CEL SCI CORP
Form 8-K
March 07, 2017

UNITED STATES
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): March 1, 2017

CEL-SCI CORPORATION
(Exact name of Registrant as specified in its charter)

Colorado	01-11889	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

CEL-SCI announced that it has received the official minutes from its February 8, 2017 meeting with the U.S. Food and Drug Administration (FDA) in regards to the partial clinical hold placed on CEL-SCI's Phase 3 head and neck cancer study. Pursuant to the partial clinical hold, patients currently receiving study treatments can continue to receive treatment at the discretion of their physicians and with their consent, and patients already enrolled in the study will continue to be followed. As of March 6, 2017, 928 patients were enrolled in this study.

The purpose of the February 8, 2017 meeting with the FDA was to discuss the issues raised by the FDA with respect to the partial clinical hold and to obtain the FDA's input and clarification on how to address these issues.

The Action Items for CEL-SCI to pursue per the minutes from the FDA are the following:

1) Provide an updated Investigator's Brochure and current procedures for compliance with requirements under 21 CFR 312 Subpart D to address the partial clinical hold.

2) Provide a list of major protocol deviations, which CEL-SCI believes will affect study results, and provide a plan to identify major protocol deviations across all patients enrolled in the Phase 3 protocol.

CEL-SCI is working diligently on responding to all Action Items.

It is CEL_SCI's belief that addressing the Action Items listed above will support a favorable decision by the FDA to lift the partial clinical hold. While CEL-SCI believes that it understands the Action Items, it is possible that CEL-SCI has not understood all issues involved. All of CEL-SCI's work is subject to the FDA's review of CEL-SCI's submission upon its completion and may or may not result in the lifting of the partial clinical hold.

Item 9.01 Financial Statements and Exhibits

On March 6, 2017 CEL-SCI issued a press release, attached as Exhibit 99, concerning the receipt of the FDA's minutes of the February 8, 2017 meeting.

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: March 6, 2017

CEL-SCI CORPORATION

By: /s/ Patricia B. Prichep

Patricia B. Prichep
Senior Vice President of Operations

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