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CEL SCI CORP
Form 8-K
August 03, 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): July 24, 2001

CEL-SCI CORPORATION

(Exact name of Registrant as specified in its charter)

Colorado	0-11503	84-0916344
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(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

CEL-SCI Corporation updated the progress of an ongoing clinical trial of its proprietary investigational therapy, Multikine(TM) at the Institute of Human Virology (IHV) at the University of Maryland Biotechnology Institute and the University of Maryland, Baltimore.

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The focus of this study is HIV-infected women with Human Papilloma Virus (HPV) induced cervical dysplasia, the precursor stage before the development of cervical cancer. Cervical cancer is the second leading cause of cancer death in women worldwide. This patient population was chosen because of the high morbidity/mortality and low success rate of current surgical therapies. Since HIV infection results in immune suppression, HPV-induced cervical dysplasia follows a more malignant and aggressive course of disease in such women. Co-infection with HPV is common in HIV-positive women and cervical cancer is considered an AIDS defining illness.

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 repeated surgical procedures will lead to a hysterectomy and the inability to bear children.

The study, which started in May 2001, is designed to enroll up to a total of 15 women at three dosage levels. As of August 2, 2001, seven patients were enrolled in the study. While no patients have completed the study, the results have been uniformly so encouraging that CEL-SCI has decided that, barring some unforeseen circumstances, it will give the highest priority to clinical trials in women with HPV-induced cervical dysplasia. The study investigators are planning to present detailed interim results of this trial before the end of this year.

With regard to HPV-induced cervical dysplasia, CEL-SCI is planning to meet with the Food and Drug Administration (FDA) in the fall to determine the best way to proceed. Given the great unmet medical need in HPV-induced cervical dysplasia, CEL-SCI is hopeful that its meetings with FDA will lead to the initiation of a clinical trial in patients with HPV-induced cervical dysplasia next year, potentially under fast track designation.

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. According to Dr. Eyal Talor, Senior Vice President of Research and Manufacturing at CEL-SCI, Multikine has been tested in more than 140 cancer patients and in 14 AIDS patients, to date, with only minimal side effects.

CEL-SCI Corporation is developing new immune system based treatments for cancer and infectious diseases. CEL-SCI has operations in Vienna, Virginia and Baltimore, Maryland.

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: August 2, 2001

CEL-SCI CORPORATION

By: /s/ Geert R. Kersten

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Geert R. Kersten