CEL SCI CORP
Form 8-K
October 16, 2001

SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (date of earliest event reported): October 9, 2001

CEL-SCI CORPORATION

(Exact name of Registrant as specified in its charter)

| Colorado | 0-11503 | 84-0916344 |
|---|---|---|
| (State or other jurisdiction of incorporation) | (Commission File No.) | (IRS Employer Identification No.) |

8229 Boone Blvd. #802
Vienna, VA 22182

(Address of principal executive offices, including Zip Code)

Registrant's telephone number, including area code: (703) 506-9460

N/A

(Former name or former address if changed since last report)

Item 5. Other Events and Regulation FD Disclosure

On October 9, 2001 the Institute of Human Virology (IHV) at the University of Maryland, Baltimore and CEL-SCI CORPORATION (AMEX: CVM) announced the presentation of new clinical data for CEL-SCI's immunotherapy drug, Multikine, at the Annual Meeting of the International Society for Interferon and Cytokine Research in Cleveland, Ohio. These findings could lead to a new treatment for HIV-infected women with HPV induced cervical dysplasia, the precursor to cervical cancer. In the U.S. alone, approximately 120,000 to 140,000 women have

this disease and are in need of effective therapy.

At the conference it was reported that all five patients treated thus far at the lowest dose in an ongoing dose escalating study showed clinical improvement by colposcopic (stereoscopic, binocular magnification of the cervix under a focused beam of light) examination. Three out of four patients had no evidence of dysplasia on biopsy seven to eight weeks after the final injection. Biopsies on the remaining volunteer showed no apparent changes in her dysplasia. One patient was lost to follow-up. All of the patients tolerated the injections well and without any associated serious adverse reactions. Enrollment at this dose level is completed. The evaluation of Multikine at a higher dose is ongoing as a preliminary to the initiation of a pivotal clinical trial in 2002.

The presentation is entitled, "Immunotherapy with Leukocyte Interleukin, Injection for Human Papilloma Virus (HPV) Induced Cervical Dysplasia in HIV Patients", and was authored by G. Taylor, L. Ely, C. Davis, O. Ioffe, E. Talor, N. Khanna, R. Redfield, and E. Tramont at the Institute of Human Virology, the University of Maryland, CEL-SCI Corporation and the National Institute of Allergy and Infectious Diseases (NIAID). This study was supported in part by a MIPS (Maryland Industrial Partnership) grant from the State of Maryland, a program designed to foster cooperation between researchers/clinicians and industry.

HPV infection is also a leading health problem in non-HIV-infected American college age women. A large concern among women who have HPV-induced cervical dysplasia is that the surgical procedures required to treat cervical dysplasia have a high morbidity rate ranging from cervical incompetence to hysterectomy and the inability to bear children. Furthermore, cervical cancer is the second leading cause of cancer death in women worldwide.

Geert Kersten, Chief Executive Officer of CEL-SCI said, "The results we have seen in this study have literally catapulted this disease to the forefront of our development work. The reasons for this are as follows:

1) We are seeing a high response rate in this very difficult to treat group of patients.

2) The drug was well tolerated and the results were achieved without any associated serious adverse reactions related to Multikine. Given the fragile health of these HIV-infected women and past experiences with other drugs in this patient population, this is very important.

3) There is no effective therapy for these HIV/HPV co-infected women and we know of no other therapies currently in clinical development for this patient population.

4) There are an estimated 120,000 to 140,000 HIV/HPV co-infected women in the U.S. alone whose needs are not adequately addressed. Co-infection with HPV is common in HIV-infected women and cervical cancer, which follows cervical dysplasia, is classified as an AIDS defining illness.

5) We believe that HPV-induced cervical dysplasia patients who are also HIV-infected, and therefore are the most difficult to treat and cure, may represent the fastest way to bring our drug Multikine to the market."

Maximilian de Clara, President of CEL-SCI added, "The market for cervical dysplasia is huge since millions of women are treated for it every year. For this reason, there is a lot of clinical work ongoing in cervical dysplasia. However, all of the agents under development are being developed in women who

have a competent immune system. CEL-SCI, on the other hand, will first focus on those women who are immuno-compromised. There are also immuno-compromised groups other than HIV-infected patients and we expect to get to those after we have started a pivotal clinical trial in the HIV-infected population."

Multikine is a mixture of immune system regulators known as cytokines and chemokines at near physiologic doses. One of the cytokines, Interleukin-2, is widely used to treat cancer. Multikine has been tested in more than 150 cancer patients and in 14 AIDS patients, to date, with only minimal side effects.

A center of the University of Maryland Biotechnology Institute, the Institute of Human Virology was established in 1996 as a partnership between the State of Maryland, the City of Baltimore, the University of Maryland System, and the University of Maryland Medical System, to create and develop a world-class center of excellence focusing on chronic viral diseases and virally-linked cancers. The IHV is dedicated to discovery, research, treatment, and prevention of these diseases and cancers. Its unique structure seeks to connect cohesive, multidisciplinary research and clinical programs so that new treatments are streamlined from discovery to patient. The IHV serves patients locally and the scientific community globally.

CEL-SCI is developing new immune system based treatments for cancer and infectious diseases. CEL-SCI has operations in Vienna, Virginia and Baltimore, Maryland. CEL-SCI's web site can be found at www.cel-sci.com.

Forward Looking Statements

When used in this report, the words "intends," "believes," "anticipated" and "expects" and similar expressions are intended to identify forward-looking statements. Such statements are subject to risks and uncertainties which could cause actual results to differ materially from those projected. Factors that could cause or contribute to such differences include, an inability to duplicate the clinical results demonstrated in clinical studies, timely development of any potential products that can be shown to be safe and effective, receiving necessary regulatory approvals, difficulties in manufacturing any of CEL-SCI's

potential products, inability to raise the necessary capital and the risk factors set forth from time to time in CEL-SCI's SEC filings, including but not limited to its report on Form 10-K for the year ended September 30, 2000. CEL-SCI undertakes no obligation to publicly release the result of any revision to these forward-looking statements which may be made to reflect the events or circumstances after the date of this report or to reflect the occurrence of unanticipated events.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: October 11, 2001

CEL-SCI CORPORATION

By: /s/ Geert R. Kersten
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Geert R. Kersten, Chief Executive Officer