

SANUWAVE Health, Inc.
Form 8-K
December 22, 2011

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 21, 2011

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

Nevada
(State or other jurisdiction
of incorporation)

000-52985
(Commission File Number)

20-1176000
(IRS Employer
Identification No.)

11680 Great Oaks Way, Suite 350, Alpharetta, Georgia
(Address of principal executive offices)

30022
(Zip Code)

Registrant's telephone number, including area code

(678) 581-6843

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))

Item 7.01 Regulation FD Disclosure

On December 21, 2011, SANUWAVE Health, Inc., a Nevada Corporation (the "Company"), announced it has received a major deficiency letter from the United States Food and Drug Administration (FDA) regarding the FDA's review of the dermaPACE® Premarket Approval Application (PMA) for the treatment of diabetic foot ulcers. A copy of the related press release is attached as Exhibit 99.1 to this Form 8-K and is incorporated herein by reference in its entirety.

The information in this Item 7.01 of this Form 8-K and the exhibit attached hereto shall not be deemed to be "filed" for purposes of Section 18 of the Securities Act of 1934, as amended, and shall not be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release, dated December 21, 2011, issued by SANUWAVE Health, Inc.

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 22, 2011

By: /s/ Christopher M. Cashman
Name: Christopher M. Cashman
Title: Chief Executive Officer and
President

EXHIBIT INDEX

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