CEL SCI CORP Form 424B3 October 04, 2011

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

PROSPECTUS SUPPLEMENT (to Prospectus dated September 30, 2011)

CEL-SCI CORPORATION
Common Stock and Warrants

By means of this prospectus CEL-SCI Corporation is offering to sell 13,333,334 shares of its common stock to investors at a price of \$0.30 per share. For every 100 shares purchased an investor will also receive 90 Series F warrants or an aggregate of 12,000,001 warrants. Each Series F warrant will entitle the holder to purchase one share of CEL-SCI's common stock. The Series F warrants may be exercised at any time prior to October 6, 2014 at a price of \$0.40 per share.

CEL-SCI has agreed to pay Chardan Capital Markets, LLC, the placement agent for this offering, a cash commission of \$140,000. CEL-SCI has also agreed to issue to Chardan Capital Market, LLC 666,667 Series G warrants. Each Series G warrant will entitle the holder to purchase one share of CEL-SCI's common stock. The Series G warrants may be exercised at any time prior to August 12, 2014 at a price of \$0.40 per share.

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 10 of CEL-SCI's prospectus dated September 30, 2011.

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 October 3, 2011 the closing price of CEL-SCI's common stock was \$0.34.

Delivery of the shares and warrants will take place on or about October 6, 2011, subject to the satisfaction of certain conditions.

The date of this prospectus supplement is October 3, 2011.

#### 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 SEPTEMBER 30, 2011.

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. We do not incorporate the information on our website into this prospectus supplement or accompanying prospectus, and you should not consider it part of this prospectus supplement or accompanying prospectus.

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:

- Multikine (Leukocyte Interleukin, Injection) investigational cancer therapy; and
- LEAPS technology, with two products, pandemic flu treatment for hospitalized patients and CEL-2000, a rheumatoid arthritis treatment vaccine.

#### MULTIKINE

CEL-SCI's lead investigational therapy Multikine (Leukocyte Interleukin, Injection) is currently being developed as a potential therapeutic agent directed at using the immune system to produce an anti-tumor immune response. Data from Phase I and Phase II clinical trials suggest Multikine has the potential to directly target the tumor cells. These data also indicate that it appears to activate the patient's own anti-tumor immune response. Multikine (Leukocyte Interleukin, Injection) is the full name of this investigational therapy, which, for simplicity, is referred to in the remainder of this document as Multikine. Multikine is the trademark that CEL-SCI has registered for this investigational therapy, and this proprietary name is subject to FDA review in connection with our future anticipated regulatory submission for approval. Multikine has not been licensed or approved by the FDA or any other regulatory agency. Neither has its safety or efficacy been established for any use.

Multikine has been cleared by the regulators in 9 countries around the world, including the U.S. FDA, for a global Phase III clinical trial in advanced primary (not yet treated) head and neck cancer patients. This trial is expected to be the largest head and neck cancer clinical study ever conducted.

It is also thought to be the first Phase III study in the world in which immunotherapy is given to cancer patients first, i.e., prior to their receiving

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any conventional treatment for cancer, including surgery, radiation and/or chemotherapy. This could be shown to be important because conventional therapy may weaken the immune system, and may compromise the potential effect of immunotherapy. Because Multikine is given before conventional cancer therapy, when the immune system may be more intact, we believe the possibility exists for it to have a greater likelihood of activating an anti-tumor immune response under these conditions. This likelihood is one of the clinical aspects being evaluated in the ongoing global Phase III clinical trial.

Multikine is a different kind of investigational therapy in the fight against cancer; Multikine is a defined mixture of cytokines. It is a combination immunotherapy, possessing both active and passive properties.

During the early investigational phase, in Phase I and Phase II clinical trials in over 220 subjects who received the investigational therapy Multikine in doses of 200 to 3200 IU as IL-2, no serious adverse events were reported as being expressly due to administration of this investigational therapy Multikine, and subjects in those clinical trials and the treating physicians reported that this investigational therapy was well tolerated in those early-stage clinical trials. Adverse events which were reported as possibly or probably related to Multikine administration were mild to moderate and included pain at the

injection site, local minor bleeding and edema at the injection site, diarrhea, headache, nausea, and constipation. No "abnormal" laboratory results were reported following Multikine treatment - other than those commonly seen by treating physicians in this patient population - regardless of Multikine administration. Similarly, in these early-phase clinical studies in patients, there was no reported increased toxicity of follow-on treatments as a result of Multikine administration. No complications following surgery (such as increased time for wound healing) were reported. No definitive conclusions can be drawn from these data about the safety or efficacy profile of this investigational therapy, and further research is required and the global Phase III study is ongoing in an effort to confirm these results. Currently, Multikine has not yet been licensed or approved for sale, barter or exchange by the FDA or by any other regulatory agency. Similarly, its safety or efficacy has not been established for any use.

