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): June 18, 2018

Nuvectra Corporation
(Exact Name of Registrant as Specified in its Charter)

Delaware	**001-37525**	**30-0513847**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification Number)**

5830 Granite Parkway, Suite 1100,
Plano, Texas 75024
(Address of principal executive offices, including zip code)

(214) 474-3103
(Registrant's telephone number, including area code)

(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 (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))

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.

On July 2, 2018, Nuvectra Corporation (the "Company") announced via press release that on June 18, 2018, it received notice from the Food & Drug Administration (the "FDA") regarding its original pre-market approval application and its subsequent amendment to such application for its Virtis™ Sacral Neuromodulation Device ("Virtis"). The FDA requested that the Company provide supplemental information related to modifications to the Virtis device, labeling and manufacturing. Specifically, the FDA asked the Company to provide a more descriptive explanation of the changes in its most recent amendment relative to what was provided in the Company's original PMA submission, as well as clarifications of data related to MRI compatibility. The Company clarified the FDA's requests on June 27, 2018 and is in the process of preparing comprehensive responses to address each request, thereby initiating a 180-day review process by the FDA.

On June 22, 2018, the Company also received notice from TÜV SÜD, the Company's notified body in Europe, regarding its Virtis application for CE Mark. TÜV SÜD notified the Company that it was unable to approve the Company's CE Mark for Virtis without additional clinical study data regarding the safety and efficacy of the device for the requested indication. On June 28, 2018, the Company confirmed TÜV SÜD's decision and initiated discussions with TÜV SÜD regarding its CE Mark application and the scope of future clinical data that may be requested. As the Company completes its assessment of TÜV's clinical requirements, it is currently evaluating the best path to pursue its application for CE Mark.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

99.1 Press Release issued by Nuvectra Corporation, dated July 2, 2018

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, thereunto duly authorized.

July 2, 2018

NUVECTRA CORPORATION

By: /s/ Walter Z. Berger
Name: Walter Z. Berger
Title: Chief Operating Officer and Chief Financial Officer

Exhibit 99.1

Company Contacts:
Nuvectra Corporation

Walter Berger, COO & CFO
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Investor Contacts:
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Nuvectra Provides Update on FDA and TÜV SÜD Review of Virtis™ PMA and CE Mark Applications

Plano, Texas, July 2, 2018 – Nuvectra Corporation (NASDAQ: NVTR), a neurostimulation medical device company, today provided an update on its U.S. Food and Drug Administration (FDA) pre-market approval (PMA) application and its TÜV SÜD application for CE Mark in Europe for Virtis™, the Company's Sacral Neuromodulation (SNM) System for the treatment of chronic urinary retention and the symptoms of overactive bladder.

As part of its review of the Virtis PMA original application and the amendment submitted in April 2018, the FDA recently requested that the Company provide supplemental information related to any modifications or changes to the Virtis device, labeling and manufacturing, as well as clarifications of data related to MRI. The Company has been in active communications with the FDA and intends to promptly file comprehensive responses to address the FDA's requests. The FDA will then have up to 180 days to review the Company's responses. The Company plans to work proactively with the FDA to complete the review process as soon as possible.

Also, TÜV SÜD recently informed the Company that clinical study data will be required before it can recommend approval of CE Mark for the Virtis system. The Company is continuing its discussions with TÜV SÜD regarding its application to clarify the breadth of clinical data that may be requested.

Scott Drees, Chief Executive Officer, commented, "Our primary focus is gaining FDA approval of the Virtis system in order to both provide therapy to patients and to address the significant market opportunity for SNM in the U.S. We remain encouraged by our recent interactions with the FDA and believe that our responses will adequately address the FDA's requests. We are pleased that our facility and pre-PMA audit have been completed without findings. We will continue to work cooperatively with the FDA to conclude the review of our application expeditiously and look forward to entering the U.S. SNM market as soon as possible following FDA approval."

Mr. Drees continued, "We will revisit our corporate strategy to enter the SNM market in Europe and will engage with TÜV SÜD to determine a reasonable clinical pathway to CE Mark approval."

About Nuvectra Corporation

Nuvectra™ is a neurostimulation company committed to helping physicians improve the lives of people with chronic conditions. The Algovita® Spinal Cord Stimulation (SCS) System is our first commercial offering and is CE marked and FDA approved for the treatment of chronic intractable pain of the trunk and/or limbs. Our innovative technology platform also has capabilities under development to support other indications such as sacral neuromodulation (SNM) for the treatment of overactive bladder, and deep brain stimulation (DBS) for the treatment of Parkinson's Disease. In addition, our NeuroNexus subsidiary designs, manufactures and markets leading-edge neural-interface technologies for the neuroscience clinical research market. Visit the Nuvectra website at www.nuvectramed.com.

Cautionary Note Regarding Forward-Looking Statements

This press release contains "forward-looking statements," including statements we make regarding the outlook for Nuvectra as an independent publicly-traded company. Forward-looking statements are based only on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, projections, anticipated events and trends, the economy and other future conditions, and therefore they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict and may be outside of our control. Our actual performance may differ materially from those indicated in the forward-looking statements. Therefore, you should not rely on any of these forward-looking statements. Any forward-looking statement made by us is based only on information currently available to us and speaks only as of the date on which it is made. Important factors that could cause our actual results to differ materially from those indicated in the forward-looking statements include: (i) our ability to successfully commercialize Algovita and to develop, complete and commercialize enhancements or improvements to Algovita; (ii) our ability to successfully compete with our current SCS competitors and the ability of our U.S. sales representatives to successfully establish market share and acceptance of Algovita, (iii) the uncertainty of obtaining regulatory approvals in the United States and Europe for our Virtis SNM system, (iv) our ability to successfully launch and commercialize the Virtis SNM system if it receives regulatory approval (v) our ability to demonstrate the features, perceived benefits and capabilities of Algovita to physicians and patients in competition with similar products already well established and sold in the SCS market; (vi) our ability to anticipate and satisfy customer needs and preferences and to develop, introduce and commercialize new products or advancements and improvements to Algovita in order to successfully meet our customers' expectations; (vii) the outcome of our development plans for our neurostimulation technology platform, including our ability to identify additional indications or conditions for which we may develop neurostimulation medical devices or therapies and seek regulatory approval thereof; (viii) our ability to identify business development and growth opportunities and to successfully execute on our strategy, including our ability to seek and develop strategic partnerships with third parties to, among other things, fund clinical and development costs for new product offerings; (ix) the performance by our development partners, including Aleva Neurotherapeutics, S.A., of their obligations under their agreements with us; (x) the scope of protection for our intellectual property rights covering Algovita and other products using our neurostimulation technology platform, along with any product enhancements or improvements; (xi) our ability to successfully build, attract and maintain an effective commercial infrastructure and qualified sales force in the United States; (xii) our compliance with all regulatory and legal requirements regarding implantable medical devices and interactions with healthcare professionals; (xiii) any supplier shortages related to Algovita or its components and any manufacturing disruptions which may impact our inventory supply as we expand our business; (xiv) any product recalls, or the receipt of any warning letters, mandatory corrections or fines from any governmental or regulatory agency; (xv) our ability to satisfy the conditions and covenants, including trailing six month revenue milestones, of our Credit Facility; and (xvi) our ability to raise capital through means other than or in addition to the Credit Facility should it become necessary to do so, through a public offering of our common stock, private equity or debt financings, strategic partnerships, or other sources. Please see the section entitled "Risk Factors" in Nuvectra's Annual Report on Form 10-K and in our other quarterly and periodic filings for a description of these and other risks and uncertainties. We undertake no obligation to publicly update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.