the Series M warrants held by Laksya such that Laksya may purchase 6,000,000 shares of CEL-SCI's common stock (as reduced from 8,800,000 shares) at a price of \$0.60 per share. The Series M warrants expire on July 31, 2012.

CEL-SCI will not pay any commissions with respect to the sale of any securities offered by this prospectus.

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. For a description of certain important factors that should be considered by prospective investors, see "Risk Factors" beginning on page 9 of CEL-SCI's prospectus dated August 4, 2010.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or has 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 NYSE AMEX under the symbol "CVM". On August 3, 2010 the closing price of CEL-SCI's common stock was \$0.54.

The date of this prospectus supplement is August 5, 2010.

PROSPECTUS SUMMARY

THIS SUMMARY IS QUALIFIED BY THE MORE DETAILED INFORMATION APPEARING ELSEWHERE IN THIS PROSPECTUS SUPPLEMENT, AS WELL AS CEL-SCI'S PROSPECTUS DATED August 4, 2010.

CEL-SCI

CEL-SCI Corporation (CEL-SCI) was formed as a Colorado corporation in 1983. CEL-SCI's principal office is located at 8229 Boone Boulevard, Suite 802,

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Vienna, VA 22182. CEL-SCI's telephone number is 703-506-9460 and its web site is www.cel-sci.com. CEL-SCI makes its electronic filings with the Securities and Exchange Commission (SEC), including its annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to these reports available on its website free of charge as soon as practicable after they are filed or furnished to the SEC.

CEL-SCI's business consists of the following:

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

MULTIKINE

CEL-SCI's lead product, Multikine(R), is being developed for the treatment of cancer. It is the first of a new class of cancer immunotherapy drugs called Immune SIMULATORS. It simulates the activities of a healthy person's immune system, which battles cancer every day. Multikine is multi-targeted; it is the only cancer immunotherapy that both kills cancer cells in a targeted fashion and activates the general immune system to destroy the cancer. We believe Multikine is the first immunotherapeutic agent being developed as a first-line standard of care treatment for cancer and it is cleared for a global Phase III clinical trial in advanced primary (previously untreated) head and neck cancer patients.

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

Multikine is designed to target the tumor micro-metastases that are mostly responsible for treatment failure. The basic concept is to add Multikine to the current cancer treatments with the goal of making the overall cancer treatment more successful. Phase II data indicated that Multikine treatment resulted in a substantial increase in the survival of patients. The lead indication is advanced primary (previously untreated) head & neck cancer (about 600,000 new

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cases per annum). Since Multikine is not tumor specific, it may also be applicable in many other solid tumors.

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

The protocol is designed to develop conclusive evidence of the efficacy of Multikine in the treatment of advanced primary (previously untreated) squamous cell carcinoma of the oral cavity (head and neck cancer). A successful outcome from this trial should enable CEL-SCI to apply for a Biologics License to market Multikine for the treatment of this patient population.

The trial will test the hypothesis that Multikine treatment administered

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

Since sufficient funding has been obtained, CEL-SCI expects to commence the pivotal Phase III clinical trial for Multikine in the second half of 2010. This follows not only many years of extensive clinical trials, but also a review of the Phase III submissions by both the FDA and the Canadian regulators.

UNIQUE COLD FILL CONTRACT MANUFACTURING SERVICE TO BE OFFERED AT CEL-SCI'S NEW MANUFACTURING FACILITY

Before starting the Phase III clinical trial, CEL-SCI needed to develop and validate the manufacturing process for Multikine as well as build and fully validate a dedicated manufacturing facility for Multikine. CEL-SCI took delivery of its new manufacturing facility in October 2008 and completed validation in January 2010.

