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CEL SCI CORP
Form 8-K
January 18, 2007

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): January 16, 2007

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 Boulevard, Suite 802
Vienna, Virginia 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)

Check appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below)

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-14(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 8.01 Other Events

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On January 16, 2007, the Company issued a press release regarding the notification from the FDA that it had no objection to the Company beginning a Phase III clinical trial using Multikine to treat head and neck cancer. A copy of this press release is attached as an exhibit.

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: January 18, 2007

CEL-SCI CORPORATION

By: /s/ Geert R. Kersten

Geert R. Kersten, Chief Executive Officer

EXHIBIT 99

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CEL-SCI
Corporation

NEWS RELEASE

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CEL-SCI Corporation
(703) 506-9460

CEL-SCI RECEIVES GREEN LIGHT FROM FDA TO PROCEED WITH PHASE III CANCER STUDY

VIENNA, VA, USA, JANUARY 16, 2007 -- CEL-SCI Corporation (AMEX: CVM, Germany: LSR.F) today announced that the U.S. Food and Drug Administration (FDA) has stated in a letter to the Company that, "... the proposed Phase III study may proceed at any time". CEL-SCI's Phase III clinical study is designed to prove that its cancer drug Multikine(R) increases the survival of head and neck cancer patients.

The study is expected to be conducted in numerous countries around the world. It is designed to develop conclusive evidence of the efficacy of the Multikine treatment regimen in advanced primary squamous cell carcinoma of the oral cavity (head and neck cancer). Upon successful completion of this study, the data will be included in CEL-SCI's worldwide Marketing Applications to make Multikine commercially available for the treatment of this patient population. Head and neck cancer is an aggressive disease affecting about 500,000 people per annum worldwide.

Geert Kersten, Chief Executive Officer of CEL-SCI, said, "So far Multikine has been shown to be non-toxic, which is very unusual for a cancer drug. In Phase II clinical studies with head and neck cancer patients it also markedly increased survival. Now we will get the chance to prove that Multikine can extend the survival of these cancer patients."

The global Phase III study will test the hypothesis that the Multikine treatment regimen, administered locally prior to the current standard therapy given to patients with advanced primary squamous cell carcinoma of the oral cavity, will extend the overall survival and enhance the local/regional control of the disease, while increasing disease free survival in these patients.

Multikine is a patented immunotherapeutic agent consisting of a defined mixture of naturally occurring cytokines, including interleukins, interferons, chemokines and colony-stimulating factors.

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

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 the Company's potential products, inability to raise the necessary capital, inability to get American Stock exchange approval for any transaction and the

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risk factors set forth from time to time in CEL-SCI Corporation's SEC filings, including but not limited to its report on Form 10-K for the year ended September 30, 2005. The Company 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 thereof or to reflect the occurrence of unanticipated events.

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