CEL SCI CORP
Form 8-K
December 22, 2016

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): December 16, 2016

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 the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligations of the registrant under any of the following provisions:

Written communications pursuant to Rule 425 under the Securities Act (17CFR 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-4(c) under the Exchange Act (17 CFR 240.13e-14c))

Item 8.01 Other Events

In August 2016, we announced that the currently available data from the Phase 3 clinical study reflected that the accumulation of deaths in the study was lower than that which was anticipated based on reported literature at the Phase 3 study's inception. If the number of deaths continued to be accumulated at the current rate, it had been determined that it would take longer than originally planned to complete the study. To minimize this eventuality, we decided it would be necessary to enroll up to 1,273 patients to have 1,146 evaluable patients. There were also other changes in the protocol, such as the required number of deaths (392) and a required overall survival of 6.5% in favor of the Multikine comparator arm. With this increased patient enrollment, we expected a corresponding increase in the number of deaths, and, if this plan were implemented, the study could be completed in a more timely manner. As required by law and in order to be able to implement the plan, we submitted an amendment to the existing Phase 3 protocol for our head and neck cancer study to multiple regulatory agencies in the countries abroad where the Phase 3 study is being conducted as well as to the FDA to allow for this expansion in patient enrollment.

On September 26, 2016, we received verbal notice from FDA that the Phase 3 clinical trial in advanced primary head and neck cancer has been placed on clinical hold. At such time, enrollment in the Phase 3 study was 926 patients.

On October 21, 2016, we received a partial clinical hold letter from FDA and, on November 18, 2016, we submitted a response to FDA's partial clinical hold letter.

In its partial clinical hold letter, FDA identified the following specific deficiencies: a) FDA stated that there is an unreasonable and significant risk of illness or injury to human subjects and cited among other things the absence of prompt reports by us to the FDA of IDMC recommendations to close the study entirely (made in spring of 2014) or at least to close it to accrual of new patients (made in spring of 2016); b) FDA stated that the investigator brochure is misleading, erroneous, and materially incomplete; and c) FDA stated that the plan or protocol is deficient in design to meet its stated objectives. In its partial clinical hold letter, FDA also identified the information needed to resolve these deficiencies. In addition, FDA's partial clinical hold letter included two requests relating to quality information regarding our investigational final drug product, which were noted by FDA as non-hold issues. We believe that our response submitted to FDA on November 18, 2016, addressed each of the deficiencies identified by FDA including detailing our belief that, under the applicable FDA guidance, there was no obligation to report the cited IDMC recommendations to the FDA at the time they were issued, and it also requested a face-to-face meeting with FDA, and outlined our commitment to diligently work with FDA in an effort to have the partial clinical hold for the study lifted.

On December 8, 2016, FDA advised us that the Agency was denying our request for a meeting at that time because FDA's review of our November 18, 2016 response was ongoing. We also were advised that we would be receiving a letter addressing our November 18, 2016 response by December 18, 2016.

On December 16, 2016, FDA issued an Incomplete Response To Hold letter to us indicating that based on the Agency's preliminary review of our November 18, 2016 submission, FDA has determined that it is not a complete response to all of the issues listed in FDA's clinical hold letter. FDA identified the following specific deficiencies: a) FDA stated that we did not provide the information identified as necessary to address FDA's statement that patients enrolled in the study are exposed to unreasonable and significant risk of illness or injury to human subjects; b) FDA stated that we did not provide the information identified as necessary to address FDA's statement that continued enrollment of patients in the study exposes the patients to unreasonable risks and FDA furthermore stated that the study is unlikely to demonstrate that the addition of our investigational drug Multikine to the standard of care is superior to standard of care and thus should be terminated for futility; (c) FDA stated that we did not provide the information identified as necessary to address FDA's statement that the investigator brochure is misleading, erroneous, and materially incomplete; (d) FDA stated that we did not provide the information identified as necessary to address FDA's statement that the proposed revised clinical protocol is inadequate in design to meet its stated objectives and

FDA furthermore stated that this deficiency cannot be addressed by further revisions to the protocol. In its incomplete response to hold letter, FDA also identified the steps we must take to address these deficiencies. In addition, FDA's incomplete response to hold letter noted with respect to FDA's two requests relating to quality information regarding our investigational final drug product, which we had been instructed by FDA to submit separately from the response to the partial clinical hold, which again were noted by FDA as non-hold issues, that our November 18, 2016, submission had not included the information addressing these two requests.