The new, state-of-the-art, manufacturing facility will be used to manufacture Multikine for CEL-SCI's Phase III clinical trial. Located near Baltimore, MD, the facility was designed and built over 18 months to CEL-SCI's specifications. In addition to using this facility to manufacture Multikine, CEL-SCI will offer the use of the facility as a service to pharmaceutical companies and others, particularly those that need to "fill and finish" their drugs in a cold environment (4 degrees Celsius, or approximately 39 degrees Fahrenheit). Fill and finish is the process of filling injectable drugs in a sterile manner and is a key part of the manufacturing process for many medicines.

The fastest area of growth in the biopharmaceutical and pharmaceutical markets is biologics, and most recently stem cell products. Biologics are usually very sensitive to heat and quickly lose their biological activity if exposed to room or elevated temperature. However, these products do not generally lose activity when kept at 4 degrees Celsius.

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The FDA and other regulatory agencies require a drug developer to demonstrate the safety, purity and potency of a drug being produced for use in humans. When filling a product at 4 degrees Celsius, minimal to no biological losses occur and therefore the potency of the drug is maintained throughout the final critical step of the drug's manufacturing process. If the same temperature sensitive drug is instead aseptically filled at room temperature, expensive and time consuming validation studies must be conducted, first, to be able to obtain a complete understanding of the product's potency loss during the room temperature fill process, and second, to create solutions to the drug's potency losses, which require further testing and validation.

CEL-SCI's unique, cold aseptic filling suite can be operated at temperatures between 2 degrees Celsius and room temperatures, and at various humidity levels. CEL-SCI's aseptic filling suites are maintained at FDA and EU ISO classifications of 5/6. CEL-SCI also has the capability to formulate, inspect, label and package biologic products at cold temperatures.

Since a 4 degrees Celsius fill and finish process can save drug manufacturers time and money, CEL-SCI believes it will be able to charge approximately \$150,000 for an eight hour fill and finish "run".

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CEL-SCI does not know of any other facility in the United States which is able to provide cold 4 degrees Celsius finish and fill services on a contract basis.

L.E.A.P.S.

CEL-SCI's patented T-cell Modulation Process uses "heteroconjugates" to direct the body to choose a specific immune response. The heteroconjugate technology, referred to as L.E.A.P.S. (Ligand Epitope Antigen Presentation System), is intended to selectively stimulate the human immune system to more effectively fight bacterial, viral and parasitic infections as well as autoimmune, allergies, transplantation rejection and cancer, when it cannot do so on its own. Administered like vaccines, LEAPS combines T-cell binding ligands with small, disease associated, peptide antigens and may provide a new method to treat and prevent certain diseases.

The ability to generate a specific immune response is important because many diseases are often not combated effectively due to the body's selection of the "inappropriate" immune response. The capability to specifically reprogram an immune response may offer a more effective approach than existing vaccines and drugs in attacking an underlying disease.

Using its LEAPS technology, CEL-SCI has pioneered development of its L.E.A.P.S. flu constructs, which could have the potential to provide a treatment or a vaccine against what is commonly referred to as the H1N1 flu or "swine flu". The Company has begun pre-clinical formulation, evaluation and testing of its initial H1N1 development candidates, which are directed at targeting "mutated" versions of H1N1 swine flu and other influenza viruses. This development program is being pursued based upon the reasonable belief in the public-health community that the influenza virus may mutate and evolve between now and the next winter flu season. In conjunction with the testing, CEL-SCI has produced several L.E.A.P.S. flu development candidates that focus on the conserved, non changing epitopes of the different

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strains of Type A Influenza viruses (H1N1, H5N1, H3N1, etc.), including "swine", "avian or bird", and "Spanish Influenza", in order to minimize the chance of viral "escape by mutations" from immune recognition. CEL-SCI's lead investigational L.E.A.P.S. treatment, LEAPS-H1N1 contains epitopes known to be associated with immune protection against influenza in animal models.

On September 16, 2009, CEL-SCI announced that the U.S. Food and Drug Administration had indicated that CEL-SCI could proceed with its first clinical trial to evaluate the effect of LEAPS-H1N1 treatment on the white blood cells of hospitalized H1N1 patients. This followed an expedited initial review of CEL-SCI's regulatory submission for this study proposal. Following completion of manufacturing, the initiation of this first study was subject to review and approval by the Institutional Review Board of any hospital participating in the study.

