

SANUWAVE Health, Inc.
Form 8-K
December 29, 2017

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) December 28, 2017

SANUWAVE HEALTH, INC.
(Exact name of registrant as specified in its charter)

Nevada 000-52985 20-1176000
(State or other jurisdiction of incorporation) (Commission File Number) (IRS Employer Identification No.)

3360 Martin Farm Road, Suite 100, 30024
Suwanee, Georgia
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code (770) 419-7525

N/A
(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 (see General Instruction A.2. below):

- 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 registration is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 or Rule 12b-2 of the Securities Exchange Act of 1934.

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.

Cautionary Statement Regarding Forward-Looking Information

This Current Report on Form 8-K contains certain statements that constitute “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended (the “Securities Act”), and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), and are covered by the safe harbor provisions of the United States Private Securities Litigation Reform Act of 1995. Words such as “anticipate,” “believes,” “budget,” “continue,” “could,” “estimate,” “expect,” “forecast,” “intend,” “may,” “plan,” “potential,” “predicts,” “project,” “should,” “will,” and “would” expressions are intended to identify such forward-looking statements. Forward-looking statements in this Form 8-K may include, without limitation, statements regarding projected growth, future revenue, benefits of entering into the investment agreements, anticipated improvements in earnings and other financial performance measures, future expectations concerning available cash and cash equivalents, assumptions underlying or relating to any of the foregoing, and other matters. Forward-looking statements involve known and unknown risks, uncertainties and other important factors that may cause actual results, performance or achievements to differ materially from results expressed in or implied by this Form 8-K. Any expectations based on these forward-looking statements are subject to risks and uncertainties and other important factors, including those discussed in SANUWAVE Health, Inc.’s Annual Report on Form 10-K filed with the Securities and Exchange Commission, including the section titled “Risk Factors” therein, and all other filings made by the Company under the Exchange Act. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the filing date of this Form 8-K. All forward-looking statements are qualified in their entirety by this cautionary statement. We assume no obligation to update the forward-looking statements, or to update the reasons why actual results could differ from those projected in the forward-looking statements.

Item 7.01

Regulation FD Disclosure.

On December 28, 2017, SANUWAVE Health, Inc., a Nevada Corporation (the “Company”), received notice from the United States Food and Drug Administration permitting marketing of the dermaPACE® System. The letter from the FDA is furnished on this Current Report on Form 8-K (this “Current Report”) as Exhibit 99.1 and incorporated by reference herein.

The Company also issued on December 29, 2017, a press release regarding the FDA’s notice and a conference call to be held by the Company on January 2, 2018, at 11:00 am eastern to discuss the FDA letter and its implications for the Company. The press release is furnished on this Current Report as Exhibit 99.2 and incorporated by reference herein.

Item 9.01

Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No. Description

<u>99.1</u>	Letter from the U.S. Food and Drug Administration to the Company
<u>99.2</u>	Press Release dated December 29, 2017 issued by the Company

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.

SANUWAVE HEALTH, INC.

Dated: December 29, 2017 By: /s/ Kevin A. Richardson, II
Name: Kevin A. Richardson, II
Title: Acting Chief Executive Officer

EXHIBIT INDEX

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