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 25, 2022**

NeuroOne Medical Technologies Corporation
(Exact name of registrant as specified in its charter)

Delaware	**000-54716**	**27-0863354**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

7599 Anagram Dr., Eden Prairie, MN 55344
(Address of principal executive offices and zip code)

952-426-1383
(Registrant's telephone number including area code)

(Registrant's 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 obligation of the registrant under any of the following provisions:

☐ 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-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, par value $0.001 per share	NMTC	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging Growth Company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01 Other Events.

As previously disclosed, in September 2021 NeuroOne Medical Technologies Corporation (the "Company") received U.S. Food and Drug Administration ("FDA") clearance to market its Evo sEEG electrode technology for temporary (less than 24 hours) use with recording, monitoring, and stimulation equipment for the recording, monitoring, and stimulation of electrical signals at the subsurface level of the brain.

In November 2021, the Company submitted a request to the FDA seeking a 510(k) clearance for use of its Evo sEEG electrode technology for less than 30 days. On March 11, 2022, the Company received a letter via email from the FDA that the FDA had denied the Company's 510(k) application based on a finding of non-substantial equivalence based on their analysis of the methodology used for exhaustive extraction testing. The FDA letter stated the Company has not demonstrated that the sEEG Electrode for less than 30-day use is substantially equivalent to the predicate device (sEEG Electrode for less than 24 hours K211367). The FDA also stated that the Company may re-submit a new 510(k) if it has biocompatibility data it believes can show its device to be substantially equivalent.

The Company's independent subject matter experts believe the data summary and rationale provided in response to the FDA requests for additional information confirms that exhaustive extraction methodology used for chemical characterization was valid and therefore addresses the necessary subacute toxicity biocompatibility endpoints for prolonged use (less than 30 days). Therefore, the Company intends to file a timely appeal of this decision to a higher level within the FDA, which places the submission on hold until a decision is made. This process may take up to 60 days from date of the appeal before an FDA decision is reached.

The Company has stated previously that it expected to be commercial ready with the Evo sEEG electrode in the first calendar quarter of 2022 pending FDA clearance. The Company now expects that additional time will be required and will continue to work with the FDA in pursuit of 510(k) clearance.

In addition, the Company is also in negotiations with Zimmer Biomet in order to reach a mutually beneficial outcome regarding previously agreed upon milestone payments.

Forward Looking Statements

This current report may include forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Except for statements of historical fact, any information contained in this presentation may be a forward–looking statement that reflects the Company's current views about future events and are subject to known and unknown risks, uncertainties and other factors that may cause its actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. In some cases, you can identify forward–looking statements by the words or phrases "may," "might," "will," "could," "would," "should," "expect," "intend," "plan," "objective," "anticipate," "believe," "estimate," "predict," "project," "potential," "target," "seek," "contemplate," "continue, "focused on," "committed to" and "ongoing," or the negative of these terms, or other comparable terminology intended to identify statements about the future. Forward–looking statements may include statements regarding the Company's appeal to the FDA regarding its recent decision on the Company's 510(k) clearance, the Company's ability to obtain 510(k) clearance, and the potential receipt of milestone payments from Zimmer Biomet. Although the Company believes that it has a reasonable basis for each forward-looking statement, we caution you that these statements are based on a combination of facts and factors currently known by it and its expectations of the future, about which the Company cannot be certain. The Company's actual future results may be materially different from what it expects due to factors largely outside its control, including risks related to changes in regulatory requirements or decisions of regulatory authorities; risks that it may not receive regulatory clearance for prolonged (less than 30 days) use; risks that it may not reach a mutually beneficial agreement with Zimmer Biomet regarding potential milestone payments; risk it may not have accurately estimated the size and growth potential of the markets for its technology; and other risks and uncertainties related to market and other conditions, the impact of general economic, industry or political conditions in the United States or internationally and those described under the heading "Risk Factors" in its filings with the Securities and Exchange Commission. These forward–looking statements speak only as of the date of the current report and the Company undertakes no obligation to revise or update any forward–looking statements for any reason, even if new information becomes available in the future.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

NEUROONE MEDICAL TECHNOLOGIES CORPORATION

Dated: March 25, 2022

By: /s/ David Rosa
David Rosa
Chief Executive Officer