We are reviewing all of our options in response to FDA's incomplete response to hold letter. As an initial matter, the Company plans to send FDA a request accompanied by the required complete meeting package for an in person meeting with the Agency to discuss all matters relating to the partial clinical hold, because, among other things, we believe that there may be some misunderstanding regarding our conduct of the Phase 3 clinical trial as well as some misinterpretation of some of the information contained in the response we submitted on November 18, 2016 to the partial clinical hold letter. Pending the scheduling of that FDA meeting and resolution of the partial clinical hold issues, we expect to prepare a comprehensive submission to FDA detailing our belief, accompanied by what we believe to be appropriate supporting data, records, and information reflecting that we have taken the steps necessary to address the specific deficiencies identified by FDA, including: a) demonstrating that patients enrolled in the study are not exposed to unreasonable and significant risk of illness or injury; b) demonstrating that continued enrollment of patients in the study does not expose the patients to unreasonable risks and that the study should not be terminated for futility; (c) demonstrating that a supplemented investigator brochure is not misleading, erroneous, or materially incomplete; (d) demonstrating that the proposed revised clinical protocol is adequate in design to meet its stated objectives and that this deficiency can be addressed by the proposed revisions to the protocol.

Subject to the partial clinical hold, we estimate that the total remaining cash cost of the Phase 3 clinical trial, excluding any costs that will be paid by our partners, would be approximately $12.1 million. Should FDA lift the partial clinical hold and allow the amended protocol submitted to them to proceed, which requires an enrollment of up to 1,273 subjects, the remaining cost of the Phase 3 clinical trial will be higher than currently estimated. This is in addition to the approximately $34.5 million that CEL-SCI already had spent on the trial as of September 30, 2016. This number may be affected by the rate of any future patient enrollment, rate of death accumulation in the study, foreign currency exchange rates, and many other factors, some of which cannot be foreseen today. It is therefore possible that the cost of the Phase 3 clinical trial will be higher than currently estimated. If FDA will only lift the partial clinical hold with termination of the current study and initiation of a new clinical trial, any such new trial can only be initiated if permitted by FDA and as appropriate other regulatory authorities around the world after the requisite submissions are made to them, and the additional duration and costs of the Phase 3 clinical program would likely exceed those already incurred in connection with the Phase 3 clinical trial. If there is a need to conduct an additional Phase 3 pivotal study, any such requirement would have significant and severe material consequences for us and could impact our ability to continue as a going concern.

We will not be able to enroll any additional patients in the Phase 3 study unless FDA lifts the partial clinical hold. In addition, in the spring of 2016, the IDMC recommended to us that new patient enrollment should stop in the Phase 3 study, but patients already on study should continue to be treated and followed. Although we had expected to work through the concerns raised by the IDMC while we worked through the partial clinical hold with FDA, the IDMC informed us on December 13, 2016, that because the study is on partial clinical hold imposed by FDA, the IDMC has no formal recommendation regarding continuation of the trial at this time. If the partial clinical hold is not lifted by FDA or if it is determined by FDA that the study has been compromised, the study may be terminated, or if the partial clinical hold is lifted by FDA but the IDMC continues to recommend that enrollment not be allowed to continue, the study may be terminated by us.

If the partial clinical hold is not lifted, the Phase 3 study will not be able to be completed to its prespecified endpoints in a timely manner, if at all, and, if the Phase 3 study cannot be completed to its prespecified endpoints, the study would not be able to be used as the pivotal study supporting a marketing application in the United States, and at least one entirely new Phase 3 pivotal study would need to be conducted to provide the pivotal study supporting a marketing application in the United States. Even if the partial clinical hold is lifted, if it is not lifted in a timely fashion, the nature and duration of the partial clinical hold could irreparably harm the data from the Phase 3 study such that it may no longer be able to be used as the pivotal study supporting a marketing application in the United States. Even if the partial clinical hold is lifted in a timely fashion, it remains possible that the regulatory authorities could determine that the Phase 3 study is not sufficient to be used as a single pivotal study supporting a marketing

application in the United States.

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: December 22, 2016 CEL-SCI CORPORATION

By: /s/ Patricia B. Prichep
Patricia B. Prichep
Senior Vice President of Operations