On November 6, 2009, CEL-SCI announced that an Institutional Review Board of The Johns Hopkins University School of Medicine had given clearance for CEL-SCI's first clinical study using LEAPS-H1N1 to proceed at Johns Hopkins. The Company announced the start of this first clinical study on November 18, 2009. This initial study will involve taking blood from 20 hospitalized, laboratory-confirmed H1N1 patients and activating their cells with the LEAPS-H1N1 investigational therapy in order to assess the cells' response as the basis for the planned future treatment of this patient population under a next-stage clinical trial protocol. In parallel, the study will involve taking blood from 20 healthy individuals not infected with H1N1 and activating their

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cells with the LEAPS-H1N1 investigational therapy to serve as a control for the patient group in the study.

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

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

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General

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 CEL-SCI's securities and borrowings from third parties, including affiliates of CEL-SCI.

None of the products or vaccines which are in development using the LEAPS technology have been approved by the FDA or any other government agency. Before obtaining marketing approval from the FDA in the United States, and by comparable agencies in most foreign countries, these product candidates must undergo rigorous preclinical and clinical testing which is costly and time consuming and subject to unanticipated delays. There can be no assurance that these approvals will be granted.

As of the date of this prospectus, 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 \$(153,868,000) at March 31, 2010 and expects to incur substantial losses for the foreseeable future.

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

THE OFFERING

Securities

Offered: Up to 6,000,000 shares of common stock are being offered to Laksya Ventures upon the exercise Series M warrants previously issued by CEL-SCI. At any time prior July 31, 2012 the Series M warrants held by Laksya may be exercised at a price of \$0.60 per share. The Series M warrants expire on July 31,

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2012.

Common Stock Outstanding: As of August 4, 2010, CEL-SCI had 204,728,670 outstanding shares of common stock. The number of outstanding shares does not give effect to shares which may be issued upon the exercise and/or conversion of options, warrants or other convertible securities previously issued by CEL-SCI. If all outstanding options, warrants and convertible securities were exercised and converted, CEL-SCI would have approximately 288,200,000 outstanding shares of common stock.

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

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need for FDA approval. See the "Risk Factors" section of the prospectus dated August 4, 2010.

NYSE Amex trading symbol: CVM

Use of Proceeds: The net proceeds from the sale of all shares offered, after deducting the estimated expenses of this offering, will be approximately \$3,600,000 and will be used for CEL-SCI's general and administrative expenses and CEL-SCI's Phase III clinical trial involving Multikine.

Forward Looking Statements

This prospectus contains various forward-looking statements that are based on CEL-SCI's beliefs as well as assumptions made by and information currently available to CEL-SCI. When used in this prospectus, the words "believe", "expect", "anticipate", "estimate" and similar expressions are intended to identify forward-looking statements. Such statements may include statements regarding seeking business opportunities, payment of operating expenses, and the like, and are subject to certain risks, uncertainties and assumptions which could cause actual results to differ materially from projections or estimates. Factors which could cause actual results to differ materially are discussed at length under the heading "Risk Factors". Should one or more of the enumerated risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those anticipated, estimated or projected. Investors should not place undue reliance on forward-looking statements, all of which speak only as of the date made.

PLAN OF DISTRIBUTION

CEL-SCI will offer the shares directly to holders of CEL-SCI's outstanding warrants. CEL-SCI will not pay any commissions with respect to the sale of any of the securities offered by this prospectus.

CEL-SCI estimates that the total expenses of this offering will be approximately \$10,000.

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DESCRIPTION OF SECURITIES

Common Stock

CEL-SCI is authorized to issue 450,000,000 shares of common stock, (the "common stock"). Holders of common stock are each entitled to cast one vote for each share held of record on all matters presented to shareholders. Cumulative voting is not allowed; hence, the holders of a majority of the outstanding common stock can elect all directors.

