
**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): October 19, 2017 (October 18, 2017)

MEDOVEX CORP.

(Exact Name of Registrant as Specified in Charter)

Nevada

(State or other jurisdiction
of incorporation)

001-36763

(Commission
File Number)

46-3312262

(IRS Employer
Identification No.)

**3060 Royal Blvd South, Suite 150
Alpharetta, Georgia**

(Address of principal executive offices)

30022

(Zip Code)

Registrant's telephone number, including area code: (844) 633-6839

(Former name or former address, if changed since last report)

Copies to:

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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))

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.

FORWARD-LOOKING STATEMENTS

This Current Report on Form 8-K contains forward-looking statements. Forward-looking statements include statements concerning plans, objectives, goals, strategies, future events or performance, and underlying assumptions and other statements that are other than statements of historical facts. These statements are subject to uncertainties and risks including, but not limited to (i) securing capital for general working purposes, and (ii) other risks and in statements filed from time to time with the Securities and Exchange Commission (the “SEC”). All such forward-looking statements, whether written or oral, and whether made by or on behalf of the Company, are expressly qualified by the cautionary statements and any other cautionary statements which may accompany the forward-looking statements. In addition, the Company disclaims any obligation to, and will not, update any forward-looking statements to reflect events or circumstances after the date hereof.

Item 7.01. Regulation FD Disclosure.

On December 29, 2017, Medovex Corp., a Nevada corporation (the “Company”) issued a press release (the “**Release**”) announcing that it has elected to voluntarily convert its previously submitted Investigational Device Exemption to a Pre-Submission with the U.S. Food and Drug Administration for its DenerveX device. A copy of the Release is attached hereto and incorporated herein by reference in its entirety as [Exhibit 99.1](#).

The information contained in this Current Report on Form 8-K shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “**Exchange Act**”), or incorporated by reference in any filing under the Securities Act of 1933, as amended (the “**Securities Act**”) or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing. The furnishing of the information in this Current Report on Form 8-K is not intended to, and does not, constitute a representation that such furnishing is required by Regulation FD or that the information contained in this Current Report on Form 8-K constitutes material investor information that is not otherwise publicly available.

The Securities and Exchange Commission encourages registrants to disclose forward-looking information so that investors can better understand the future prospects of a registrant and make informed investment decisions. This Current Report on Form 8-K and exhibits may contain these types of statements, which are “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995, and which involve risks, uncertainties and reflect the Registrant’s judgment as of the date of this Current Report on Form 8-K. Forward-looking statements may relate to, among other things, operating results and are indicated by words or phrases such as “expects,” “should,” “will,” and similar words or phrases. These statements are subject to inherent uncertainties and risks that could cause actual results to differ materially from those anticipated at the date of this Current Report on Form 8-K. Investors are cautioned not to rely unduly on forward-looking statements when evaluating the information presented within.

Item 9.01 Financial Statements and Exhibits

(d) [Exhibits](#).

<u>Exhibit No.</u>	<u>Description</u>
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99.1	Press Release dated December 29, 2017
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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 thereunto duly authorized.

Date: December 29, 2017

MEDOVEX, CORP.

By: */s/ Jarrett Gorlin*

Name: Jarrett Gorlin

Title: Chief Executive Officer

Medovex Corporation Converts IDE Submission to a Pre-Submission with Food and Drug Administration for its DenerveX System

Adds Six New Independent Sales Agents in Germany and Collecting Patient Data for Anticipated Filing of Scientific Post Procedural Outcomes of Patients Abstract

ATLANTA, Dec. 29, 2017 (GLOBE NEWSWIRE) — Medovex Corp. (OTCQB:MDVX) (“Medovex” or the “Company”), the developer of the DenerveX® System, a new and novel device designed for enduring relief of Facet Joint Syndrome related to chronic back pain, a non-addictive, non-opioid drug alternative capable of restoring a patient to a more normal and active lifestyle, today announced it has elected to voluntarily convert its previously submitted Investigational Device Exemption (IDE), to a Pre-Submission with the U.S. Food and Drug Administration (“FDA”), for its DenerveX System targeting pain associated with the Facet Joint.

Jill Schweiger, Sr. Vice President Regulatory and Clinical Affairs for Medovex commented, “Early dialogue with the FDA has been both encouraging and productive. The feedback gained from recent interactions convinced us that converting the IDE submission to a pre-submission beneficially allows us to engage in a more interactive and collaborative review of the planned clinical investigation. The standard IDE review timeframe is 30 days, while our submission exceeded nearly 2500 pages of technical data. We are confident that early collaboration with FDA regarding its planned clinical evaluation will help ensure that the study design will ultimately yield the results that will support the safety and effectiveness of the DenerveX System.”

Schweiger concluded, “Significant time, effort and resources have been invested in what we continue to believe will ultimately be a successful submission and review by the FDA, followed by a US clinical trial in the future.”

The DenerveX System is already CE Marked in Europe and it is commercially available in Europe and certain other international markets.

In addition, the Company recently added six new independent spine surgery sales agents for additional distribution throughout Germany.

The Company is also working as planned with several early adopting physicians on the collection of the initial clinical results in the UK and Germany for post procedural outcomes of patients treated with the DenerveX System. This data is expected to support a scientific abstract being planned for submission late in 2018. To maintain the best chance of abstract acceptance, the scientific abstract will include data collection from various sites, comprehensive analysis and will not be released to the public before presentation.

Jarrett Gorlin, Medovex Chief Executive Officer stated, “We are confident that the data will show a consistent trend with the data initially reported in the manual method by Dr. Haufe in his clinical paper.”

Please also follow us on Facebook at <https://www.facebook.com/medovex/>.

About Medovex

Medovex was formed to acquire and develop a diversified portfolio of potentially ground breaking medical technology products. Criteria for selection include those products with potential for significant improvement in the quality of patient care combined with cost effectiveness. The Company’s first pipeline product, the DenerveX System, is intended to provide long lasting relief from pain associated with facet joint syndrome at significantly less cost than currently available options. To learn more about Medovex Corp., visit www.medovex.com.

Safe Harbor Statement

Certain statements in this press release constitute “forward-looking statements” within the meaning of the federal securities laws. Words such as “may,” “might,” “will,” “should,” “believe,” “expect,” “anticipate,” “estimate,” “continue,” “predict,” “forecast,” “project,” “plan,” “intend” or similar expressions, or statements regarding intent, belief, or current expectations, are forward-looking statements. While the Company believes these forward-looking statements are reasonable, undue reliance should not be placed on any such forward-looking statements, which are based on information available to us on the date of this release. These forward looking statements are based upon current estimates and assumptions and are subject to various risks and uncertainties, including without limitation those set forth in the Company’s filings with the Securities and Exchange Commission (the “SEC”), not limited to Risk Factors relating to its business contained therein. Thus, actual results could be materially different. The Company expressly disclaims any obligation to update or alter statements whether as a result of new information, future events or otherwise, except as required by law.

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