

Edgar Filing: CEL SCI CORP - Form 8-K

CEL SCI CORP
Form 8-K
August 25, 2008

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): August 19, 2008

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 8.01. Other Events

On August 19, 2008 CEL-SCI entered into an agreement with Teva Pharmaceutical Industries Ltd. (Teva), a leading global pharmaceutical company, under which CEL-SCI granted Teva an exclusive license to market and distribute CEL-SCI's cancer drug Multikine in Israel and Turkey (the "Territory"). Although the licensing agreement is initially restricted to the areas of head and neck cancer, Teva has the right, subject to certain conditions, to include other

Edgar Filing: CEL SCI CORP - Form 8-K

cancers during the term of the agreement. Multikine is currently thought to be potentially useful in treating many tumor types.

Pursuant to the agreement, Teva will participate in CEL-SCI's upcoming global Phase III clinical trial. Teva will fund a portion of the Phase III clinical study and Teva's clinical group will conduct part of the clinical study in Israel under the auspices of CEL-SCI and its Clinical Research Organization. Teva will also be responsible for registering Multikine in the Territory. If Multikine is approved, CEL-SCI will be responsible for manufacturing the product, while Teva will be responsible for sales in the Territory. Revenues will be divided equally between CEL-SCI and Teva.

CEL-SCI is developing Multikine for approval as a first line indication in head and neck cancer. To that end, CEL-SCI's upcoming Phase III clinical trial is an 800 patient clinical study designed to demonstrate that administration of Multikine to head and neck cancer patients before they receive any conventional cancer treatment will increase their survival. Head and neck cancer is one of the world's most common cancers affecting about 600,000 people per year.

In Phase II clinical trials Multikine was shown to be safe and well-tolerated and improved the patients' overall survival by 33% at a median of three and a half years following surgery. The U.S. Food and Drug Administration (FDA) gave the go-ahead for a Phase III clinical trial with Multikine in January 2007 and granted orphan drug status to Multikine in the neoadjuvant therapy of squamous cell carcinoma (cancer) of the head and neck in May 2007. In the summer of 2007 CEL-SCI started construction of a manufacturing facility to produce Multikine for the Phase III trial and subsequent sales. This facility is expected to be completed soon.

Multikine, a patented defined mixture of naturally derived cytokines, is the first immunotherapeutic agent in a new class of drugs called "Immune SIMULATORS". Immune SIMULATORS simulate the way the human body's natural immune system acts in defending against cancer. As opposed to other immunotherapies which are designed to target a single or limited number of specific antigens or molecules, Immune SIMULATORS are multi-targeted; they simultaneously cause a direct and targeted killing of the specific tumor cells and activate the immune system to produce a stronger anti-tumor attack on multiple fronts.

Multikine is also the first immunotherapeutic agent being developed as a first-line standard of care treatment for cancer. It can be administered prior to any other cancer therapy since that is the period when the anti-tumor immune response can still be fully activated. Once the disease has advanced, and the patient has received radiation and/or chemotherapy, the immune system is severely weakened and is less able to mount an effective anti-tumor immune

2

response. Other immunotherapies are administered after the patient has received chemotherapy and/or radiation, which can limit their effectiveness.

3

Edgar Filing: CEL SCI CORP - Form 8-K

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 25, 2008

CEL-SCI CORPORATION

By: /s/ Patricia B. Prichep

Patricia B. Prichep
Senior Vice President of Operations