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

CEL-SCI completed validation of its new manufacturing facility in January 2010. The state-of-the-art facility is being used to manufacture Multikine for CEL-SCI's Phase III clinical trial. In addition to using this facility to manufacture Multikine, CEL-SCI, only if the facility is not being used for Multikine, may 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), however, priority will always be given to Multikine. 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. These compounds and therapies are derived from or mimic human cells or proteins and other molecules (e.g., hormones, etc.). Nearly all of the major drugs developed for unmet medical needs (e.g., Avastin(R), Erbitux(R), Rituxan(R), Herceptin(R),

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Copaxon(R), etc.) are biologics. Biologics are usually very sensitive to heat and quickly lose their biological activity if exposed to room or elevated temperature. Room or elevated temperatures may also affect the shelf-life of a biologic with the result that the product cannot be stored for as long as desired. However, these products do not generally lose activity when kept at 4 degrees Celsius.

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

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

L.E.A.P.S.

CEL-SCI's patented T-cell Modulation Process, referred to as LEAPS (Ligand Epitope Antigen Presentation System LEAPS is designed to 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 the LEAPS technology, CEL-SCI has created a potential peptide treatment for H1N1 (swine flu) hospitalized patients. This LEAPS flu treatment is designed to focus on the conserved, non-changing epitopes of the different strains of Type A Influenza viruses (H1N1, H5N1, H3N1, etc.), including "swine", "avian or bird", and "Spanish Influenza", in order to minimize the chance of viral "escape by mutations" from immune recognition. CEL-SCI's LEAPS flu treatment contains epitopes known to be associated with immune protection against influenza in animal models.

On September 16, 2009, the U.S. Food and Drug Administration advised CEL-SCI that it could proceed with its first clinical trial to evaluate the

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effect of LEAPS-H1N1 treatment on the white blood cells of hospitalized H1N1 patients. This followed an expedited initial review of CEL-SCI's regulatory submission for this study proposal.

On November 6, 2009, CEL-SCI announced that The Johns Hopkins University School of Medicine had given clearance for CEL-SCI's first clinical study to proceed using LEAPS-H1N1. Soon after the start of the study, the number of hospitalized H1N1 patients dramatically declined and the study has been unable to complete the enrollment of patients. If the disease reemerges, then CEL-SCI will be able to continue the study.

This pandemic flu work is being pursued in collaboration with the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health, USA. In May 2011 NIAID scientists presented data at the Keystone Conference on "Pathogenesis of Influenza: Virus-Host Interactions" in Hong Kong, China.showing the positive results of efficacy studies in mice of L.E.A.P.S. H1N1 activated dendritic cells (DCs) to treat the H1N1 virus. Scientists at the NIAID found that H1N1-infected mice treated with LEAPS-H1N1 DCs showed a survival advantage over mice treated with control DCs. The work was performed in collaboration with scientists led by Kanta Subbarao, M.B.B.S., M.P.H, of the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health, USA.

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

therapies.

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

None of the LEAPS investigational products have been approved for sale, barter or exchange by the FDA or any other regulatory agency for any use to treat disease in animals or humans. The safety or efficacy of these products has not been established for any use. Lastly, no definitive conclusions can be drawn from these early-phase, preclinical-trials data involving these investigational products. Before obtaining marketing approval from the FDA in the United States, and by comparable agencies in most foreign countries, these product candidates must undergo rigorous preclinical and clinical testing which is costly and time consuming and subject to unanticipated delays. There can be no assurance that these approvals will be granted.

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#### General

All of CEL-SCI's products are in the development stage. 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 \$(185,195,000) at June 30, 2011 and expects to incur substantial losses for the foreseeable future.

THE OFFERING

### Securities Offered:

13,333,334 shares of common stock are being offered to investors at a price of \$0.30 per share. For every 100 shares purchased an investor will also receive 90 Series F warrants. Each Series F warrant will entitle the holder to purchase one share of CEL-SCI's common stock. The Series F warrants may be exercised at any time prior to October 6, 2014 at a price of \$0.40 per share. CEL-SCI has also agreed to issue to Chardan Capital Market, LLC 666,667 Series G warrants. Each Series G warrant will entitle the holder to purchase one share of CEL-SCI's common stock. The Series G warrants may be exercised at any time prior to August 12, 2014 at a price of \$0.40 per share.

Common Stock Outstanding:

As of October 3, 2011 CEL-SCI had 214,723,023 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. If all outstanding warrants and convertible securities were exercised and converted (exclusive of the shares and warrants which are sold by means of this prospectus supplement), CEL-SCI would have

approximately 301,225,000 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 need for FDA approval. See the "Risk Factors" section of CEL-SCI's prospectus dated September 30, 2011.

