

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): January 29, 2019

Nuvectra Corporation

(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-37525
(Commission
File Number)

30-0513847
(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 Results of Operations and Financial Condition.

On January 29, 2019, Nuvectra Corporation issued a press release regarding the status of its FDA submission for its Virtis Sacral Nerve Stimulation product. A copy of the press release is attached hereto as Exhibit 99.1 to this Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
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99.1	<u>Press Release dated January 29, 2019.</u>
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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.

NUVECTRA CORPORATION

Date: January 29, 2019

/s/ Walter Z. Berger

Walter Z. Berger

Chief Operating Officer and Chief Financial Officer

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated January 29, 2019



**Company Contacts:
Nuvectra Corporation**

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Nuvectra Provides Update on Virtis™ FDA PMA Submission

Plano, Texas, January 29, 2019 – Nuvectra Corporation (NASDAQ: NVTR), a medical device company dedicated to neuromodulation, announced today that the U.S. Food and Drug Administration (FDA) has advised that its review of Company's pre-market approval (PMA) application for its Virtis Sacral Neuromodulation (SNM) system has been extended beyond the expiration of the FDA's 180-day review period.

Scott Drees, Chief Executive Officer, commented, "FDA has informed us that they have not yet concluded their review and as such will require an extension of our 180-day review period. To date, FDA has not identified any additional deficiencies or requested any additional information. The Company is continuing to work closely with FDA to conclude our PMA review."

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. 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 and timing 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 and when 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) our reliance on each of Integer, our exclusive and sole manufacturer and supplier of parts and components for Algovita, and Minnetronix, Inc., our sole-source supplier of external peripheral devices; (xiv) any supplier shortages related to Algovita or its components and any manufacturing disruptions which may impact our inventory supply as we expand our business; (xv) any product recalls, or the receipt of any warning letters, mandatory corrections or fines from any governmental or regulatory agency; (xvi) our ability to satisfy the conditions and covenants of our Credit Facility; and (xvii) our ability to raise capital should it become necessary to do so, through another 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.