

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): April 2, 2018

NanoVibronix, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other
jurisdiction
of incorporation)

001-36445
(Commission File Number)

01-0801232
(IRS Employer
Identification No.)

9 Derech Hashalom Street
Nesher, Israel
(Address of principal executive offices)

36651
(Zip Code)

Registrant's telephone number, including area code: (914) 233-3004

(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))

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 April 2, 2018, NanoVibronix, Inc. (the “Company”) released a press release providing a business update for the year ended December 31, 2017. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is hereby incorporated by reference herein.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit

No. Description

99.1 Press release dated April 2, 2018

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.

NanoVibronix, Inc.

Date: April 2, 2018

By: /s/ Stephen Brown

Name: Stephen Brown

Title: Chief Financial Officer



NanoVibronix Provides Year-End 2017 Business Update and Files 10-K

ELMSFORD, NY – April 2, 2018 - NanoVibronix, Inc. (NASDAQ: NAOV), a medical device company utilizing the Company's proprietary and patented low intensity surface acoustic wave (SAW) technology, today provided a business update for the year ended December 31, 2017.

Brian Murphy, Chief Executive Officer of NanoVibronix, commented, "We have now transitioned from an R&D-focused to a fully commercial organization. Towards this end, we achieved a number of major milestones in 2017 that we believe helped lay the foundation for an aggressive sales and marketing push that is now underway in 2018. First, we released successful interim results for two of our existing products, UroShield® and PainShield®, in the fourth quarter of 2017. In one trial, we reported that less than 4% of patients using UroShield developed infections versus 52% in the control group. This initial data has helped attract significant attention, given the fact that catheter-associated urinary tract infection (CAUTI) is a major global health concern and one of the leading causes of hospital acquired infections."

"Similarly, we reported interim results for PainShield, showing a significant improvement in pain scores, quality of life, and a reduction in medications for patients with Trigeminal Neuralgia -- one of, if not the most, painful chronic conditions. We believe our instrument has the potential to help millions of patients worldwide suffering from this painful and debilitating condition. Moreover, we believe this device has potential across a broad array of indications, where our device may help reduce the need for opioids. Final results from both the UroShield and PainShield studies are expected to be ready for submission to a peer-reviewed journal in the second quarter of 2018."

"We have also begun executing our strategy to add new distributors worldwide. In December, we signed IMS Ultrasound (UK) Ltd as an exclusive distributor for UroShield in the United Kingdom, and recently added PainShield to their exclusivity in the United Kingdom. Also, in December, we announced that we have signed Morulaa HealthTech as a regulatory and marketing partner in India. Having just recently commenced our sales and marketing efforts, we are in advanced discussions with a number of other leading distributors around the world."

"As we head into 2018, we are adding key senior executives that will help with our global sales and marketing initiatives. At the same time, we have begun to generate attention in the national media, which we believe is helping drive awareness for our products. We are also witnessing increased support for PainShield among major sports celebrities that are now using the device and have been outspoken on its benefits."

“Lastly, we are continuing to develop our product pipeline and expand our intellectual property portfolio, including a U.S. patent we received in 2017 entitled, “System and Method for Surface Acoustic Wave Treatment of Skin,” which further expands our intellectual property portfolio through 2033. Our proprietary SAW technology has been proven to promote profusion and increase oxygen saturation, both essential to a wide range of indications requiring soft tissue repair. Accordingly, we announced the execution of a collaborative agreement with a global cosmetics company to conduct a small trial to assess the efficacy of the company’s anti-aging cosmetic device. Following completion of the trial, we look forward to providing further updates.”

“Overall, we are extremely pleased with our progress in a relatively short period of time. Importantly, we believe we have maintained a solid balance sheet and are carefully managing our expenses, while continuing to fund product development, clinical trials for additional 510(k) clearances, and continue to implement strategically focused marketing programs. We also believe that the fact we are now listed on the NASDAQ will also help us generate more awareness within the financial community as we continue to execute on our business model.”

The Company’s also filed its Form 10-K on March 29, 2018, which is available on the Company’s website www.nanovibronix.com.

About NanoVibronix

NanoVibronix Inc. (NASDAQ: [NAOV](http://www.naoqv.com)) is a medical device company headquartered in Elmsford, NY with research and development in Neshar, Israel, that is focused on developing medical devices utilizing its proprietary and patented low intensity surface acoustic wave technology. The company’s technology allows for the creation of low-frequency ultrasound waves that can be utilized for a variety of medical applications, including the disruption of biofilms and bacteria colonization, as well as providing pain relief. The devices can be administered at home, without the assistance of medical professionals. The company’s primary products include PainShield, UroShield and WoundShield. Additional information about the company is available at: www.nanovibronix.com.

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Forward-looking Statements

This press release contains “forward-looking statements.” Such statements may be preceded by the words “intends,” “may,” “will,” “plans,” “expects,” “anticipates,” “projects,” “predicts,” “estimates,” “aims,” “believes,” “hopes,” “potential” or similar words. Forward-looking statements are not guarantees of future performance, are based on certain assumptions and are subject to various known and unknown risks and uncertainties, many of which are beyond the Company’s control, and cannot be predicted or quantified and consequently, actual results may differ materially from those expressed or implied by such forward-looking statements. Such risks and uncertainties include, without limitation, risks and uncertainties associated with (i) market acceptance of our existing and new products, (ii) negative clinical trial results or lengthy product delays in key markets, (iii) an inability to secure regulatory approvals for the sale of our products, (iv) intense competition in the medical device industry from much larger, multinational companies, (v) product liability claims, (vi) product malfunctions, (vii) our limited manufacturing capabilities and reliance on subcontractors for assistance, (viii) insufficient or inadequate reimbursement by governmental and other third party payers for our products, (ix) our efforts to successfully obtain and maintain intellectual property protection covering our products, which may not be successful, (x) legislative or regulatory reform of the healthcare system in both the U.S. and foreign jurisdictions, (xi) our reliance on single suppliers for certain product components, (xii) the fact that we will need to raise additional capital to meet our business requirements in the future and that such capital raising may be costly, dilutive or difficult to obtain and (xiii) the fact that we conduct business in multiple foreign jurisdictions, exposing us to foreign currency exchange rate fluctuations, logistical and communications challenges, burdens and costs of compliance with foreign laws and political and economic instability in each jurisdiction. More detailed information about the Company and the risk factors that may affect the realization of forward looking statements is set forth in the Company’s filings with the Securities and Exchange Commission (SEC), including the Company’s Annual Report on Form 10-K and its Quarterly Reports on Form 10-Q. Investors and security holders are urged to read these documents free of charge on the SEC’s web site at <http://www.sec.gov>. The Company assumes no obligation to publicly update or revise its forward-looking statements as a result of new information, future events or otherwise.