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NYSE Amex trading symbol: CVM

Use of Proceeds: The net proceeds from the sale of the securities

offered, after deducting the placement agent's commission and the estimated expenses of this offering, will be approximately \$3,855,000 and

will be used for CEL-SCI's general and

administrative  $% \left( 1\right) =\left( 1\right) =\left($ 

clinical trials involving Multikine (Leukocyte

Interleukin, Injection).

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

Chardan Capital Markets, LLC, the placement agent for this offering, has agreed to place for sale, and CEL-SCI has agreed to grant to the placement agent the right to place for sale, shares of CEL-SCI's common stock, as well as Series F warrants, which together have a value of approximately \$8,800,000.

The placement agent may solicit purchases of some or all of the shares and warrants directly from the public at the public offering price set forth on the cover page of this prospectus supplement.

The placement agent will not acquire any shares or Series F warrants  $\mbox{ for its own account.}$ 

The placement agent will receive from CEL-SCI a cash commission of \$140,000. CEL-SCI has also agreed to issue to Chardan Capital Market, LLC 666,667 Series G warrants. Each Series G warrant will entitle the holder to purchase one share of CEL-SCI's common stock. The Series G warrants may be exercised at any time prior to August 12, 2014 at a price of \$0.40 per share.

The following table shows the fees that CEL-SCI has agreed to pay to the

placement agent in connection with this offering:

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Per share \$0.0105 Total \$140,000

The placement agent may, from time to time, engage in transactions with and perform services for CEL-SCI in the ordinary course of its business.

It is expected that the closing of this offering will take place on October 6, 2011. CEL-SCI estimates that its portion of the total expenses of this offering, exclusive of the placement agent's commission and expense reimbursement, will be approximately \$5,000.

### DESCRIPTION OF SECURITIES

By means of this prospectus CEL-SCI Corporation is offering to sell 13,333,334 shares of its common stock to private investors at a price of \$0.30 per share. For every 100 shares purchased the investor will receive 90 Series F warrants. Each Series F warrant will entitle the investor to purchase one share of CEL-SCI's common stock at \$0.40.

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 and all of the shares of common stock offered as a component of the Units will be, upon issuance, fully paid and non-assessable.

Series F Warrants

Each Series F warrant allows the holder to purchase one share of CEL-SCI's common stock.

Initially, the Series F warrants will allow the holders to purchase up to 12,000,001 shares of CEL-SCI's common stock at a price of \$0.40 per share at any time prior to October  $6,\ 2014$ .

The exercise price of the warrants, as well as the shares issuable upon the exercise of the warrants, will also be proportionately adjusted in the event of any stock splits.

In case CEL-SCI reorganizes its capital, reclassifies its capital stock, consolidates or merges with or into another corporation (where CEL-SCI is not the surviving corporation or where there is a change in or distribution with respect to CEL-SCI's common stock), or sells, transfers or otherwise disposes of all or substantially all its property, assets or business to another corporation and, pursuant to the terms of such reorganization, reclassification, merger, consolidation or disposition of assets, shares of common stock of the successor or acquiring corporation, or any cash, shares of stock or other securities or property of any nature whatsoever (including warrants or other subscription or purchase rights) in addition to or in lieu of common stock of the successor or acquiring corporation, are to be received by or distributed to the holders of CEL-SCI's common stock, then the holders of the Series F warrants will have the right to receive, upon the exercise of the Series F warrants, the shares of common stock or other securities of the successor or acquiring corporation or of CEL-SCI, if it is the surviving corporation, as well as any other property receivable upon or as a result of such reorganization, reclassification, merger, consolidation or disposition of assets as if holders of the Series F warrants had exercised their warrants immediately prior to such event. The foregoing also applies in the event there is a tender offer for CEL-SCI's shares by either a third person or CEL-SCI.

In certain cases, the holders of the Series F warrants (in the event of a reclassification of CEL-SCI's common stock, or a consolidation, merger, sale of assets, tender offer, or similar transaction), will have the right to sell their Series F warrants to CEL-SCI, or any successor to CEL-SCI, at a price which is equal to the value of the warrants as determined by the Black Scholes Option Pricing Model.

#### 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. 001-11889) are incorporated by reference into this prospectus:

o Annual Report on Form 10-K for the fiscal year ended September 30, 2010.

- o Report on Form10-Q for the three and six months ended December 31, 2010.
- o Report on Form 10-Q for the three months ended March 31, 2011.
- o Report on Form 8-K filed on April 15, 2011.
- o Proxy Statement relating to April 15, 2011 annual shareholders' meeting.
- o Report on Form 10-Q for the three and nine months ended June 30, 2011.
- o Report on Form 8-K filed on September 6, 2011.

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

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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.