Holders of common stock are entitled to receive such dividends as may be declared by the Board of Directors out of funds legally available therefor and, in the event of liquidation, to share pro rata in any distribution of CEL-SCI's assets after payment of liabilities. The board is not obligated to declare a dividend. It is not anticipated that dividends will be paid in the foreseeable future.

Holders of common stock do not have preemptive rights to subscribe to additional shares if issued by CEL-SCI. There are no conversion, redemption, sinking fund or similar provisions regarding the common stock. All of the outstanding shares of common stock are fully paid and non-assessable.

Warrants

See CEL-SCI's prospectus dated August 4, 2010 for information concerning CEL-SCI's outstanding warrants.

ADDITIONAL INFORMATION

CEL-SCI is subject to the requirements of the Securities Exchange Act of 1934 and is required to file reports, proxy statements and other information with the Securities and Exchange Commission. Copies of any such reports, proxy statements and other information filed by CEL-SCI can be read and copied at the Commission's Public Reference Room at 100 F. Street, N.E., Washington, D.C. 20549. The public may obtain information on the operation of the Public Reference Room by calling the Commission at 1-800-SEC-0330. The Commission maintains an Internet site that contains reports, proxy and information statements, and other information regarding CEL-SCI. The address of that site is <http://www.sec.gov>.

CEL-SCI will provide, without charge, to each person to whom a copy of this prospectus is delivered, including any beneficial owner, upon the written or oral request of such person, a copy of any or all of the documents incorporated by reference below (other than exhibits to these documents, unless the exhibits are specifically incorporated by reference into this prospectus). Requests should be directed to:

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

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The following documents, filed with the Commission by CEL-SCI (Commission File No. 0-11503), are incorporated by reference into this prospectus:

- (1) Annual Report on Form 10-K for the fiscal year ended September 30, 2009.

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- (2) Report on Form 10-Q for the three months ended December 31, 2009.
- (3) Report on Form 10-Q for the three and six months ended March 31, 2010.
- (4) Proxy Statement relating to its July 16, 2010 annual shareholders' meeting.

All documents filed with the Commission by CEL-SCI pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act subsequent to the date of this prospectus and prior to the termination of this offering shall be deemed to be incorporated by reference into this prospectus and to be a part of this prospectus from the date of the filing of such documents. Any statement contained in a document incorporated or deemed to be incorporated by reference shall be deemed to be modified or superseded for the purposes of this prospectus to the extent that a statement contained in this prospectus or in any subsequently filed document which also is or is deemed to be incorporated by reference in this prospectus modifies or supersedes such statement. Such statement so modified or superseded shall not be deemed, except as so modified or superseded, to constitute a part of this prospectus.

CEL-SCI has filed with the Securities and Exchange Commission a Registration Statement under the Securities Act of 1933, as amended, with respect to the securities offered by this prospectus. This prospectus does not contain all of the information set forth in the Registration Statement. For further information with respect to CEL-SCI and such securities, reference is made to the Registration Statement and to the exhibits filed with the Registration Statement. Statements contained in this prospectus as to the contents of any contract or other documents are summaries which are not necessarily complete, and in each instance reference is made to the copy of such contract or other document filed as an exhibit to the Registration Statement, each such statement being qualified in all respects by such reference. The Registration Statement and related exhibits may also be examined at the Commission's internet site.

No dealer salesman or other person has been authorized to give any information or to make any representations, other than those contained in this prospectus. Any information or representation not contained in this prospectus must not be relied upon as having been authorized by CEL-SCI. This prospectus does not constitute an offer to sell, or a solicitation of an offer to buy, the securities offered hereby in any state or other jurisdiction to any person to whom it is unlawful to make such offer or solicitation. Neither the delivery of this prospectus nor any sale made hereunder shall, under any circumstances, create an implication that there has been no change in the affairs of CEL-Sci since the date of this prospectus. create an implication that there has been no change in the affairs of CEL-SCI since the date of this prospectus.